Legislation on biotechnology in the Nordic countries – an overview 2014

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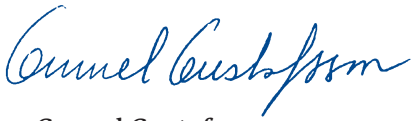
Preface

The Nordic Committee on Bioethics is since 1 January 2014 under the auspices of NordForsk.

NordForsk is a platform for joint Nordic research and research infrastructure cooperation. The organisation was established in 2005 by the Nordic Council of Ministers with the intention to strengthen the Nordic Research and Innovation Area. NordForsk´s mandate is to identify and respond to strategic priorities for Nordic research cooperation, and thereby create Nordic added value.

Ethics is a field of emerging importance to NordForsk. This applies both to conduct of research and to professional research ethics, especially when it concerns research across borders. We will put effort into highlighting the added value of Nordic cooperation in this field, but also see where the Nordic countries can learn from each other's experiences. Against this background, The Nordic Committee on Bioethics is a welcome addition to ongoing and future activities. We are looking forward to a fruitful collaboration for both aspects of ethics.

Oslo June 2014



Gunnel Gustafsson
Director of NordForsk

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Inledning

Nordisk kommitté för bioetik grundades 1996. Men redan 1987 inleddes samarbete på bioteknikens område mellan de nordiska länderna.[A] Många frågeställningar och utmaningar har aktualiserats sedan dess. Det kan till exempel gälla kartläggning av genomet, undersökning av embryon före implantationen eller användning av stamceller för behandlingsändamål.

En av kommitténs uppgifter är att bevaka hur lagstiftning på bioteknikens område utvecklas inom Norden. Det finns förvånande skillnader mellan ländernas regelverk i kontroversiella biotekniska frågor, exempelvis vid assisterad befruktning[B] samt fosterdiagnostik och screening[C]. År 2000 rekommenderade Nordiska rådet en kartläggning av lagstiftning och regelverk gällande bioteknik i Norden. Den första rapporten publicerades år 2003, följd av en mer omfattande översikt 2006[D]. Teknikens snabba framsteg och den nya lagstiftning som tillkommit i syfte att kontrollera utvecklingen ger anledning att uppdatera tidigare rapporter.

EU har i allt högre grad infört regleringar på vissa av bioteknikens områden, men inom sjukvården är unionens mandat i stort sett bara komplementärt. Unionen kan dock vidta åtgärder för att säkerställa hög kvalitet och säkerhet i hanteringen av organ, vävnader och blod samt läkemedel och medicinsk utrustning. EU har alltså inflytande över till exempel kliniska försök, marknadsgodkännande av läkemedel samt hantering av vävnader or blod, medan till exempel tillgång till assisterad befruktning och gentester inte omfattas av dess mandat. EU-lagstiftning är bindande för Danmark, Finland och Sverige, medan Norge och Island inte är medlemmar av unionen. Tabellerna ger hänvisningar till EU:s grundläggande regelverk på respektive område.

De juridiska villkoren kan också påverkas av annan överstatlig lagstiftning än EU:s. Det viktigaste internationella biomedicinska dokumentet är Europarådets konvention från 1997 om skydd av de mänskliga rättigheterna och människans värdighet med avseende på tillämpningen av biologi och medicin, samt dess tilläggsprotokoll. Konventionens och tilläggsprotokollens rättsliga status framgår av tabell 16.

Med denna rapport hoppas vi förmedla en övergripande bild av lagstiftningen inom Norden. Dock kan en sådan översikt inte ge tillräckligt detaljerad information i alla frågor. Vi rekommenderar därför läsaren att kontakta rapportörerna för respektive land; dessa listas i rapportens avslutande del.

Sirpa Soini

Lagstiftning om bioteknik i norden – en översikt 2014

Länkar till gällande lagstiftning i respektive land:

Danmark	www.retsinfo.dk
Island	http://eng.velferdarraduneyti.is/legislation/
Finland	www.finlex.fi
Norge	www.lovdata.no
Sverige	www.lagrummet.se

Nordisk kommitté för bioetik vill tacka jur. kand. Sirpa Soini (Institutet för hälsa och välfärd, Finland), för uppdatering av ramverket samt informationen när det gäller Finland. Kommittén tackar också de juridiska experter från övriga nordiska länder som har kontrollerat att materialet är aktuellt och lämnat de uppgifter som behövs: docent Janne Rothmar Herrmann (Köpenhamns universitet, Danmark), jur. mag. Laufey Helga Gudmundsdottir (Ministeriet för välfärd, Island), fil. dr. Hallvard Kvale (Bioteknologinemnda, Norge), fil. dr. Anne Ingeborg Myhr (Genøk-Center för biosäkerhet, Norge) och JD Jane Stoll (Uppsala universitet, Sverige).

A Soini, Sirpa: The Nordic Committee of Bioethics. I Elisabeth Rynning och Mette Hartlev (Red.), Nordic health law in a European context. LIBER AB, 2011.

B Nordisk kommitté för bioetik, Assisted reproduction in the Nordic countries. A comparative study of policies and regulation. Nordiska ministerrådet, Köpenhamn, 2006.

C Summary of conference on Prenatal Diagnosis – individual and society, 2010: http://ncbio.org/english/arkiv/oslo-summary-final.pd

D Nordisk kommitté för bioetik, Legislation on biotechnology in the Nordic countries. Nordiska ministerrådet, Köpenhamn, 2006.

Introduction

The Nordic Committee on Bioethics was established in 1996. However, Nordic collaboration in the biotechnological arena started as far back as 1987.A Many new issues have emerged since then; for instance, in connection with the ability to read the entire genome, examine embryos before implantation and use stem cells for therapeutic purposes.

One of the tasks of the Nordic Committee on Bioethics is to follow legislative developments within the sphere of biotechnology in the Nordic countries. The Nordic countries have adopted surprisingly different regulatory approaches to sensitive biotechnological issues, e.g. assisted reproductionB and prenatal diagnostics and screening.C In 2000, the Nordic Council recommended charting the legislation and regulations pertaining to biotechnology in the Nordic countries. The first report was published in 2003, with a second, broader overview in 2006.D Given the rapid progress of technology and the emergence of legislation to regulate the field, it is due time to update the tables from the previous reports.

The European Union is increasing regulation of various areas of biotechnology, but its mandate in the field of health basically remains complementary. However, to meet common safety concerns, the EU may adopt measures that set high standards of quality and safety of organs, tissue, blood, and medicinal products and devices. Thus areas such as clinical trials, market authorisation of medicinal products and handling of tissue and blood lie within the EU's sphere, whereas access to assisted reproduction and genetic testing, for instance, do not. EU legislation is binding for Denmark, Finland and Sweden, but Norway and Iceland are not members of the EU. The tables provide references to key EU regulations in the respective areas.

In addition to EU legislation, other supranational legislation may affect the legal landscape as well. The most important international biomedical document is the Council of Europe's Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine from 1997 and the additional protocols. The legal status of the Convention and its protocols are listed in Table 16.

We hope that these tables can give the reader an overall picture of the legislation in the Nordic countries. However, it should be noted that the format cannot provide comprehensive information with all the necessary details. We therefore recommend contacting the respective country rapporteurs listed below.

Sirpa Soini

A Soini, Sirpa: The Nordic Committee on Bioethics, in Elisabeth Rynning and Mette Hartlev (Eds.), Nordic Health Law in a European Context. LIBER AB, 2011

B Nordic Committee on Bioethics, Assisted Reproduction in the Nordic Countries. A comparative study of policies and regulation. Nordic Council of Ministers, Copenhagen, 2006.

C Summary of conference on Prenatal Diagnosis – Individuals and Society, 2010: http://ncbio.org/english/arkiv/oslo-summary-final.pdf

D Nordic Committee on Bioethics, Legislation on Biotechnology in the Nordic Countries. Nordic Council of Ministers, Copenhagen, 2006.

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inks to legislation in force in the respective countries:

Denmark	www.retsinfo.dk
Iceland	http://eng.velferdarraduneyti.is/legislation/
Finland	www.finlex.fi
Norway	www.lovdata.no
Sweden	www.lagrummet.se

The Nordic Committee on Bioethics wishes first to thank LL.M. Sirpa Soini (National Institute for Health and Welfare, Finland) for updating the framework and providing material for the Finnish part, and secondly the national legal experts from the other Nordic countries: Associate Professor Janne Rothmar Herrmann (University of Copenhagen, Denmark), Mag.Jur. Laufey Helga Gudmundsdottir (Ministry of Welfare, Iceland), Ph.D. Hallvard Kvale (Norwegian Biotechnology Advisory Board, Norway), Ph.D. Anne Ingeborg Myhr (GenØk – Centre for Biosafety, Norway) and LL.D. Jane Stoll (University of Uppsala, Sweden) who have checked that the material is up-to-date and provided the information needed.

