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Nordic Committee on
Bioethics

Legislation on Biotechnology in the Nordic Countries – An overview

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Nordic Committee on Bioethics

The Nordic Committee on Bioethics was established in 1989 to identify and survey ethical issues related to legislation, research and developments in biotechnology in the Nordic countries and internationally. The committee has two members from each Nordic country. It contributes to the public debate by organising workshops, publishing reports and spreading information to national authorities and ethics committees.

www.ncbio.org

Nordic co-operation

Nordic co-operation, one of the oldest and most wide-ranging regional partnerships in the world, involves Denmark, Finland, Iceland, Norway, Sweden, the Faroe Islands, Greenland and Åland. Co-operation reinforces the sense of Nordic community while respecting national differences and similarities, makes it possible to uphold Nordic interests in the world at large and promotes positive relations between neighbouring peoples.

Co-operation was formalised in 1952 when *the Nordic Council* was set up as a forum for parliamentarians and governments. The Helsinki Treaty of 1962 has formed the framework for Nordic partnership ever since. The *Nordic Council of Ministers* was set up in 1971 as the formal forum for co-operation between the governments of the Nordic countries and the political leadership of the autonomous areas, i.e. the Faroe Islands, Greenland and Åland.

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Introduction

The aim of this booklet is to provide an overview of the current legislation in the field of biotechnology in different Nordic countries. This is needed not only by law-makers, politicians and researchers in the Nordic countries, but also at the European level and even more widely. For the first edition in 2003, a small number of hard copies of the leaflet were taken. Similar approach has been taken with this second edition. However, as the legal situation in this field is constantly evolving, the most up-to-date version of the tables can be found on the Nordic Committee on Bioethics website at www.ncbio.org.

The Nordic Committee on Bioethics initiated in 2001 a project on the Nordic regulation of biotechnology, related ethical questions, and their reflections on political decision-making. The principal authors assigned to this project were Professor Linda Nielsen (University of Copenhagen) and Berit Faber (Danish Council of Ethics) from Denmark. The present overview of the legislation on biotechnology in the Nordic countries is produced on the foundations laid by the already mentioned project, and developed further into a separate by-product by Dr. Salla Lötjönen, a Finnish member of the Nordic Committee on Bioethics, with the assistance of the Committee secretary Helena von Troil, and legal experts from Denmark, Iceland, Norway and Sweden.

The initial choice of topics for the overview (assisted reproduction, genetic testing and gene therapy, biobanks and embryo research, stem cell research and cloning) have been amended to the second edition with tables on preimplantation genetic diagnosis, abortion, prenatal diagnosis, clinical research on humans and animal experimentation. This was done in order to cover a wider area of law and biotechnology. However, in time, the material may be extended to cover even more new topics, and also for that reason, the reader of this document may wish to refer to the internet version of the tables. For this update, legislation has been followed until 29 April 2005.

The Nordic Committee on Bioethics wishes to thank first of all Linda Nielsen and Berit Faber for providing the initial framework and collecting much of the original material for the first edition of this overview, and secondly the national legal experts, Ph.D.Mette Hartlev (University of Copenhagen), Director Guðríður Þorsteinsdóttir (Ministry of Health and Social Security of Iceland), Dr. Marit Halvorsen (University of Oslo), and Professor Elisabeth Rynning (University of Uppsala), who have checked that the material is up-to-date and provided the information needed for the new tables. Additional support on the table for animal

experimentation was provided by Director Ulla-Marjut Jaakkola (University of Turku).

The Nordic Committee on Bioethics gratefully acknowledges the support for the project received from the Nordic parliamentarians and the Nordic Council of Ministers in providing the funds for the project.

Salla Lötjönen
Nordic Committee on Bioethics

Description of the tables

The leaflet includes nine tables on assisted reproduction (table 1), preimplantation genetic diagnosis (table 2), abortion (table 3), prenatal diagnosis (table 4), embryo research, stem cell research and cloning (table 5), clinical research on humans (table 6), biobanks (table 7), genetic testing and gene therapy (table 8), and animal experimentation (table 9). Facts concerning each of the Nordic countries (in alphabetical order) have been represented parallel to each other in the vertical columns. Horizontally, laws covering the field in question have been stated under each title, and some key issues from the legislation have been chosen for comparison. The titles of the laws in their original language have been presented in the footnotes with some more detailed information, if necessary.

More information on the national laws in the Nordic countries may be searched via electronic databases on national legislation such as:

www.retsinfo.dk. (Denmark)
www.finlex.fi (Finland)
www.ministryofhealth.is (Iceland)
www.lovdata.no (Norway)
www.lagrummet.se (Sweden)

Introduktion

Målet med denna publikation är att ge en översikt över lagstiftningen inom området bioteknologi i de nordiska länderna. Översikten är till nytta för lagstiftare, politiker och forskare i de nordiska länderna samt på europeisk nivå och även utöver det. Ett litet antal exemplar av första versionen trycktes 2003. Utgångspunkten för denna andra version är den samma. Lagstiftningssituationen inom bioteknologin förändras hela tiden. Därför har Nordisk kommitté för bioetik publicerat den andra versionen enbart på sin internet hemsida. Den färskaste versionen av tabellerna finns på www.ncbio.org.

Den nordiska kommittén för bioetik tog år 2001 initiativ till ett projekt om regleringen av bioteknologi i Norden, etiska frågor och hur de reflekteras i det politiska beslutsfattandet. Projektets huvudförfattare var professor Linda Nielsen (Köpenhamns universitet) och Berit Faber (Det Etiske Råd) från Danmark. Föreliggande översikt över lagstiftningen om bioteknologi i de nordiska länderna har producerats på basen av ovannämnda projekt och vidare utarbetats till en separat publikation av dr. Salla Lötjönen, finländsk medlem av Nordisk kommitté för bioetik med hjälp av sekreteraren och övriga kommittémedlemmar samt juridiska experter från Danmark, Island, Norge och Sverige.