1. Assisted reproduction

	Denmark	Finland	Iceland	Norway	Sweden
Law	Consolidated Act on Artificial Fertilisation (923/2006)[1]	Act on Fertility Treatments (1237/2006)[2]	Act on Artificial Fertilisation and Use of Human Gametes and Embryos for Stem-Cell Research, No 55/1996 Regulation No 144/2009 on Artificial Fertilisation (English version not available)	Act relating to the application of biotechnology in human medicine, etc. (5.12.2003/100)[3]	Genetic Integrity Act (GIA) (1.7.2006/351)[4]
Licence for premises	Yes (when regarded as a tissue centre).	Yes.	Yes.	Yes.	Yes.[5]
Age limit - man - woman	None. 45.	None.[6]	None, but according to Article 3 of Act No 55/1996, ART may only be carried out if "the woman is of natural child-bearing age and has the physical capability and sufficiently good health to cope with the strain of the treatment, pregnancy and birth of the child. A factor to be taken into account is that the pregnancy and birth not be expected to entail damaging consequences for mother or child, on the basis of normal medical and obstetric standards."	None.	Ability to carry out parental responsibilities throughout childhood.[7]
Relevance of family status/relationship of the applicants (single, same-sex, marriage)	Single women, married couples and lesbian couples have access to treatment.	Fertility treatment is allowed for heterosexual couple (married or cohabitation) or single women. Single males are excluded. Cannot be married to another person than the other applicant.	Fertility treatment is allowed for heterosexual couples, lesbian couples (married or in a registered cohabitation) and single women. Male couples and single men are excluded.	Assisted reproduction can only be performed on a woman who is married or cohabitant in a marriage-like relationship with another man or woman.	Single applicants are not permitted. Applicants for assisted reproduction must be married, registered partners or cohabitants, and one of the applicants must be the woman being treated, thus ruling out same-sex male couples from accessing ART.
Must consideration be given to the welfare of the child? By whom/which instance?	Yes. If the physician doubts the couple's parental abilities, the State Administration (Statsforvaltningen) decides on access to treatment.	Yes. The physician making the decision on fertility treatment.	Yes. The physician making the decision on fertility treatment.	Yes. The physician making the decision on fertility treatment.	Yes. Special requirements in situations where donated gametes are used. The physician making the decision about fertility treatment. The decision should be made in consultation with a counsellor with appropriate competence.

1 The original Act 460/1997 has been amended several times. The amendments adopted since the most recent consolidated version can be found on www.retsinfo.dk.
2 For a Swedish version or English translation, see www.finlex.fi.
3 The Norwegian acts referenced in this document can be found at www.lovdata.no. Unofficial English translations, which are not always updated to the most recent versions, can be found at http://www.ub.uio.no/ujur/ulov/english.html.
4 Lag (2006:351) om genetisk integritet m.m. For an (unofficial) English translation of the Act, see http://www.smer.se/news/the-genetic-integrity-act-2006351/
5 Genetic Integrity Act, Chapter 6, Section 2 (Insemination); Chapter 7, Section 4 (IVF). See also Regulations and Guidelines on the use of tissue and cells in health and medical care and in clinical research etc. (SOSFS 2009:32), Chapter 4, Section 1.
6 Under administrative orders, treatment of women over 40 years of age in the public sector requires a medical statement that infertility is not caused by age.
7 In assessing this, the physician should consider, inter alia, the couple's age. See Regulations and Guidelines on the use of tissue and cells in health and medical care and in clinical research etc. (SOSFS 2009:32), Section 12 (Guidelines). Note that insemination or IVF may only be carried out if it can be presumed that the prospective child will grow up under good conditions. See Genetic Integrity Act, Chapter 6, Section 3 (Insemination); Chapter 7, Section 5 (IVF); Regulations and Guidelines (SOSFS 2009:32), Sections 11 & 12.

Table 1 continued	Denmark	Finland	Iceland	Norway	Sweden
Selection of the characteristics of the donor. Which?	Selection of gametes to ensure resemblance with parents is allowed, i.e. race, height, weight, eye colour.	When using donated gametes, the law allows the selection of gametes whose donor resembles in appearance the respective parent of the child to be born.	The physician providing treatment selects a suitable donor. He must try to respect the wishes of the applicant, so that, for example, the physique, height, eye and hair colour and blood type of the donor is in conformity with the parent.	The physician performing the treatment selects a suitable sperm donor.	The physician performing the treatment selects a suitable donor.
Written consent of the participants	Yes, from both	Yes, from both.	Yes, from the women and her partner if she is married or in a registered cohabitation.	Yes, from both before each treatment.	Yes, written consent is required from the spouse or partner of the woman being treated.
Limits to the no. of offspring using the same donor	Maximum 12 pregnancies in Denmark from same donor.	No legal limits.	No.	Sperm from one donor can be used for conceiving up to eight children.[8]	No statutory limits.
Limits to the techniques allowed (ICSI etc.)	New techniques to treat and diagnose must not be adopted before approval by the Board of Health.	No legal limits.	Artificial fertilisation may be carried out by artificial insemination or by in vitro fertilisation.	New techniques must be approved by the Norwegian Directorate of Health.	No express statutory limits but the Government or its designated authority may, to protect life and health, issue regulations on, inter alia, IVF.[9]
Cryopreservation - sperm - oocytes - embryos	5 years. Oocytes and embryos must be destroyed in case of the woman's death; embryos must be destroyed in case of separation or divorce.	No legal limits.	10 years for sperm, oocytes and embryos.	Yes.[10] Yes.[11] 5 years.	Yes.[12] Yes.[13] 5 years.[14]
Donation - sperm - oocytes - embryos	Sperm and oocytes can be donated by anyone. Donation of embryos is prohibited.	Yes, all.	Donation of sperm and oocytes is allowed. Donation of embryos is not allowed.	Yes. No. No.	Yes. Yes. No.
Donor anonymity	Yes, woman/couple has a choice between an anonymous and a known donor.	No.	Optional.	No.	No.
Surrogacy	Not allowed.	Not allowed.	Not allowed.[15]	Not allowed.	Not expressly prohibited by law.[16]

8 Specified in directive IS-12/2008 from the Norwegian Directorate of Health: http://www.helsedirektoratet.no/publikasjoner/assistert-befruktning-med-donorsed/Publikasjoner/assistert-befruktning-med-donorsed.pdf
9 SFS 2006:351, Chapter 8, Section 8.
10 Semen may not be used for assisted reproduction after the death of the donor.
11 Eggs may be preserved if the woman is either approved for assisted reproduction or is undergoing treatment with a risk of infertility as the outcome, and only as long as it is in her interest and it is within good practice. The eggs must be destroyed if the woman dies.
12 Sperm from a deceased donor may not be used for insemination or IVF.
13 Ova from a deceased donor may not be used for fertilisation.
14 If there are exceptional grounds, the National Board of Health and Welfare may consent to the extension of the storage time.
15 On 18 January 2012 the Althingi passed a parliamentary resolution calling on the Minister of Welfare to assemble a working group to prepare a parliamentary bill to allow surrogacy for benevolent purposes. The working group has been established and the bill is being prepared.
16 Note, however, that surrogacy in conjunction with assisted reproduction is not legally possible because assisted reproduction may not be carried out unless at least one of the intended parents is genetically connected to the child; the woman giving birth must also be one of the intended parents.

Table 1 continued	Denmark	Finland	Iceland	Norway	Sweden
Legal mother	Woman giving birth.	Woman giving birth.	Woman giving birth.	Woman giving birth.	Woman giving birth.
Legal father	Husband, if mother is married (presumption). Otherwise declaration of fatherhood at the State Administration or determined by the court in certain cases. In cases of assisted reproduction, the intended father agrees to accept paternity as a precondition of treatment. In cases of sperm donation, it is possible that no father is appointed, or in cases of lesbian couples, co-motherhood can be established.	Husband, if mother is married (presumption). Otherwise declaration of fatherhood at the Magistrate or determined by the court in certain cases.	Article 6 of the Children Act No 76/2003: A woman who has given consent for her wife (female partner) to undergo assisted reproduction treatment shall be regarded as the parent of the child conceived in this way. The same shall apply to women who have registered their partnership in the National Register. (Paragraph 2) A man who has given consent for his wife to undergo assisted reproduction treatment shall be regarded as the father of the child conceived in this way. The same shall apply to a man and a woman who have registered their cohabitation in the National Register. (Paragraph 3) A man who donates sperm for use in assisted reproduction treatment of a woman other than his wife or cohabiting partner may not be identified by a court judgement as the father of the child conceived with his sperm. (Paragraph 4) A man who has donated sperm for a purpose other than that stated in the fourth paragraph shall be regarded as the father of a child conceived with his sperm unless the sperm has been used without his knowledge or after his death. (Paragraph 5). According to Article 3(2) of the Children Act No76/2003, no paternity may be established for the child of a single woman when the child is conceived by assisted reproduction.	Consenting husband/partner. Otherwise declaration of fatherhood or determined by the court in certain cases. If the mother is married to or cohabitant with another woman, this woman can become the legal co-mother of the child. A child cannot have both a legal father and a legal co-mother.	Consenting husband or partner of the woman being treated. A consenting female partner becomes a “legal parent”.

2. Preimplantation genetic diagnosis (PGD)

	Denmark	Finland	Iceland	Norway	Sweden
Law	Consolidated Act on Artificial Fertilisation (923/2006) with later amendments	Act on Fertility Treatments (1237/2006)[17]	Act on Artificial Fertilisation and Use of Human Gametes and Embryos for Stem-Cell Research, No 55/1996 Regulation on Artificial Fertilisation No 144/2009 (English version not available)	Act relating to the application of biotechnology in human medicine, etc. (5.12.2003/100)	Genetic Integrity Act (1.7.2006/351)[18]
Indications	In cases of known and severe risk that the child will suffer from a serious illness, to establish or rule out a severe chromosomal anomaly or, with the approval of the Board of Health, to select an embryo which will be tissue compatible with an older sibling in serious need of treatment.	The health of the child to be born may be influenced by selecting gametes or embryos that have been verified to be free of serious disease. No list or authorisation of indicated diseases.	Hereditary diseases.	PGD can only be provided to couples where one or both are carriers of a serious monogenetic or chromosomal heritable genetic disorder and there is a large risk of the disorder being transferred to a future child.	PGD is only available to couples where the man or woman is a carrier of a serious monogenetic or chromosomal hereditary disease and there is a high risk that the genetic disease or impairment will be transferred to the child.

17 For a Swedish version or English translation, see www.finlex.fi.
18 Lag (2006:351) om genetisk integritet m.m. See also Regulations and guidelines on prenatal diagnosis and preimplantation genetic diagnosis (SOSFS 2012:20) issued by the National Board of Health and Welfare.

Table 2 continued	Denmark	Finland	Iceland	Norway	Sweden
Sex selection	No, unless the selection is made in order to avoid a sex-related hereditary condition known to be a risk for the couple in question.	No, unless there is a risk of a sex-related hereditary condition when using the couples' own gametes.	No, unless there is a risk of a sex-related hereditary condition. In detail: There is no explicit legal position regarding selection based on sex. However, international standards are applied in practice, i.e. Article 14 of the Oviedo Convention on non-selection of sex. In Article 11 of the Icelandic Act on Artificial Fertilisation and Use of Human Gametes and Embryos for Stem-Cell Research (No 55 from 1996 with later amendments) it is stated that "a health institution which has been granted a licence under Paragraph 1 of Article 2 may, with the informed consent of the gamete donors, perform research, experiments and procedures on embryos which have been created by in vitro treatment, and are a part of that, or have been created in order to diagnose hereditary diseases in the embryos themselves. The same applies to research which aims to advance treatment for infertility, or to enhance understanding of the causes of congenital diseases and miscarriages." Other research on embryos than explicitly mentioned in the article is therefore not permitted.	No, unless there is a risk of a sex-related hereditary condition when using the couples' own gametes.	No, unless there is a risk of a known sex-related hereditary condition in relation to one of the genetic parents.
Tissue typing	Yes, if there are weighty reasons in order to treat an older sibling. Approval must be granted by the Board of Health.	No.	No.	Yes, if a sibling suffers from a serious and untreatable disease, and only as a supplement to testing for the specific heritable disease.	Yes, if there are exceptional grounds, permission may be obtained from the National Board of Health and Welfare to try to have a child that can become a donor of blood stem cells to a severely ill sibling. [19]
Licence requirement	Yes, a general licence requirement from the Danish Medicines Agency (Tissue Act 273/2006).	No.	Yes.	For every couple applying, PGD must be approved by a PGD board appointed by the Ministry of Health and Care Services.	No.

19 SFS 2006:351; Prop 2005/06:64 p. 100; SOU 2004:20 pp. 31, 99–100, 227–228.

3. Preimplantation genetic screening (PGS)

	Denmark	Finland	Iceland	Norway	Sweden
Law	Consolidated Act on Artificial Fertilisation (923/2006) § 7 (2) allows genetic testing in connection with IVF treatment in order to detect or rule out significant chromosomal abnormalities.	Act on Fertility Treatments (1237/2006)[20] does not stipulate PGS explicitly. Case-by-case analysis and interpretation.	No special laws or regulations.	Act relating to the application of biotechnology in human medicine, etc. (5.12.2003/100) allows genetic testing of embryos only for PGD.	Genetic Integrity Act (1.7.2006/351)[21]
Indications		No legal criteria.			Only permitted within clearly defined research projects that have been subject to ethical evaluation and approval by a research ethics committee.[22]
Nota bene		Is used in practice.			

20 For a Swedish version or English translation, see www.finlex.fi.
21 Lag (2006:351) om genetisk integritet m.m. See also Regulations and guidelines on prenatal diagnosis and preimplantation genetic diagnosis (SOSFS 2012:20) issued by the National Board of Health and Welfare.
22 In accordance with the Act on ethics review of research involving humans (5.6.2003/460) (Lag (2003:460) om etikprövning av forskning som avser människor).

4. Abortion

	Denmark	Finland	Iceland	Norway	Sweden
Law	Health Act (consolidated Act 913/2010)	Abortion Act (239/1970) and decree (359/1970)	Act on Counselling and Education regarding Sex and Childbirth and on Abortion and Sterilisation Procedures, No 25/1975.	Act on abortion (13.6.1975/50)	Abortion Act (12.6.1974/595)[23]

23 Abortlagen (1974:595). See also the Regulations on Abortion (SOSFS 2009:15) issued by the National Board of Health and Welfare.

Table 4 continued	Denmark	Finland	Iceland	Norway	Sweden
Grounds for abortion	1) Autonomy-based right to abortion until the end of the 12th week of pregnancy. After the 12th week, abortion is allowed when: 2) There is danger to the woman's life or serious detriment to her physical or mental health and this danger is exclusively or predominantly medically founded (the danger indication). 3) The pregnancy, birth or caring for the child poses a risk to her health because of an existing illness or weakness or because of her other life circumstances (the medical indication). 4) The woman has become pregnant as a result of a sexual abuse crime (the ethical indication). 5) The risk that the child will suffer from a serious physical or mental illness because of a genetic disorder or other foetal illness or damage (the eugenic indication). 6) The woman's social conditions, age and ability to care for the child (the social indication).	1) The woman's life or health is in danger due to a disease, physical defect or weakness. 2) Delivery and care of a child would place a considerable strain on the woman in view of the living conditions of the woman and her family and other circumstances (social grounds). 3) The woman has become pregnant as result of a sexual abuse crime. Requires the reporting of the crime to the police. 4) The woman was less than 17 or more than 40 years of age at the time of conception, or has already had four children. 5) There is a justified assumption that the child will be mentally impaired or will have, or will later develop, a serious disease or a serious physical defect. 6) There is a disease, mental impairment or other comparable disorder affecting one or both parents that seriously limits their capacity to care for the child.	Social, medical or on grounds of sexual abuse. See Article 9 of Act No 25/1975.	Until the end of the 12th week of pregnancy, no specific grounds for abortion are required. After the 12th week of pregnancy, abortion is allowed when: 1) The pregnancy, childbirth or care of the child may cause unreasonable strain on the woman's physical or mental health. 2) The pregnancy, childbirth or care of the child may place the woman in a difficult life situation. 3) There is a major risk that the child may suffer from a serious disease as a result of its genotype, or disease or harmful effects during pregnancy. 4) The woman became pregnant as a result of a sexual abuse crime. 5) The woman suffers from severe mental illness or is mentally impaired to a considerable degree.	No specific grounds for abortion are needed until the end of the 18th week of pregnancy. Abortions or terminations of pregnancy performed after the 18th week of pregnancy require permission from the National Board of Health and Welfare. Where it concerns late abortions or terminations, the legislation makes a distinction between the terms "abortion" and "termination of pregnancy" (avbrytande av havandeskap). This is evident in Section 6, where the term "abortion" is replaced with "termination of pregnancy". According to the preparatory works, the difference reflects the view that the life of the foetus, if possible, should be saved with a termination of pregnancy.[24] *Grounds for "abortion":* Exceptional grounds must be shown and permission may not be granted if there is reason to believe that the foetus is viable.[25] The requirement of "exceptional grounds" means that a special circumstance, medical and/or social, must be shown to exist before permission for the abortion may be granted. As a rule, the National Board of Health and Welfare will not approve abortions after the 22nd week of pregnancy since there is a risk that the foetus is viable after this time.[26] *Grounds for "termination of pregnancy":* If the pregnancy, as a result of illness or physical defect in the woman, results in serious danger to her life or health, the National Board of Health and Welfare may give permission for a termination of the pregnancy after the 18th week has passed, and irrespective of how long the pregnancy has progressed.[27]