Det urspungliga urvalet av ämnesområden för översikten (assisterad befruktning, genetisk testning och genterapi, biobanker och embryoforskning, stamcellsforskning och kloning) har utökats i den andra versionen med tabeller om preimplantatorisk genetisk diagnostik, abort, prenatal diagnostik, klinisk forskning på människor samt djurförsök. Detta gjordes för att täcka ett vidare område av lagstiftning och bioteknologi. I framtiden kan materialet eventuellt utvidgas till ytterligare nya områden, vilket även det är en anledningen till att läsaren hänvisas till mer aktuell information i den version av tabellerna som finns på kommitténs hemsidor. För denna uppdaterade version har lagstiftningen beaktats fram till 29.4.2005.

Nordisk kommitté för bioetik vill tacka främst Linda Nielsen och Berit Faber för att ha skapat ramarna och samlat in mycket av materialet till översikten. Vi vill dessutom rikta vårt varma tack till de nationella juridiska experterna dr. Mette Hartlev (Köpenhamns universitet), dir. Guðríður Þorsteinsdóttir (Islands social- och hälsovårdsministerium), dr. Marit Halvorsen (Universitetet i Oslo) och professor Elisabeth Rynning (Uppsala universitet) som har granskat att materialet är aktuellt samt bidragit med den information som behövdes för de nya tabellerna. Dir. Ulla-Marjut Jaakkola (Universitetet i Åbo) har hjälpt till med tabellen om djurförsök.

Nordisk kommitté för bioetik är tacksam för det stöd projektet har fått av de nordiska parlamentarikerna samt finansieringen från Nordiska ministerrådet.

Salla Lötjönen
Nordisk kommitté för bioetik

Beskrivning av tabellerna

Publikationen omfattar nio tabeller om assisterad befruktning (tabell 1), preimplantatorisk genetisk diagnostik (tabell 2), abort (tabell 3), prenatal diagnostik (tabell 4), embryoforskning, stamcellsforskning och kloning (tabell 5), klinisk forskning på människor (tabell 6), biobanker (tabell 7), genetisk testning och genterapi (tabell 8) och djurförsök (tabell 9). Fakta från de nordiska länderna (i alfabetisk ordning) presenteras parallellt i de lodräta kolumnerna. Vågrätt presenteras lagarna om ämnesområdet i fråga under varje rubrik och några nyckelfrågor i lagstiftningen som har valts för jämförelse. Lagarnas namn på originalspråket återfinns i fotnoterna, vid behov kompletterat med mera detaljerad information.

Ytterligare information om de nationella lagarna i de nordiska länderna kan hittas genom sökning i elektroniska databaser, t.ex.:

www.retsinfo.dk (Danmark)
www.finlex.fi (Finland)
www.ministryofhealth.is (Island)
www.lovdata.no (Norge)
www.lagrummet.se (Sverige)

Table 1. Assisted reproduction

	Denmark	Finland	Iceland	Norway	Sweden
Law	Act on artificial fertilisation (10.6.1997/460)[1]	No specific legislation Governmental bill on assisted reproduction[2] was withdrawn from the Parliament in March 2003.	Act on artificial fertilisation (29.5.1996/55) [3] Regulation on artificial fertilisation (30.9.1997/568).[4]	Act on the medical use of bio-technology (5.12.2003/100)[5]	Act on insemination (20.12.1984/1140)[6] In vitro fertilisation act (14.6.1988/711)[7] Act concerning measures for purposes of research or treatment involving human ova (14.3.1991/115)[8].
License of premises	No	-	Yes	Yes	Yes[9]
Age limit - woman - man	 Not over 45 -	 - -	 42(45) 50	 - -	 Normal age of menopause Ability to carry out parental responsibilities throughout childhood[10]
Marriage/ Cohabitation	Yes	-	Yes	Yes	Yes[11]
Welfare of the child	-	-	Yes	Yes	Yes
Written consent - woman - man	 Yes Yes	 - -	 Yes Yes	 Yes Yes	 No Yes[12]

[1] Lov nr. 460 av 10 juni 1997 om kunstig befrugtning som ændret ved lov nr. 427 af 10. juni 2003, lov nr. 69 af 4. februar 2004 og lov nr. 240 af 5. april 2004.

[2] Hallituksen esitys Eduskunnalle laeiksi sukusolujen ja alkioiden käytöstä hedelmöityshoidossa ja isyyslain muuttamisesta/Regeringens proposition till Riksdagen med förslag till lag om användning av könsceller och embryon vid assisterad befruktning samt till lag om ändring av lagen om faderskap HE/RP No. 76/2002.

[3] Lög um tæknifrjóvgun nr. 55/1996.

[4] Reglugerð nr. 568/1997 um tæknifrjóvgun með áorðnum breytingum skv. reglugerð nr 585/1997.

[5] Lov 2003-12-05 nr 100: Lov om humanmedisinsk bruk av bioteknologi m.m. (bioteknologiloven) som endret ved lov nr. 45 av 25. juni 2004.

[6] Lag (1984:1140) om insemination.

[7] Lag (1988:711) om befruktning utanför kroppen.

[8] Lag (1991:115) om åtgärder i forsknings- eller behandlingssyfte med ägg från människa. The title and certain sections of this law were changed 1.4.2005, see Governmental bill 2003/04:148.

[9] Different requirements for different treatments apply. See section 3 of the Act on insemination and section 4 of the In vitro fertilisation act.

[10] Section 5 of the In vitro fertilisation act and guidelines of the National Board of Health and Welfare, SOSFS 2002:13 on assisted procreation.

[11] The Swedish Parliament recently passed a bill permitting assisted procreation also for homosexual female couples, as of 1.7.2005, see Governmental bill 2004/05:137. This means that what is said in the table above about 'man' or 'husband/cohabitant' will also be applicable to female cohabitant or registered partner of the woman giving birth. The female partner will become a legal parent (not called 'mother' but 'parent'). If the child is thus conceived by assisted procreation under one of the above mentioned Acts, it will have two legal parents, but none of them will be a father.

[12] See fn. 11 above.

Table 1 continued

	Denmark	**Finland**	**Iceland**	**Norway**	**Sweden**
Cryopreservation - semen - eggs - embryos	 - 2 years 2 years	 - - -	 10 years 10 years 5 years	 Yes[13] Yes[14] 5 years	 - - 5 years
Donation - semen - egg - embryos	 Yes Yes[15] No	 - - -	 Yes Yes No	 Yes No No	 Yes Yes No
Donor anonymity	Yes	-	Optional	No	No
Surrogacy	No[16]	-	No	No	No[17]
Legal mother	Woman who gives birth	Woman who gives birth	Woman who gives birth	Woman who gives birth	Woman who gives birth
Legal father	Consenting husband/partner	Husband (presumption) or man declared as father by court[18]	Consenting husband/partner	Consenting husband/partner	Consenting husband/partner[19]

[13] Semen may not be used for assisted reproduction after the death of the donor.