24 SOU 2005:90 p 98.
25 SFS 1974:595, Section 3.
26 SOU 2005:90 p. 97.
27 SFS 1974:595, Section 6. And note that 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 4 continued	Denmark	Finland	Iceland	Norway	Sweden
Gestational limits	As early as possible. Ground 1 above: 12-week limit. Ground 2 above: no gestational limit. Grounds 3–6 above: abortion is not allowed once the foetus has reached the point of viability (in practice the upper limit has been set to 22–24 weeks).	As early as possible. If the woman was less than 17 years of age at the time of conception or there are other special reasons, Valvira[28] may authorise abortion at a later stage of pregnancy, although not after the 20th week (Act 5 § 3). If as a result of amniocentesis or an ultrasonic examination, serological tests, or another reliable examination, it is established that the embryo is affected by a serious disease or physical disability, provided that the 24th week of pregnancy has not expired (Act 5 a §). If the woman has a medical emergency, pregnancy may be terminated at any time if it endangers the woman's life.	Article 10 of Act No 25/1975: The abortion shall be performed as soon as possible, preferably before the end of the 12th week of pregnancy. No abortion may be performed after the 16th week of pregnancy, unless indisputable medical reasons exist, and the woman's life and health would be placed at greater risk by continued pregnancy and/or birth. Abortion shall also be permissible after 16 weeks, should there be a great likelihood of malformation, genetic fault or foetal damage. Such an exception is only permitted by written authority of the committee according to Article 28.	As early as possible. Permission may be granted for abortion after the 12th week, but not after the 18th week, unless there are particularly compelling reasons. If there is reason to believe that the foetus is capable of survival, permission for an abortion will not be granted.	See above.

28 Valvira is the acronym for the National Supervisory Authority for Health and Welfare.

Table 4 continued	Denmark	Finland	Iceland	Norway	Sweden
Required permissions/procedure	1) Autonomy-based; the health care system is obliged to provide the procedure upon the woman's request. 2) The physician is given full discretion to decide if he/she finds that the legal/medical conditions have been met. 3–6) Permission must be sought from the regional Abortion Council (appellate body is the Abortion Appellate Council consisting of one judge and two medical doctors who must be qualified in gynaecology, psychiatry or similar).	1) In the cases referred to in the grounds for abortion above, Items 1–3 and 6 of Section 1, on the recommendation of two physicians *or,* in the cases to be defined in detail by decree, by authorisation of Valvira. 2) In case 4 referred to in the grounds for abortion above, by decision of the physician who will perform the operation. 3) In case 5 referred to in the grounds for abortion above, and in special cases and after 12 gestational weeks, by authorisation of Valvira. The recommendation of the two physicians must contain the separate written opinion of each physician, with the grounds being stated in detail. Of the two physicians, one must be a physician who renders opinions on the termination of pregnancy (physician with the authority to render an opinion), while the other must be the physician who performs the operation (operating physician). The physician with the authority to render an opinion and the operating physician shall not be entitled, without reason, to refuse to consider a request for termination of pregnancy. If the decision of the physician(s), as needed, is negative, an application for authorisation of abortion may be submitted to Valvira.	A written report supported by reasoned argument must be made by two physicians, or a physician and a social worker in the case of social factors alone. Decision can be appealed to a committee appointed by the Minister of Health consisting of a physician, a lawyer and a social worker. After the end of the 16th week, permission from the above-mentioned committee is required.	Application from a woman aged 16 and over before the 12th week. If the woman is below 16 years of age or mentally impaired: application by legal representative. After the 12th week, the decision is taken by a committee. Consent from state authority needed if a woman is below 16 years of age or mentally impaired and legal representatives discourage abortion.	Abortions or terminations performed after the 18th week of pregnancy require permission from the National Board of Health and Welfare; see above. Applications submitted to the Board for permission for a late abortion or termination of pregnancy require that a medical and psychosocial investigation has been undertaken. Applications are to be submitted in accordance with the Regulations on Abortion.[29]
Opinion of prospective father	No right to be consulted or heard.	Prospective father will be consulted, if deemed necessary.	If possible, the man is to make the application for the procedure together with the woman, unless special circumstances make this inadvisable.	No obligation to consult the prospective father.	No obligation to consult the prospective father.

29 SOSFS 2009:15, Chapter 5, Sections 1–2.

5. Prenatal diagnosis and/or screening (national programmes)

	Denmark	Finland	Iceland	Norway	Sweden
Law	The Board of Health's guidelines from 2004	Health Care Act (1326/2010) and Screening Decree (339/2011) for national programme; Abortion Act (239/1970)	No existing legislation. Clinical guidelines from the Directorate of Health.	Act relating to the application of biotechnology in human medicine, etc. (5.12.2003/100)	Genetic Integrity Act (1.7.2006/351)[30]
National statutory programme	The Board of Health's guidelines.	Yes, harmonised by and defined in the Screening Decree.	Clinical guidelines from the Directorate of Health.	No national screening programme.	No national screening programme.
Nuchal translucency ultrasound and blood test	All pregnant women are offered an early screening consisting of an early blood test and measurement of neck oedema during an ultrasound scan.	For detection of chromosomal abnormalities: *primarily* through early pregnancy combined screening (blood screening test in weeks 9+0 to 11+6 of the pregnancy and measurement of neck oedema in connection with a general ultrasound scan in weeks 11+0 to 13+6); *or alternatively* through a second trimester blood serum test in weeks 15+0 to 16+6 of the pregnancy.	Available for all between weeks 11 to 14 (optional, not part of antenatal care).	Prenatal diagnosis available for pregnant women above 38 years of age at term and other specific risk groups. Also available after individual assessment on social grounds.[31]	Offered to all pregnant women. Times vary slightly depending on the individual centres.[32] All investigations are voluntary. All pregnant women must be offered general information about prenatal diagnosis. This should occur at the time of the first prenatal visit. The content of the general information includes the purpose of prenatal diagnosis, the different investigation methods that might be used and what the various investigations entail. Further information must be given to those with a medically established increased risk of giving birth to an impaired child. The woman decides, with her doctor, whether to undergo prenatal diagnosis or prenatal genetic diagnosis after receiving the information.
Ultrasound	A general early pregnancy ultrasound scan (approx. weeks 10+0 to 13+6). For the detection of severe abnormalities (approx. weeks 19+0 to 21+0).	A general early pregnancy ultrasound scan in weeks 10+0 to 13+6 of the pregnancy. For the detection of severe structural abnormalities in weeks 18+0 to 21+6 of the pregnancy or after week 24+0 of the pregnancy.	Available for all in weeks 19–20 (part of antenatal care).	Ultrasound as part of regular prenatal care does not come under the scope of the law. Ultrasound for the purpose of prenatal diagnosis: see above.	Offered to all pregnant women. Time varies between centres (see above), usually between weeks 17 to 19 of the pregnancy.

30 Lag (2006:351) om genetisk integritet m.m, Chapter 4. See also Regulations and guidelines on prenatal diagnosis and preimplantation genetic diagnosis (SOSFS 2012:20) issued by the National Board of Health and Welfare.
31 Specified in directive IS-23/2003 from the Norwegian Directorate of Health: http://www.helsedirektoratet.no/publikasjoner/veiledende-retningslinjer-for-bruk-av-ultralyd-i-svangerskapet/Publikasjoner/veiledende-retningslinjer-for-bruk-av-ultralyd-i-svangerskapet.pdf
32 See for example the brochures Foster diagnostik och riskvärdering (Centrum för fostermedicin, Karolinska Universitetssjukhuset) http://www.karolinska.se/upload/Kvinnokliniken/CFM/Broschyr%20webb%20att%20publicera.pdf
cf. Fosterdiagnostik (Uppsala Akademiska sjukhuset) http://www.akademiska.se/Global/KB/Kvinnosjukv%C3%A5rd/Dokument/Fosterdiagnostik%20foldern.pdf

Table 5 continued	Denmark	Finland	Iceland	Norway	Sweden
Invasive tests	Offered in cases when the calculated risk number (based on the early blood test and early ultrasound scan) is lower than 1:300.	Not stipulated specifically; i.e. amniocentesis is used when indicated in practice.	Individual assessment.	Available for pregnant women above 38 years of age at term and other specific risk groups. Also available after individual assessment on social grounds, and as a follow up to findings in ultrasound and blood tests.	Offered by the physician to risk groups, or if indicated after evaluation of the initial prenatal diagnosis. Individual assessment.
Limitations on the conditions	Not stipulated; general regulation indicates that invasive tests must be medically indicated and balanced against the risk of spontaneous abortion.	Not stipulated.	Clinical guidelines from the Directorate of Health.	Examination methods must be approved by the Ministry of Health and Care Services.	Prenatal diagnosis: [33] -May only be offered if the medical benefit is greater than the anticipated risks. -May not be offered for the purpose of taking pictures of and recording film of a foetus if there is no medical purpose behind the procedure. -May not be used to determine the sex of a foetus unless there is a risk of a known sex-related hereditary condition in relation to one of the genetic parents.
Information on sex	Not stipulated, but the general regulation on the right to information indicates a right to be told the sex if visible (but the ultrasound is conducted purely for diagnostic reasons, so the patient cannot demand that time is spent on seeking to determine the sex).	Not stipulated.	No specific rules or regulations.	Prohibited in the first 12 weeks of pregnancy, unless woman carries serious X-linked disease.	May only be disclosed if the woman requests the information, unless the information concerns the health status of the foetus.[34]
Termination of pregnancy	For grounds, see Table 4.	For grounds, see Table 4.	For grounds, see Table 4.	For grounds, see Table 4.	For grounds, see Table 4.

33 SOSFS 2012:20, Chapter 3, Section 3.
34 Lag (1995:831) om transplantation mm; Regulations on Donation and safeguarding of organs, tissues and calls (SOSFS 2009:30) issued by the National Board of Health and Welfare; SFS 2006:351.

6. Organ and tissue transplantation

	Denmark	Finland	Iceland	Norway	Sweden
Law[35]	Health Act (consolidated Act 913/2010)	Act of the Medical Use of Human Organs and Tissues (101/2001)	Act on the procurement of organs, No 16/1991	Act relating to transplantation, hospital autopsies and the donation of bodies etc. (9.2.1973/6) Regulation on demands for quality and safety regarding handling of human cells and tissue (7.3.2008/222) Regulation on quality and safety regarding human organs intended for transplantation (22.11.2013/1334) (entered into force on 1 January 2014)	Law on Transplantation etc. (8.6.1995/831) Genetic Integrity Act (1.7.2006/351)[36]
Conditions and limitations	A competent adult can donate renewable organs/tissue if the procedure can take place without immediate danger to the donor and only to benefit the treatment of the recipient and only if no organ could be procured from a deceased person and no other treatment is just as effective. In practice, kidney transplantations are only accepted between relatives.	A competent adult can donate a renewable organ, tissue or cells to benefit others. A competent adult can donate non-renewable organs or tissue only for the benefit of a close relative or another person in a close relationship.	A competent adult can donate an organ or tissue for use as part of a medical treatment for another individual. The life or health of the donor cannot be put in obvious danger.	Organs or other biological material may be removed from a consenting person when the procedure does not involve any immediate risk to the donor's life or health. Biopsies etc. do not fall under the law.	Biological material intended for transplantation or for other medical purposes may not be taken from a living person if the operation can pose a serious risk to the donor's life or health. If the biological material intended for transplantation is not renewable, the donor must be related to, or be in a close relationship with, the recipient unless there are exceptional grounds requiring the use of a non-related donor.
Consent	Informed written consent.	Informed consent as a main rule.	Informed consent.	Written consent required when the donor is a living person.	Consent is required from the donor. Consent must be written if the organ or biological material is not renewable, or where the intervention can result in noticeable damage or inconvenience for the donor.

35 EU Directive 45/2010 on standards of quality and safety of human organs intended for transplantation.
36 Lag (2006:351) om genetisk integritet m.m. See also Regulations and Guidelines on prenatal diagnosis and preimplantation genetic diagnosis (SOSFS 2012:20) issued by the National Board of Health and Welfare.

Table 6 continued	Denmark	Finland	Iceland	Norway	Sweden
Minors	Minors can donate renewable organs/tissue only in exceptional circumstances and only if it is life-saving for the recipient. Minor and parent must both agree. No lower age limit. Denmark has made reservations regarding Article 20 in the Oviedo Convention on Biomedicine and Human Rights (as such the minor can donate e.g. bone marrow to both siblings and parents). Minors may not donate non-renewable organs/tissue.	Minors may only donate a renewable organ or tissue, and only for treating a sibling's health-threatening condition if there are no other alternatives. A more mature minor may also donate a renewable organ or tissue to a close relative or another person in a close relationship.	Donation is not allowed.	If there are compelling reasons, persons under 18 years of age may donate with endorsement of a legal custodian, if the County Governor approves. Separate, more stringent rules for persons under 12 years of age or persons without the capacity to consent.	Where the donor is a minor, or an adult without the capacity to consent, consent must be obtained from the custodian or guardian respectively.
Permission		Valvira's permission is needed for organ or tissue removal from living persons.	No.	Based on written consent. Norway is the only country in Scandinavia without a registry of donors.	Permission from the National Board of Health and Welfare is required before taking biological material for the purpose of transplantation from minors or adults without the capacity to consent. If the biological material intended for transplantation is not renewable, permission will only be granted if there are exceptional grounds. The application must be submitted by the custodian or guardian and supported by the medical practitioner in question. Biological material may not be taken from a living person for medical purposes other than transplantation without the permission of the National Board of Health and Welfare if the material is not renewable or if the intervention can in another way result in noticeable damage or inconvenience to the donor.

Table 6 continued	Denmark	Finland	Iceland	Norway	Sweden
Organs of a deceased person	Consent to organ donation by either the deceased or his/her relatives. The deceased may consent by oral expression of view to relatives, in writing, by carrying a donor card or by notifying a public registry. Consent to organ donation may concern only limited/specified organs or full consent, and it may be made conditional on the acceptance of the relatives.	Presumed consent; not against the wishes of the deceased. Relatives cannot overrule consent, but they may be heard. Valvira's permission is not required.	Informed consent of the deceased. If that is not available, the consent of the closest relative is needed, provided that organ donation is not regarded as against the wishes of the deceased.	Organs or other biological material may be removed from a person who dies during illness or is brought dead to a hospital, unless there is reason to believe it is contrary to the views of the deceased or next-of-kin, or there are other special grounds.	Biological material intended for transplantation or other medical purposes may be taken from a deceased person if he or she has agreed to it, or if it can be shown that the measure would be consistent with the wishes of the deceased. In addition, biological material may be taken if the deceased has not, in writing or orally, expressed opposition to this, or if there is no other reason to assume that such an intervention would be against the deceased's wishes. Biological material may not be removed from the deceased if the information about his or her wishes is conflicting or if a person who has a close relationship with the deceased is opposed to the intervention.
Stem cell transplantation	General rules regarding consent and authorisation. Complementary (EU-based) rules on premises, quality etc. for tissue centres.	General rules regarding consent and authorisation. Complementary rules on premises, quality etc. for tissue centres.	No specific laws or regulations.	General rules regarding consent and authorisation. More stringent rules for persons below 12 years of age. The Ministry of Health and Care Services must approve treatments depending on use of embryonic cells.	General rules regarding consent and authorisation. Approval of the National Board of Health and Welfare required for donors who are minors and adults who do not have legal capacity.