[14] Eggs may be preserved if the woman either is approved for assisted reproduction, or undergoes treatment with risk of infertility as outcome, and only as long as it is in her interest and it is within good practice.

[15] However, this is restricted to women receiving assisted reproduction treatments.

[16] Surrogacy is not specifically forbidden, however, a number of provisions in the Act on artificial fertilisation and the Act on adoption impedes surrogacy.

[17] Surrogacy is not regulated, thus not formally prohibited.

[18] Paternity Act (Isyyslaki/Lag om faderskap, 5..9.1975/700). According to a ruling by the Finnish Supreme Court No. 85 (11.9.2000), a man who has acknowledged in writing to be the father of a child born by methods of assisted reproduction, cannot withdraw his acknowledgment.

[19] See fn. 11 above.

Table 2. Preimplantation genetic diagnosis

	Denmark	Finland	Iceland	Norway	Sweden
Law	Act on artificial fertilisation (10.6.1997/460)[20]	No existing legislation	Act on artificial fertilisation (29.5.1996/55) Regulation on artificial fertilisation (30.9.1997/568)	Act on the medical use of bio-technology (5.12.2003/100)[21]	Guidelines[22]
Hereditary disorder	Yes, if risk of severe hereditary disorder	-	Yes, if risk of hereditary disease in the embryo	Yes, if risk of severe and untreatable sex-linked hereditary disorder. After individual exemption by a special committee also if disorder is not sex-linked.	Yes, if risk of severe, progressively developing hereditary disorder that will lead to premature death.
Chromosomal disorder	Yes, to couples undergoing IVF-treatment	-	Yes, in order to diagnose genetic defects leading to hereditary disease in the embryo (as part of IVF treatment)	-	Yes, if risk of severe, progressively developing chromosomal disorder that will lead to premature death.
Sex selection	No, unless risk of sex-linked disorder	-	No, unless risk of sex-linked disorder	No, unless risk of sex-linked hereditary disorder	
Tissue typing	Yes, if sibling suffers from a serious and untreatable disease. Individual authorisation from National Board of Health.	-	No	Yes, if sibling suffers from a serious and untreatable disease. Individual exemption by a special committee.	

[20] Lov nr. 460 av 10 juni 1997 om kunstig befrugtning som ændret ved lov nr. 427 af 10. juni 2003, lov nr. 69 af 4. februar 2004 og lov nr. 240 af 5. april 2004.

[21] Lov nr. 100 af 5. december 2003 om humanmedisinsk bruk av bioteknologi m.v. som endret ved lov nr. 45 av 25. juni 2004.

[22] Governmental bill 1994/95:142 (Regeringens proposition 1994/95:142 Fosterdiagnostik och abort) and Standing social committee 1994/95:SoU 18 (Socialutskottet 1994/95:SoU 18 Fosterdiagnostik och abort). In the public report 'Genethics, integrity and ethics' (SOU 2004:20), it is proposed that the National Board of Health and Welfare be authorised to issue binding regulations concerning preimplantation and prenatal genetic diagnosis, and that these provisions be made slightly less strict than the present guidelines (leaving out the requirement of risk of premature death).

Table 3. Abortion

	Denmark	Finland	Iceland	Norway	Sweden
Law	Act on abortion and foetus reduction (16.6.2004/541)[23]	Abortion act (24.3.1970/239)[24]	Act on counselling and education on sexual health and childbearing and on induced abortion and sterilisation (22. 5.1975/25) [25]	Act on abortion (13.6.1975/50)[26]	Abortion act (12.6.1974/595)[27]
Right to abortion on request	Yes Until end of 12th week of pregnancy	No	No, only on social or medical grounds	Yes Until end of 12th week of pregnancy	Yes Until end of 18th week of pregnancy
Grounds / gestational limit					
- Life of woman	No upper limit	No upper limit	No upper limit	No upper limit	No upper limit[28]
- Mental or physical health of woman	Special permission until foetal viability (20-22 weeks)	12 weeks, 20 with special permission	Up to 16 weeks, after 16 weeks with special permission until foetal viability	18 weeks, or until foetal viability if very weighty grounds	Foetal viability (22 weeks), with special permission.
- Sexual abuse	Special permission until foetal viability (20-22 weeks)	12 weeks, 20 with special permission	Up to 16 weeks	Same as above	Same as above
- Economic or social reasons	Special permission until foetal viability (20-22 weeks)	12 weeks, 20 with special permission	Up to 16 weeks	Same as above	Same as above
- Foetal impairment	Special permission until foetal viability (20-22 weeks). If severe foetal impairment, no upper limit.	12 weeks without special permission, 24 weeks with permission if severe foetal impairment.	Up to 16 weeks, after 16 weeks if severe impairment, with specific permission until foetal viability	Same as above	Same as above Severe foetal impairment may affect viability assessment.

[23] Lovbekendtgørelse nr. 541 af 16. juni 2004 om svangerskabsafbrydelse og fosterreduktion.

[24] Laki raskauden keskeyttämisestä/Lag om avbrytande av havandeskap (24.3.1970/239).

[25] Lög um ráðgjöf og fræðslu varðandi kynlíf og barneignir og um fóstureyðingar og ófrjósemisaðgerðir 1975 nr. 25 22. maí.

[26] Lov nr. 50 af 13. juni 1075 om svangerskapsavbrudd som endret ved lov nr. 87 af 29. august 2003.

[27] Abortlagen (1974:595).

[28] When a pregnancy is ended in order to save the life of the woman under section 6 of the Abortion act, this does not constitute a legal abortion. If the foetus is viable, the aim will be to save the foetus as well as the woman.