7. Embryo research

	Denmark	Finland	Iceland	Norway	Sweden
Law	Consolidated Act on Artificial Fertilisation (923/2006)	Medical Research Act (488/1999) and decree (986/1999) Act of the Medical Use of Human Organs and Tissues (101/2001)	Act on Artificial Fertilisation and Use of Human Gametes and Embryos for Stem-Cell Research, No 55/1996	Act relating to the application of biotechnology in human medicine, etc. (5.12.2003/100)[37]	Genetic Integrity Act (1.7.2006/351)[38]
Creation for research purposes	Creation only for research purposes is not allowed.	Creation only for research purposes is not allowed.	Creation only for research purposes is not allowed.	Creation only for research purposes is not allowed.	Yes.
Research time	Maximum 14 days after creation of the embryo (cryopreservation time excluded).	Maximum 14 days after creation of the embryo (cryopreservation time excluded).	It is prohibited to cultivate embryos for more than 14 days outside the body or once the primitive streak has appeared.	Maximum 14 days after creation of the embryo (cryopreservation time excluded).	Up to 14 days.
Consent	Yes, from the couple (or donor).	Donors of germ cells. Exemptions for research in the Act of the Medical Use of Human Organs and Tissues (101/2001)	Donors of germ cells.	Donors of germ cells. If donor sperm is used, informed consent from the donor must have been obtained at the time of the donation.	Donors and their partners.
Storage for research	Maximum 5 years.	Maximum 15 years.	Not permitted.	Maximum 5 years.	Maximum 5 years. The National Board of Health and Welfare may extend the time if there are exceptional grounds.
Use of embryos after research	Only used for fertility treatment if genetically unmodified and the embryo's development has not been damaged.	Not permitted. Embryos must be destroyed.	Not permitted.	Not permitted. Embryos must be destroyed.	Not permitted. Embryos must be destroyed without delay.
Further use after research	Only used for fertility treatment if genetically unmodified and the embryo's development has not been affected.	Cannot be transferred to a human or kept alive more than 14 days.	An ovum on which nuclear transfer has been carried out may not be grown for more than 14 days or once the primitive streak has appeared. It is prohibited at all stages to implant in a woman's uterus an ovum on which nuclear transfer has been performed.	Not permitted. Embryos must be destroyed.	See above.

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 (2006:351) om genetisk integritet m.m, Chapter 5. See also Regulations and Guidelines on the use of tissue and cells in health and medical care and in clinical research etc. (SOSFS 2009:32) issued by the National Board of Health and Welfare.

Table 7 continued	Denmark	Finland	Iceland	Norway	Sweden
Stem cell research, particular regulation?	Stem cell research can only be conducted on surplus embryos (or imported stem cell lines which fulfil the same criterion).	No specific regulations, but the provisions on embryo research as such do not apply after creation of deprived cell lines.	No other than aforementioned legislation.	Research on surplus embryos and embryonic cells may only be used for research for the purpose of: 1) developing and improving methods and techniques for in vitro fertilisation for the purpose of achieving pregnancy; 2) developing and improving methods and techniques for genetic examination of embryos with the aim of establishing whether a serious monogenic or inheritable chromosomal disease exists (PGD); 3) gaining new knowledge with the aim of future treatment of serious diseases among human beings.	Genetic Integrity Act (2006:351)[39]
Licence for premises	Yes, the Danish Medicines Agency must authorise premises that process cells and tissue for human use.	Yes, the Finnish Medicines Agency (Fimea) must authorise premises that process cell lines for future human use.	Yes, issued by the Minister of Health.	Yes, issued by a Regional Committee for Medical and Health Research Ethics.	No specific provisions. The requirements contained in Chapter 7 of the GIA (IVF) would apply.
Ethical review	Ethical review as in any medical research.	Ethical review as in any medical research.	Yes, by the National Bioethics Committee.	Research on embryos and embryonic cells must be approved by a Regional Committee for Medical and Health Research Ethics.	Ethical review required in accordance with the Act on ethics review of research involving humans (5.6.2003/460).[40]

39 Covers somatic cell nuclear transfer (SCNT) embryos.
40 Lag (2003:460) om etikprövning av forskning som avser människor.

8. Cloning

	Denmark	Finland	Iceland	Norway	Sweden
Law[41]	Consolidated Act on Artificial Fertilisation (923/2006) Biomedicine Convention and its additional protocol on cloning 1998 (ETS No 168)	Penal Code 89/1889 Biomedicine Convention and its additional protocol on cloning 1998 (ETS No 168) Medical Research Act (488/1999)	Act on Artificial Fertilisation and Use of Human Gametes and Embryos for Stem-Cell Research, No 55/1996	Act relating to the application of biotechnology in human medicine, etc. (5.12.2003/100)	Genetic Integrity Act (1.7.2006/351)
Reproductive cloning	Banned.	Banned.	Not allowed, cf. Article 14 (d) of Act No 55/1996.	Banned.	Prohibited.
Therapeutic cloning	Nuclear transplant on oocytes is banned.	Experimental use.	Not mentioned in laws or regulations.	Banned.	The creation of human embryos for research using somatic cell nuclear transfer (SCNT) is permitted under the GIA. Requires approval by an ethics committee and by donors.

41 The Council of Europe Additional Protocol to Biomedicine Convention on Cloning (ETS No. 168, 1998) has been ratified by Finland and Iceland.

9. Clinical research on humans

	Denmark	Finland	Iceland	Norway	Sweden
Law	Act on Biomedical Research (593/2011) Medicines Act (506/2013) EU Regulation 536/2014*	Medical Research Act (488/1999) and Decree Pharmaceutical Act (395/1987) (complementary on clinical drug trials) EU Regulation 536/2014*	No specific legislation yet.[42] Accumulation of acts: Patients' Rights Act, No 74/1997; Regulations on Scientific Research in the Biomedical Field No 286/2008; Act on Artificial Fertilisation and Use of Human Gametes and Embryos for Stem-Cell Research, No 55/1996; Medicinal Products Act, No 93/1994.	Act on medical and health research (20.6.2008/44) Some clinical trials that involve both research and treatment also fall under the Act relating to patients' rights (2.7.1999/63).	Act on ethics review of research involving humans (5.6.2003/460)[43] EU Regulation 536/2014*
Scope of field of the law	All research projects in Denmark involving human beings or any kind of human tissue, cells etc. need permission from a regional research ethics committee. In the case of medicinal and medicinal devices trial projects, permission from the Danish Medicines Agency is also required before the project can be initiated.	Medical research, defined as: research involving intervention in the integrity of a person, human embryo or human foetus for the purpose of increasing knowledge of health, the causes, symptoms, diagnosis, treatment and prevention of diseases or the nature of diseases in general. The Finnish Medicines Agency issues necessary regulations on good clinical practice as referred to in the Medical Research Act.	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.	The Act applies to all medical and health research on human beings, human biological material or personal health data. Such research also includes pilot studies and experimental treatments. The Act does not apply to establishment of health registries.	Two main categories (not just aimed at biomedicine): a) research involving the 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.
Consent	As a general rule, informed consent is required.	Informed consent is required.	Formal, informed consent is required (normally in writing).	Informed consent is required, unless otherwise stated in law. Broad consent is possible for human biological material and personal health data being used in broadly defined research projects.	Consent must be freely given, explicit, specified and documented (normally in writing). Written consent is not mandatory by law, only that the consent is documented.

* Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC Text with EEA relevance shall apply as from six months after the publication of the notice referred to in Article 82(3), but in any event no earlier than 28 May 2016.

42 A legislative proposal for a new act on biomedical research was put before the Althingi in November 2013. Amendments to the Biobanks Act will be made simultaneously.
43 Lag (2003:460) om etikprövning av forskning som avser människor.

Table 9 continued	Denmark	Finland	Iceland	Norway	Sweden
Exceptions from consent	The research ethics committee can derogate from this rule in certain cases, e.g. in cases of registry-based research and in emergency situations, if it benefits the health of the patient in the long term or benefits the patient group, and there is only minimal risk to and discomfort for the patient.	Emergency situations when immediate health benefits are expected. However, in clinical trials on medicinal products, the consent of a close relative, another person in a close relationship or a legal representative is required.	Exception from obtaining informed consent from participants can be accepted in the following cases: 1. If the participant/patient is incapable of giving informed consent, e.g. is unconscious; all known options for treatment have been exhausted; the trial is likely to help his/her situation or help individuals in a similar situation; there is no record that the incapacitated person would oppose participation; the person concerned is given the opportunity to consent to or refuse participation as soon as possible. 2. When a National Bioethics Committee (NBC) approved protocol is amended, the NBC decides on a case-by-case basis if it is necessary to call for extended/renewed consent from participants to cover the scope of the amendment. 3. Epidemiological studies where the work is restricted to unidentifiable data or biological samples. 4. In protocols where participation is limited to answering questionnaires that cannot be traced back to the person concerned, response is considered informed consent.	In clinical emergencies under certain conditions, including insignificant risk to the patient. A Regional Committee for Medical and Health Research Ethics may, under certain conditions, allow human biological material collected for diagnostics and treatment to be used for research without patients' consent. Consent is not necessary if data or biological material is anonymised.	See below regarding incompetent adults and other individuals who cannot give consent. For drug trials, the Medical Products Agency requires written consent, but may grant a dispensation from this requirement. For other research than drug trials, the regional ethics committee may grant exceptions to the requirement of new informed consent for new use of biobank samples or the processing of sensitive personal data.

Table 9 continued	Denmark	Finland	Iceland	Norway	Sweden
Minors	Consent from parents is required. Consent must reflect the interests of the minor, and the opinions of the minor should be taken into account, when relevant. The research ethics committee can authorise derogation from the need for parental consent for minors aged between 15 and17 years.	Minors may be research subjects only where it is not possible to obtain the same scientific results using other research subjects and only where the risk of harming or distressing the research subject is very slight. Benefits must be anticipated for the minor or his/her subgroup. Consent from the minor's guardian/legal representative is required. The minor's own opinion must be taken into account. A 15-year-old person is capable of giving consent him-/herself.	Studies which require the participation of children, or members of vulnerable social groups, shall be evaluated with especial care by the ethics committees, as these groups are entitled to special protection. Such studies may involve, for instance, adults who, due to mental impairment, disease or other factors are incapable of granting consent. Such individuals shall be involved in decision-making as far as possible. Child subjects shall be involved in decision-making in so far as their development permits, and without exception if they are aged 12 years or older.	Research on subjects below 16 years of age may only be performed if the following conditions are met: a) the potential risks to or disadvantages for the person are insignificant; b) the individual involved is not averse to it; and c) there is reason to assume that the results of the research may be of use to the person concerned or to other people with the same age-specific disorder, disease, injury or condition. There is a requirement that it is not possible to conduct similar research on people who are not minors. Consent must be obtained from parents or others with parental responsibility for research that entails testing medicinal products on minors between 16 and 18 years of age. The Ministry of Health and Care Services may by administrative regulation decide that for special types of research projects children between the ages of 12 and 16 may themselves consent to research on personal health data.	Persons who are 15 years old may consent to being research subjects provided that they have the ability to understand the implications of participation. Persons under 18, who do not have the ability to understand the implications of participation, require the consent of their custodians. Even with valid consent, research will not be performed against the will of the research subject. Married research subjects under 18 years of age may give their own consent.

Table 9 continued	Denmark	Finland	Iceland	Norway	Sweden
Incompetent adults	Similar to minors. Consent by relative/guardian/general practitioner or the Board of Health.	Basic grounds similar to those of minors. Written consent by a close relative or other person closely connected with the person, or a legal representative, according to the research subject's presumed wishes.	Same as for minors. See above.	Written consent by closest relative or legal custodian. There is a requirement that there is no reason to believe that the patient would be opposed to participation, and that it is not possible to conduct equivalent research on competent adults.	In limited situations research may be performed without consent, if it is not possible to obtain consent from the research subject due to illness, psychiatric illness, diminishing health status or some other reason that prevents consent being given. In the above situations, research can be undertaken if: 1. The research is expected to result in knowledge that would otherwise not be possible to attain; and 2. The research is expected to lead to a direct benefit for the research subject, or to someone else who suffers from the same or a similar illness or disorder. The research may only be undertaken if it involves an insignificant risk of harm and inconvenience to the research subject. Consultation must be made with the research subject's next-of-kin or guardian. If the research subject, or any of those consulted, are opposed to the research being carried out the research may not be undertaken.
Vulnerable groups (e.g. pregnant women, prisoners)	No specific regulations, but on a professional ethics basis the general framework on vulnerable groups set out in the Helsinki declaration applies.	Pregnant women and nursing mothers may be research subjects only where it is not possible to obtain the same scientific results using other research subjects and the research is likely to: 1) directly benefit the health of the woman or the unborn child; or 2) benefit pregnant women or nursing mothers, or foetuses, newborn children or unweaned children. Prisoners or forensic patients may be research subjects only where the research is likely to be of direct benefit to their own health or the health of people related to them or the health of other prisoners or forensic patients.	Same as for minors. See above.	Pregnant women and nursing mothers may be research subjects only where it is not possible to obtain the same scientific results using other research subjects and the research is likely to directly benefit the health of the woman or the unborn child. Prisoners or forensic patients may be research subjects only where the research is likely to be of direct benefit to their own health or the health of people related to them or the health of other prisoners or forensic patients.	No.
Return of research results		Not required.	Not required, but the ethics committees may require the researchers to submit progress reports and findings.	Not required.	Not required.
Ethical review	National or regional ethics committee.	National or regional ethics committee.	National Bioethics Committee or institutional ethics committees.	Regional Committees for Medical and Health Research Ethics.	Regional ethics committees and one central ethics committee.

10. Human biobanks

	Denmark	Finland	Iceland	Norway	Sweden
Law	No specific act on biobanking, i.e. the general legal framework set out in the Data Protection Act, the Health Act and the Act on Biomedical Research applies.	Biobank Act (688/2012)	Biobanks Act, No 110/2000[44] and Regulation No 1146/2010, on the storage and utilisation of biological samples in biobanks (English version not available).	Act relating to treatment biobanks (21.2.2003/12) Act on medical and health research (20.6.2008/44) Act on personal health data filing systems and the processing of personal health data (18.5.2001/24)	Act on biobanks in health care (23.5.2002/297)[45]
Scope of field (e.g. clinical/research/ both)	n/a	The aim of the Biobank Act is to support research where human biological samples are being used, foster transparent and open use of samples, and safeguard privacy and self-determination of the people whose samples are handled. The scope of application is storage and handling of human origin biological samples for *biobank research* that is defined as: "research that exploits the samples and related data that are being stored in a biobank and the aims of which are health promotion, understanding of disease mechanisms or development of products and practices to be used in the health care and cure".	The Biobanks Act applies to the collection of biological samples, and their keeping, handling, utilisation and storage in biobanks. The Act does not apply to temporary keeping of biological samples taken for purposes of clinical testing, treatment, or for specific scientific study, provided such samples are destroyed when the tests, treatment or research are completed. Temporary keeping means storage for up to five years, unless the National Bioethics Committee authorises a longer period of storage. Should the long-term preservation of such samples be desired, they are to be stored in a biobank.	The Act relating to treatment biobanks regulates the collection, storage, processing and destruction of human biological material that is part of a treatment biobank/diagnostic biobank. The Act on medical and health research regulates medical research on humans, human biological material, or health records. The aim of the Act on personal health data filing systems and the processing of personal health data is to contribute to information on and knowledge of the state of public health, causes of impaired health and illness trends for administration, quality assurance, planning and management purposes.	The Act applies to: 1. Biobanks established in Sweden as part of a care provider's medical activities, irrespective of where the material is stored. 2. Tissue samples from a biobank that are released for storage and use on the premises of another care provider, an institution for research or diagnostics, a public research institution, a pharmaceutical company or other legal entity, and which are traceable to the person or persons from whom they originate. Relevant parts of the Act apply to tissue samples taken and collected for transplant purposes in accordance with the Transplants Act (1995:831). The Act does not apply to specimens routinely collected in the course of medical care for analysis, and which are solely intended to form the basis of a diagnosis and the ongoing care and treatment of the donor, and which are not stored for a long period (normally 2 months).

44 A legislative proposal for a new Act on Biomedical Research was put before the Althingi in November 2013. Amendments to the Biobanks Act will be made simultaneously.
45 Lag (2002:297) om biobanker i hälso- och sjukvården m.m. See also Regulations and Guidelines on biobanks in health care (SOSFS 2002:11) as amended by SOSFS 2013:2 issued by the National Board of Health and Welfare.