Table 3 continued

	Denmark	**Finland**	**Iceland**	**Norway**	**Sweden**
Procedural requirements	Applications for abortion after the expiration of 12th week of pregnancy must be submitted to a regional board consisting of two doctors and an administrative official Decision of the board may be appealed to a national Abortion Appeals Panel.	Decision by one physician before 12th week: - woman underage at time of conception - aged 40 + - given 4 births - woman's health is in immediate danger Written decision by two physicians in all other cases, except - foetal condition - pregnancy is past 12th weeks Permission from National Agency for Medicolegal Affairs: - after 12th week - foetal condition	Abortion before the end of 16th week: written report of two physicians is required, or a physician and a social worker, if there are social reasons. Decision can be appealed to a committee appointed by the Minister of Health consisting of a doctor, a lawyer and a social worker. After the end of 16th week, permission from the above-mentioned committee is required.	Application from woman aged 16 + before 12th week; if woman below 16 or mentally impaired: application by legal representative. After 12th week decision by two physicians. Consent from state authority needed if woman is below 16 or mentally impaired and legal representatives discourage abortion.	Applications for abortion after expiration of 18th week must be submitted to the National Board of Health and Welfare. Special reasons required for authorisation. Permission is also required for ending a pregnancy in order to save the life of the woman, unless there is an emergency situation.

Table 4. Prenatal diagnosis

	Denmark	Finland	Iceland	Norway	Sweden
Law	Guidelines on prenatal diagnostics[29]	No existing legislation.	Guidelines from the Directorate of Health (under revision)[30]	Act on the medical use of biotechnology (5.12.2003/100)[31]	Guidelines[32]
Nuchal fold ultrasound test and blood test	Available for all week 11-13	-	Available for all by week 11-14	-	Varying degree of availability, individual assessment.
Ultra sound	Available for all week 18	-	Available for all week 19	Ultrasound as part of regular antenatal care does not come under the scope of the law.	Available for all (normally week 16).
Invasive tests (AC/CVS) available for - all - individual assessment - risk-groups	Individual assessment	-	Individual assessment	Individual assessment	Risk groups and individual assessment
Limitation on the conditions that apply to examination	No specific regulation.	-	Guidelines from the Directorate of Health (under revision)[33]	Examination methods should be approved by the Ministry of Health	No specific regulation
Information of sex	No specific regulation	-	No specific rules or regulations	Prohibited in the first 12 week of pregnancy, unless woman carries serious gender-bound disease.	No specific regulation

[29] Sundhedsstyrelsen, 'Retningslinier for fosterdiagnostik – prænatal information, risikovurdering, rådgivning og diagnostik', 2004.
[30] Klínískar leiðbeingar í vinnslu um meðgönguvernd, (vefsett 7. febrúar 2005).
[31] Lov nr. 100 af 5. december 2003 om humanmedisinsk bruk av bioteknologi m.v. som endret ved lov nr. 45 av 25. juni 2004.
[32] National Board of Health and Welfare, 'Allmänna råd (SOSFS 1997:20) om information om fosterdiagnostik'.
[33] Klínískar leiðbeingar í vinnslu um meðgönguvernd,(vefsett 7. febrúar 2005).

Table 5. Embryo research, stem cell research and cloning

	Denmark	**Finland**	**Iceland**	**Norway**	**Sweden**
Embryo research	Act on artificial fertilisation (10.6.1997/460)[34]	Medical research act (9.4.1999/488)[35]	Act on artificial fertilisation (29.5.1996/55)[36]	Act on the medical use of bio-technology (5.12.2003/100)[37]	Act concerning measures for purposes of research or treat-ment involving human ova (14.3.1991/115)[38]
Research	Up to 14 days	Up to 14 days	Up to 14 days	Prohibited	Up to 14 days
Storage	2 years	15 years	Not for research	-	5 years
Stem cell research					
Specific regulation	Yes Research is only allowed on surplus embryos	No	No	Yes	SNCT embryos are now covered by the 1991 Act[39]
Ongoing or recent scrutiny	No	Yes	No	Yes	Recent
Reproductive Cloning	Act on artificial fertilisation (10.6.1997/460)	Medical research act (9.4.1999/488)	Act on artificial fertilisation (29.5.1996/55)	Act on the medical use of bio-technology (5.12.2003/100)	Act concerning measures for purposes of research or treat-ment involving human ova (14.3.1991/115)
Allowed	No	No	No	No	No

- = not applicable

[34] Lov nr. 460 av 10 juni 1997 om kunstig befrugtning som ændret ved lov nr. 427 af 10. juni 2003, lov nr. 69 af 4. februar 2004 og lov nr. 240 af 5. april 2004.

[35] Laki lääketieteellisestä tutkimuksesta/Lag om medicinsk forskning (9.4.1999/488).

[36] Lög um tæknifrjóvgun nr. 55/1996.

[37] Lov 2003-12-05 nr 100: Lov om humanmedisinsk bruk av bioteknologi m.m. (bioteknologiloven) som endret ved lov nr. 45 av 25. juni 2004.

[38] Lag (1991:115) om åtgärder i forsknings- eller behandlingssyfte med ägg från människa.

[39] The Act was changed and amended 1 April 2005, see Govermental bill 2003/04:148. It now applies both to fertilised human ova and to such ova as have been subjected to somatic cell nuclear transfer (SNCT).

Table 6. Clinical research on humans

	Denmark	Finland	Iceland	Norway	Sweden
Law	Act on the biomedical research ethics committee system (28.5.2003/402)[40] Act on medicinal products (28.7.1995/656)[41]	Medical research act (9.4.1999/488)[42] Act on medicinal products (10.4.1987/395)[43]	Act on the Rights of Patients (28.5.1997/74)[44] Regulation on Scientific Research in the Health Sector 29.7.1999/522)[45] Act on Artificial Fertilisation 29.5.1996/55)[46] The Medical Products Act (20.5.1994/93)[47]	No existing legislation[48]	Act on ethics review of research involving humans (5.6.2003/460)[49]
Purpose	Sets the legal framework for the scientific ethical evaluation of biomedical research on: - live born human individuals, - human germ cells intended to be used in fertilization, - human fertilized eggs, - embryos and foetuses, - tissue, cells and genetic material from humans, foetuses and the like or deceased individuals.	Gives the regulatory basis for ethics committees in medical research and sets the legal framework for medical research on: - live humans, - human embryos, - foetuses.	To ensure human rights and human dignity in medical research on humans	-	Protection of individual humans and respect for human dignity in research.

[40] Lov nr. 402 af 28. maj 2003 om et videnskabsetisk komitésystem og behandling af biomedicinske forskningsprojekter

[41] Lovbekendtgørelse nr. 656 af 28. juli 1995 med de ændringer, der følger af lov nr. 1228 af 27. december 1996, lov nr. 1043 af 23. december 1998, lov nr. 493 af 7. juni 2001, lov nr. 255 af 8. maj 2002, lov nr. 297 af 15. maj 2002, lov nr. 966 af 4. december 2002, lov nr. 1052 af 17. december 2002 og lov nr. 382 af 28. maj 2003.

[42] Laki lääketieteellisestä tutkimuksesta/Lag om medicinsk forskning (9.4.1999/488).

[43] Lääkelaki/Läkemedelslag (10.4.1987/395).

[44] Lög um réttindi sjúklinga nr. 74/1997.

[45] Reglugerð um vísindarannsóknir á heilbrigðissviði nr. 552/1999.

[46] Lög um tæknifrjóvgun, nr. 55/1996.

[47] Lyfjalög nr. 93/1994.

[48] Legislation under preparation, see Committee report 'Good research – better health' (God forskning – bedre helse) NOU 2005:1.

[49] Lag (2003:460) om etikprövning av forskning som avser människor.

Table 6 continued

	Denmark	**Finland**	**Iceland**	**Norway**	**Sweden**
Scope - medical research - other research on humans	Yes No, e.g. research using solely already existing data or research by interview is excluded unless human tissue is involved.	Yes No, e.g. research using solely already existing data or research by interview is excluded.	Yes Yes. All research conducted with the aim to achieve further knowledge, making it, *inter alia*, possible to improve health and cure diseases. This includes access to clinical records and biological samples.	-	Two main categories (not just aimed at biomedicine): a) research involving processing of sensitive personal data without consent b) research involving physical interventions, physical or psychological manipulation or studies on biological material from identifiable dead or living humans.
Ethics committees - composition - functions	Regional committee: 7-15 members (3-7 researchers and 4-8 lay persons) National Committee for Biomedical Research Ethics: 19 members (majority of lay persons) To grant permission for research and review whether biomedical research projects will be carried out in a responsible manner, and that the rights and safety and well-being of trial subjects are protected, while at the same time creating the possibility of developing new, valuable knowledge.	Hospital district committees: Chair + minimum of 6 members, of which minimum two lay persons. Sub-Committee on Medical Research functions as the National Ethics Committee.[50] To deliver a reasoned opinion on whether the research project is ethically acceptable. For the opinion, ethics committees shall examine the research plan in the light of Medical research act, data protection legislation, international obligations and the rules and guidelines that govern medical research. Ethics committees also monitor and direct handling of issues in research ethics in their region.	National Bioethics Committee: five members, specialists in health sciences, scientific ethics and human rights. Also interdisciplinary institutional ethics committees. The National Bioethics Committee evaluates collaborative projects, multinational studies and other protocols for scientific studies, which do not fall under the aegis of institutional ethics committees. Institutional ethics committees evaluate protocols for scientific studies conducted by relevant parties within their hospitals.	-	Six regional boards for ethics review, each with a minimum of two divisions: 16 members appointed by the Government (10 research, 5 lay persons and 1 chairperson who is a judge) One Central board for ethics review: 7 members appointed by the Government (4 researchers, 2 lay persons and 1 chairperson who is a judge) To ethically review research applications and to give opinions. The Central board reviews appeals and referrals, and also has a supervisory function.

[50] See Decree on the National Advisory Board on Health Care Ethics (Asetus valtakunnallisesta terveydenhuollon eettisestä neuvottelukunnasta/Förordning om en riksomfattande etisk delegation inom hälso- och sjukvården), (26.6.1998/494).

Table 6 continued

	Denmark	Finland	Iceland	Norway	Sweden
Consent	Written informed consent	Written informed consent	Formal, informed consent (normally in writing).	-	Free, explicit, specified and documented consent (normally in writing).
Exceptions from written informed consent - emergencies - other	 Yes (not drug trials) No	 Yes (not drug trials) Yes - witnessed oral consent if the participant is unable to write - when written consent (giving personal data) is against the best interests of the participant	 No specific rules or regulations. Yes, ethics committees may grant exceptions for amendments to studies where consent has been obtained, and for epidemiological studies and use of unidentifiable biological samples.	-	Written consent is not mandatory by law, only that the consent be documented. For drug trials, the Medical Products Agency requires written consent, but may dispense from this requirement. For other research than drug trials, the REC may grant exceptions from the requirement of new informed consent for new use of biobank samples or the processing of sensitive personal data.
Children - non-therapeutic research allowed - age limit for independent consent - proxy - relevance of refusal	 Yes 18 years However, based on assessment of the nature, risk and harmfulness REC may grant exemptions if 15 years Custodian Always valid	 Yes 15, if expected health benefit and understands implications of participation Custodian or other legal representative According to the age and understanding of the child	 Yes No specific rules or regulations[51] Parent or other legal guardian Always valid, no specific rules or regulations	-	 Yes 15 and ability to understand implications of participation Custodians When able to understand implications of participation

[51] When there are no specific national rules or regulations, the National Bioethics Committe shall apply the Recommendations of the Committee of Ministers of the Council of Europe, the Helsinki Declaration, and the International Ethical Guidelines for Biomedical Research Involving Human Subjects.

Table 6 continued

	Denmark	**Finland**	**Iceland**	**Norway**	**Sweden**
Incompetent adults				-	
- non-therapeutic research allowed	Yes	Yes, on certain conditions	Yes, on certain conditions		Yes, on certain conditions
- proxy	Double consent requirement from both legal guardian or close relative and general practitioner (alternatively medical officer of health)	Close relative, other close person or legal representative	Legal guardian or close relative, other close person or legal representative		Right of veto for close relatives and legal representatives
- relevance of refusal	Always valid	Always valid	Always valid		Always valid
- advance directives	Not mentioned in the law, might be relevant in proxy decision-making	Not mentioned in the law, relevant in proxy decision-making	Not mentioned in law or regulations		Not mentioned in the law
Other mentioned vulnerable groups	If reservation regarding free consent (e.g. persons living in social institutions, prisoners, employees) special rules may apply. Psychiatric patients in involuntary care cannot be included in medical research.	Pregnant or breast-feeding women, prisoners	No specific rules or regulations	-	No

- = not applicable

Table 7. Biobanks

	Denmark	Finland	Iceland	Norway	Sweden
Law	Act on rights of patients (1.7.1998/482)[52] Act on processing of personal data (31.5.2000/429) [53] Act on the biomedical research ethics committee system (28.5.2003/402)[54]	Act on the use of human organs and tissues for medical purposes (2.2.2001/101)[55] Medical research act.[56]	Act on biobanks (13.5.2000/110)[57]	Act on biobanks (21.2.2003/12)[58]	Act on biobanks in health care (23.5.2002/297)[59]
Purpose	Amendment to the Act on patients rights was added in 2004 to include provisions on the self-determination of patients with regard to biological samples taken in connection with their care or samples that are given to private enterprises for storage or for development of pharmaceuticals.	The 2001 Act covers inter alia the collection, storage, and use of organs and tissue taken in connection with diagnosis and treatment. Includes also provisions on the use of human organs, tissues and tissue samples for a purpose other than that for which they were removed or retained. Medical research act covers clinical research and research on embryos and foetuses.	To authorise the collection, keeping, handling and utilisation of biological samples ensuring confidentiality, safeguarding interests of the donor and serving purposes of science, medicine and the public good.	Regulates the collection, storage and use of human biological material and certain information derived thereof. The law safeguards ethical considerations, considerations to privacy, human rights, integrity and non-discrimination and serve purposes of healthcare, medical science and public good.	Regulation of the collection, storage and use of human biological material for certain purposes, with due respect for the integrity of the individual human being.
License required	No	Yes, but only for removal or use of non-regenerative tissue, the donor of the tissue is a minor, incompetent or deceased, or when the tissue is or has been taken in connection with abortion. [60] Medical research act requires licence for research on embryos.	Yes	No, for banks for diagnostic or treatment purposes, but notification is required. Yes, for banks with research purposes.	No, but notification is required.

[52] Lov nr. 482 af 1. juli 1998 om patienters retsstilling som ændret ved lov nr. 312 af 5. maj 2004.

[53] By the decision of the Danish Data Protection Authority, biobanks are covered by the Act on processing of personal data, if the samples are linked to an identifiable person.

[54] Lov nr. 402 af 28. maj 2003 om et videnskabsetisk komitésystem og behandling af biomedicinske forskningsprojekter.

[55] Laki ihmisen elimien ja kudoksien lääketieteellisestä käytöstä/Lag om användning av mänskliga organ och vävnader för medicinska ändamål (2.2.2001/101).

[56] Laki lääketieteellisestä tutkimuksesta/Lag om medicinsk forskning (9.4.1999/488).

[57] Lög um lífsýnasöfn nr. 110/13.5.2000.

[58] Lov 2003-02-21 nr 12 om biobanker (biobankloven).

[59] Lag (2002:297) om biobanker i hälso- och sjukvården m.m.

[60] Laki ihmisen elimien ja kudoksien lääketieteellisestä käytöstä/Lag om användning av mänskliga organ och vävnader för medicinska ändamål (2.2.2001/101).

Table 7 continued

	Denmark	**Finland**	**Iceland**	**Norway**	**Sweden**
Consent - to storage	No consent if sample taken for diagnosis or treatment[61] Informed written consent if sample taken for research purposes	Informed, written consent (except samples that are taken on routine bases for diagnosis and treatment and not stored)	Presumed consent if collected for *diagnostic purposes*, possibility to opt out. Informed consent if collected for *scientific research.*	Presumed consent for diagnostic/therapeutic use. Informed consent for scientific research.	Informed consent (exception for samples that are taken on routine basis, exclusively for diagnosis, care or treatment of the donor and that are not stored for any longer period, normally 2 months).
- different use	Depends on purpose. Samples collected in connection with medical treatment may be used for other purposes unless patient chooses to opt out (registration in special opt-out database). Rules in Act on processing of personal data applies and Act on the biomedical research ethics committee system applies and may require consent.	New consent – however, the National Authority for Medicolegal Affairs may grant an exception depending on the primary purpose of the sample and the circumstances of the new use or when the donor is deceased.	Informed consent if samples collected for diagnostic purposes are to be used for *genetic research*, subject to evaluation of National Bioethics Committee (NBC) and Data Protection Authority (DPA).	Narrow opening for use without consent if approved by ethics committee.	New informed consent is required for further use of samples – however, if the new purpose is research or a clinical trial, the board for ethics review may allow exceptions.
Withdrawal of consent	Patient can ask for destruction or retrieval of samples collected in connection with patient care, but it may be overridden by public or private interests. Withdrawal of consent is not accepted for samples collected for clinical research.[62]	Any time	Any time – but in the case of a biobank with clinical samples, the board of the biobank may with the approval of the NBC and the DPA authorise the use for purposes when important interests are at stake.	Any time, with exceptions regulated by law, or when the material/information is integrated in other material or scientific work.	Any time – however, depersonalised samples may be used despite withdrawal.

- = not applicable

[61] Consent is not required. However, as patients have the right to retain or demand the destruction of samples, it could be argued that storage is based on presumed consent.

[62] This does not follow clearly from the Act on Biomedical Research Ethics Committee System, but the National Committee for Biomedical Research Ethics has taken this position. See Den Centrale Videnskabsetiske Komités Årsberetning 2003, p. 37 f.

Table 8. Genetic testing and gene therapy

	Denmark	Finland	Iceland	Norway	Sweden
Genetic testing	Act on the use of health information in the labour market (24.4.1996/286)[63] Act on the use of health information in insurance writing (10.6.1997/413)[64]	Act on protection of privacy in the labour market (8.6.2001/477)[65]	No specific regulation; general rules according to Act on the rights of patients apply (28.5.1997/74)[66]	Act on the medical use of biotechnology (5.12.2003/100)[67]	Act concerning the use of certain genetic technology in medical screening (14.3.1991/114)[68]
Health care sector	No specific regulation – the Act on the rights of patients (1.7.1998/482)[69] applies	No specific regulation – the Act on the status and rights of patients (17.8.1992/785)[70] applies	No specific regulation – general rules according to Act on the rights of patients apply	Must be used for medical purposes only	No regulation in individual cases exists, the above Act applies to certain types of medical screening only.[71]
Other sectors - labour market	Prohibited – but a test may be suggested in particular situations	Prohibited	Discrimination on grounds of data derived from a biological sample is prohibited by the Act on biobanks (13.5.2000/110)[72]	Prohibited	Unregulated
- insurance	Prohibited	Voluntary moratorium		Prohibited	Prohibited by temporary agreement if amount below 580.000 SEK[73]
Gene therapy	No specific regulation except on gametes Act on artificial fertilisation (10.6.1997/460)[74]	No specific regulation except on embryos and gametes Medical research act[75]	No specific regulation General rules according to Act on the rights of patients (28.5.1997/74)[76]	Act on the medical use of biotechnology (5.12.2003/100)[77]	No specific regulation except on ova. Act concerning measures for purposes of research or treatment involving human ova (14.3.1991/115)[78]

[63] Lov nr. 286 av 24 april 1996 om brug af helbredsoplysninger på arbejdsmarkedet.

[64] Lov nr. 413 av 10 juni 1997 om ændring af lov om forsikringsaftaler og lov om tilsyn med firmapensionskasser (Forbud mod anvendelse af visse helbredsmæssige oplysninger ved tegning m.v. af forsikringer og pensioner).

[65] Laki yksityisyyden suojasta työelämässä/Lag om integritetsskydd i arbetslivet (8.6.2001/477).

[66] Lög um réttindi sjúklinga nr. 74/1997.

[67] Lov 2003-12-05 nr 100: Lov om humanmedisinsk bruk av bioteknologi m.m. (bioteknologiloven) som endret ved lov nr. 45 av 25. juni 2004.

[68] Lag (1991:114) om användning av viss genteknik vid allmänna hälsoundersökningar.

[69] Lov nr. 482 af 1. juli 1998 om patienters retsstilling som ændret ved lov nr. 312 af 5. maj 2004.

[70] Laki potilaan asemasta ja oikeuksista/Lag om patientens ställning och rättigheter (17.8.1992/785).

[71] In the public report 'Genethics, integrity and ethics' (SOU 2004:20), a new Act on genetic integrity is proposed. This Act is intended to regulate various aspects of genetic testing.

[72] Lög um lífsýnasöfn nr. 110/13.5.2000.

[73] The agreement was made between the states and the Swedish Insurance Federation in 1999. In the public report 'Genethics, integrity and ethics (SOU 2004:20), it is proposed that an Ordinance on use of genetic information in insurance be introduced. The amount limits would then be doubled.

[74] Lov nr. 460 av 10 juni 1997 om kunstig befrugtning som ændret ved lov nr. 427 af 10. juni 2003, lov nr. 69 af 4. februar 2004 og lov nr. 240 af 5. april 2004.

[75] Laki lääketieteellisestä tutkimuksesta/Lag om medicinsk forskning (9.4.1999/488).

Table 8 continued

	Denmark	**Finland**	**Iceland**	**Norway**	**Sweden**
Application					
- somatic cells	-	-	-	Only in case of serious disease	-
- gametes	No	Only in case of research of serious hereditary disease.	No[79]	No	No, unless gametes are used to produce a fertilised egg or a SCNT embryo after manipulation.[80]

- = not applicable

[76] Lög um réttindi sjúklinga nr. 74/1997.

[77] Lov 2003-12-05 nr 100: Lov om humanmedisinsk bruk av bioteknologi m.m. (bioteknologiloven) som endret ved lov nr. 45 av 25. juni 2004.

[78] Lag (1991:115) om åtgärder i forsknings- eller behandlingssyfte med ägg från människa. The title and certain sections of this law were changed 1 April 2005.

[79] As all research, experiments and operations on embryos is prohibited except under very restricted conditions specified in the Act on artificial fertilisation, gene therapy including embryonic stem cells (or gametes) would not be allowed.

[80] The Act prohibits research aimed at producing hereditary genetic effects, as well as the development of methods for such purposes (new wording of section 2 of the Act since 1 April 2005).

Table 9. Animal experimentation

	Denmark	Finland	Iceland	Norway	Sweden
Law	Act on animal experimentation (9.9.1993/726)[81]	Act on animal protection (4.4.1996/247)[82] Decree on animal experimentation (20.12.1985/1076)[83]	Act on animal welfare (16.3.1994/15)[84]	Act on animal care with amendments (20.12.1974/73).[85]	Animal protection act (2.6.1988/534)[86]
Scope (which animal categories are covered by law)	All vertebrates	All vertebrates[87]	Any live non-human vertebrates, including free-living larval and/or reproducing larval forms. Foetal or embryonic forms are excluded.	Mammals, birds, toads, frogs, salamanders, reptiles, fish and crayfish.	All vertebrates used for scientific purposes, i.e. scientific research or teaching, diagnosis of disease, production of pharmaceutical or chemical products, and other similar purposes.
Ethics committee system (institutional, local, regional, national)	National Council for Animal Experiments	Institutional or local committees and authorities of county government[88]	The national animal research committee	National ethics committee[89]	Seven regional boards for ethics review of animal research, appointed by the National Agency for Animal Protection.

[81] Lovbekendtgørelse nr. 726 af 9. september 1993 om dyreforsøg som ændret ved lov nr. 1081 af 20. december 1995, lov nr. 433 af 31. maj 2000 og lov nr. 315 af 5. maj 2004.

[82] Eläinsuojelulaki/Djurskyddslag (4.4.1996/247).

[83] Asetus koe-eläintoiminnasta/Förordning om försöksdjursverksamhet (20.12.1985/1076). A proposal for a new Animal experimentation act has been given to the Parliament in the spring 2005 (HE/RP 32/2005).

[84] Lög um dýravernd nr. 15, 16. mars, 1994. Under the Animal welfare act is the Regulation on animal experiments (regulation nr. 279 from 5.th of april, 2002). The regulation is based on The Icelandic Animal welfare act and Council directive of 24. November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes (86/609/EEC).

[85] Lov 1974-12-20 nr. 73 om dyrevern.

[86] Djurskyddslagen (1988:534). However, many of the specific provisions on review of animal research are found in sections 40-55a of the complementing Ordinance on animal protection, Djurskyddsförordningen (1988:539). See also regulation from the National Agency for Animal Protection: Djurskyddsmyndighetens föreskrifter och allmänna råd (DFS 2004:4) om djurförsök m.m.

[87] According to the new proposal, also free moving larval forms of vertebrates are included.

[88] In the proposal for a new Animal experimentation act, a centralised system for evaluation of animal experimentation is proposed.

[89] Forsøksdyrutvalget

Table 9 continued

	Denmark	**Finland**	**Iceland**	**Norway**	**Sweden**
Composition of ethics committee	11 members: 1 lawyer as chairman, 10 members appointed by - research communities (2) - National Board of Health (1) - Industry (1) Non-governmental health charities[90] (1) Ethical Council concerning Animals (1) Animal welfare organisations (4)	Minimum of 4 members (+ personal substitutes): 1 person directing and supervising animal experimentation 1 person responsible for animal care 2 persons knowledgeable in animal experimentation, laymen voluntary91	3 members: The chief veterinary officer (chairman), scientist (a veterinarian), ethicist	7 members; 1 veterinary 1 physician 1 biologist 1 practicing animal researcher 1 geneticist 1 lawyer 1 representing the Society for prevention of cruelty to animals. Since 2000, a trial period with an 8th member who is an animal research technician.	14 members (6 scientists and 6 laypersons + 1 chairperson and 1 vice chair, both judges). The laypersons shall include a minority of representatives of animal welfare organisations.
Is positive ethics committee approval compulsory for research or research funding?	Yes	For research, yes For funding, yes, generally	Yes, an approval from the national animal research committee is compulsory for research.	Yes	Yes (Exemptions may be prescribed by the National Agency for Animal Protection)
Specific criteria for cost-benefit evaluation	Experiments on living animals should only be carried out when no other suitable alternative methods are available and the expected benefits to human should outweigh the costs to the animals. The animals must not be subjected to more suffering than is absolutely necessary. As few animals should be used as possible	Part of overall evaluation, specific guidelines in test use by some committees.	No formal criteria used. Experiments are evaluated according to the national animal welfare act and the national regulation of animal experiments: 1.Living animals can only be used if the purpose can not be reached by appropriate means other than the use of animals. 2. There must be a realistic possibility that the purpose of the experiment can be reached. 3. The animals must not be subjected to more suffering than is absolutely necessary. 4. As few animals should be used as possible.	No specific criteria, but cost-benefit is evaluated as part of the overall evaluation.	Yes, requires a balance of the importance of the research against the suffering of the animal. Further prerequisites: 1. The purpose can not be reached by appropriate means other than the use of animals 2. The animals must not be subjected to more suffering than is absolutely necessary, and 3. Only animals bred for the purpose shall be used.

[90] 'Sygdomsbekaempende organisationer', e.g. The Cancer Association or The Heart Association.

[91] In practice, animal experimentation committees consist of 6-12 members. According to the proposed new law, the composition of the central animal experimentation board will consist of 16 members + 1 chair or vice chair, both lawyers. Members shall be composed of 4 scientists, 4 veterinarians, 4 persons from animal welfare organisations or experts in ethics, and 4 persons of animal care. Most evaluations will be done in four sub-committees consisting of one member from each specialist area.

Table 9 continued

	Denmark	Finland	Iceland	Norway	Sweden
Specific criteria for genetically modified animals	No specific rules in Act of Animal Experiments. However, special rules in Act on use of biotechnology92 requires authorisation from Danish Working Environment Authority and the National Forest Agency.	Approval by the ethics committee needed: 1. for creating new gm-strains and new hybrids, 2. breeding gm-strains with harmful phenotype, 3. tail cutting but not ear puncture for DNA definition of harmless gm-strain for breeding	No specific criteria for experiments on GMAs. However, there is special legislation on GMOs, contained use, import, handling, marketing and release.	No	Not concerning ethics review93
Means of destruction of animals after experimentation	General rules regarding health and safety in working environment applies together with general rules regarding the handling of biological material considered to be risk refuse	Burying, incineration for risk carcass94	The carcasses of experimental animals are buried after experimentation, according to the Icelandic regulation on the handling of waste material (29.9.2003/737).[95]	No specific legislation for animals. They are treated as risk refuse.	No specific legislation, EC Regulation No 1774/2002 on animal by-products applies.
Scope of statistics collected of used animals	1.Animals in experimental procedures 2. Purpose of experimentation and number of animals used for various purposes. Statistics is in accordance with the decisions made in the EU and the Council of Europe.	1. Animals in experimental procedures (according to the EC and Council of Europe requirements) 2. Animals sacrificed as tissue or organ donors (according to national regulations) 3. Animals used for breeding (according to national regulations)	The annual report from the national animal research committee includes: 1.Total number of animals in experimental procedures classified by species. 2.Total number of animals classified by different scientific purposes.	As a minimum: yearly report from ethics committee must include statistical information as required in European Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes (ETS 123, 18.3.1986), Articles 27-28 and Appendix B of the same Convention.	Detailed provisions from the National Agency for Animal Protection[96]

[92] Lovbekendgørelse nr. 981 af 3. december 2002 om miljø og genteknologi som ændret ved lov nr. 436 og 440 af 9. juni 2004 og lov nr. 1473 af 20. december 2004.

[93] However, other provisions in the Environment Code, e.g. chapter 13, section 8. See also Ordinance (2000:271) on continued use of genetically modified organisms and regulation issued by the Swedish Board of Agriculture, Statens jordbruksverks föreskrifter (SJVFS 2003:28) om användning av genetiskt modifierade djur.

[94] According to the proposed new legislation, the Ministry of Agriculture and Forestry will give more detailed instructions on means of destruction of experimented animals in a ministerial decree. At the international level, experimental animals are defined as 'Category 1 material', which shall be disposed either by incineration or burial after processing in a processing plant according to Article 4 of the Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption, Official Journal of the European Communities, No L 273/1 (10.10.2002).

[95] Reglugerð um meðhöndlun úrgangs nr. 737/2003.

[96] Djurskyddsmyndighetens föreskrifter (DFS 2004:13) om statistikföring vid djurförsök. Requires yearly reports on the total number of animals used, divided into a) class of animal, e.g. mammals, birds, reptiles etc., and b) type of research, e.g. biomedical research or teaching experiments, environmental research, experiments in behavioural sciences etc.