Table 10 continued	Denmark	Finland	Iceland	Norway	Sweden
Definition of a biobank	A structured collection of human biological material accessible by certain criteria and where the information contained in the samples can be traced to identifiable persons.	An entity owned and maintained by a biobank operator (i.e., legal person(s)) where human biological samples and related data are collected and stored for future research purposes.	A biobank is a collection of biological samples which are permanently preserved. *Research biobank:* A collection of research samples to be preserved for more than five years. *Clinical biobank:* A collection of clinical samples to be preserved for more than five years.	Treatment biobank/diagnostic biobank: A collection of human biological material contributed for the purpose of medical examination, diagnosis and treatment. Research biobank: A collection of human biological material that is used or is to be used for research purposes.	A collection of biological material from one or more human beings that is preserved indefinitely or for a specific period and whose origin is traceable to an individual or individuals.
Purpose of a biobank	n/a	Storage and handling of human origin biological samples for *biobank research*.	The purpose is to authorise the collection, keeping, handling and utilisation of human biological samples, in such a way that confidentiality is ensured, that the interests of donors of biological samples are safeguarded and that the utilisation of the biological samples serves the purposes of science and medicine, and is conducive to the public good.	Collection, storage and handling of human material used for health purposes, including diagnosis, treatment and education in an ethical manner.	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.
Licence/legal oversight	Notification to the Data Protection Authority.	Establishment of a biobank requires ethical review by Tukija.[46] Valvira[47] is the supervising authority. A biobank must be registered in Valvira's biobank register to be legally competent to operate.	Yes, licence is issued by the Minister of Health. The responsible party for the biobank is responsible for the implementation of internal monitoring, and for ensuring that security assessments are carried out regularly. The Data Protection Authority monitors the security of personal data in biobanks. The National Bioethics Committee monitors the activities of research biobanks. The Directorate of Health monitors the activities of clinical biobanks.	The Ministry of Health and Care Services must be notified about the establishment of diagnostic biobanks. Establishment of a research biobank must be approved by a Regional Committee for Medical and Health Research Ethics.	No licence is required, but notification must be made to the Health and Social Care Inspectorate, within one month of the decision to establish a biobank.[48] A decision to allow a biobank to be used for the purpose of research or clinical trials may not be made until the matter has been subject to ethical review and approved by a research ethics committee. A registry of biobanks is maintained by the Health and Social Care Inspectorate. The Health and Social Care Inspectorate is the supervising authority in relation to compliance with the Act.

46 Tukija is the acronym for the National Medical Research Ethics Committee, www.tukija.fi .
47 Valvira is the acronym for the National Supervisory Authority for Health and Welfare.
48 In accordance with SFS 2002:297, Chapter 2, Section 5. The Health and Social Care Inspectorate (IVO: Inspektionen för vård och omsorg) took over this role from the National Board of Health and Welfare in 2013.

Table 10 continued	Denmark	Finland	Iceland	Norway	Sweden
Consent (how broad/specific?)	Anyone not wishing their cells or tissue used for anything other than the treatment and diagnosis of themselves may register in the Use of Tissue Registry (opt-out system), i.e. no consent required if sample is taken for diagnostic or treatment purposes. Informed written consent if sample is taken for research purposes.	Primarily informed consent based on adequate information about the biobank in question, nature of biobank activities, risks, right to withdraw etc. Transfer of old clinical and research samples subject to personal or public notification procedure, and subsequent opt-out assumption.	Informed consent if sample is collected for research purposes. This consent shall be given freely and in writing after the donor of a biological sample has been informed of the objective of the sample collection, the benefits, risks associated with its collection, and that the biological sample will be permanently stored at a research biobank. Presumed consent to storage in clinical biobank if sample is collected for diagnostic purposes, provided that general information on this is provided by a health care professional or health institution. Possibility to opt out.	Presumed consent for diagnostic/therapeutic use. Informed consent for scientific research. Narrow opening for use without consent if approved by a Regional Committee for Medical and Health Research Ethics and if the patient's integrity and welfare are respected.	Informed consent. Before tissue samples may be collected and preserved, the donor must be informed of the intention and purpose or purposes of the biobank in question and must give his or her consent. An account of the information given and the nature of the consent must be documented in the patient's medical record. 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.
Consent of minors	See general rules on biomedical research in item 9 above.	Parents, legal custodians. Child's own consent in addition when deemed mature enough.	Not regulated, but general rules apply.	Minors between 16 and 18 years of age may consent to partaking in medical research, unless prevented by law or by the nature of the enterprise. For children under the age of 16, consent from parents or legal custodian is needed.	Informed consent, as above, must be given by the child's legal custodians. If the child is regarded as sufficiently mature, the child may consent him or herself.
Consent of incompetent adults	See general rules on biomedical research in item 9 above.	Legal custodians.	Not regulated, but general rules apply.	Closest relative or legal custodian.	If the patient lacks the capacity to consent, the physician responsible for the care of the patient may make a decision to collect and preserve a tissue sample in a biobank if it is for the patient's care and treatment and deemed necessary with consideration to the patient's safety.[49]
Reconsent when reached maturity/competence	Not required.	Not required.	Not regulated.	Not required.	Yes.[50]

49 SOSFS 2002:11, Chapter 4, Section 4.
50 SOSFS 2002:11, Chapter 4, Section 5.

Table 10 continued	Denmark	Finland	Iceland	Norway	Sweden
Withdrawal of consent	Patient can ask for destruction or retrieval of samples collected in connection with patient care, but this may be overridden by public or private interests. Withdrawal of consent has not been accepted in practice by the research ethics committee for samples collected for clinical research.	Any time with written notification to the person in charge of the biobank.	Any time – but in the case of a biobank with clinical samples, the board of the biobank may, with the approval of the National Bioethics Committee and the Data Protection Authority, authorise the use for purposes when important interests are at stake.	Withdrawal can be done any time, with exceptions regulated by law. For treatment biobanks, consent cannot be withdrawn when the material or the information is anonymised, if the material is integrated into another biological product after processing, or if the information has already been included in scientific works.	Any time – however, depersonalised samples may be used despite withdrawal.
Right to own information			The licensee of a biobank is not deemed to be the owner of the biological samples, but has right of disposal over them, with the limitations laid down by law, and is responsible for their handling being consistent with the provisions of this Act, and of government directives based on it. The licensee may thus not pass the biological samples on to another party, nor use them as collateral for financial liabilities, and they are not subject to attachment for debt.	Right of access to the information registered.	
Storage time for samples and data		Need for further storage must be assessed every 10 years. Otherwise until withdrawal of consent.	No specific rules.	No maximum storage time specified for samples. Data used for research and treatment is not to be stored longer than necessary. Certain permanent health registries, in instances specified in the Act on personal health data filing systems and the processing of personal health data, may be stored “for historical, statistical or scientific reasons”.	Storage time for tissue samples is determined from the durability and usefulness of the sample in question in relation to the purpose or purposes for which the biobank was established. The storage time for the different types of tissue samples preserved in a given biobank must be provided in the biobank’s local (written) instructions and routines.[51]

51 SOSFS 2002:11, Chapter 2, Section 1; Chapter 5, Section 5.

Table 10 continued	Denmark	Finland	Iceland	Norway	Sweden
Access criteria		Basically transparent and similar access criteria for all researchers. Access principles and restriction must be registered. The intended use must comply with: -the notified field of the biobank's field of activities - consent - the biobank's access principles - legislation. The recipient must have appropriate professional and scientific competence. A proper connection to the recipient's tasks is also required. A biobank may limit access only on certain grounds mentioned in the Biobank Act and its own complementary criteria. A biobank must make an administrative decision about access even if it is not a public authority.	The responsible party for the biobank grants access to biological samples for further diagnosis of diseases. He/she may also grant access to biological samples for purposes of quality control, development of methods and tuition, provided that the samples are not personally identified. The board of the biobank must draw up agreements with scientists on access to biological samples. Access to biological samples for scientific studies may not, however, be granted until the permission of the Data Protection Authority has been granted and a research protocol has been approved by the National Bioethics Committee or other ethics committee. When granting access to clinical biobanks, the board of the biobank shall take care to ensure that access on grounds of research does not reduce the possibilities to further diagnose diseases to the donors' benefit. When access is granted to clinical samples for scientific studies, the samples shall be provided without personal identification. When granting access to clinical biobanks which have been established in hospitals or other public institutions, for research purposes, the board of the biobank shall take due account of conformity and equality. Access to clinical biobanks for research purposes shall be based on professional and scientific grounds with respect to the donors' interests. The board of the biobank is obligated to support refusals of access with arguments. The board of the biobank may, with the approval of the Data Protection Authority and the National Bioethics Committee, authorise the use of biological samples for other purposes than those for which the samples were originally collected, provided that exigent interests are at stake, and that the potential benefit outweighs any potential inconvenience to the donor of a biological sample or other parties.	The Regional Committee for Medical and Health Research Ethics may decide that human biological material collected for diagnostics and treatment can be used for research without the patient's consent. This presupposes that the research is of considerable significance for society, and that the patient's integrity and welfare are respected. The patient must have been informed about this possibility, and been given the opportunity to reserve against such use. Informed consent is needed for all research on predictive and presymptomatic genetic information, and carrier diagnostic information, if the research has consequences for diagnosing or treating the patient or if information about an individual patient is returned to him/her. Human biological material, predictive and presymptomatic genetic information, and carrier diagnostic information cannot be released to insurance companies or employers. Release of such material to a prosecuting authority or court of law can only take place by administrative regulation in exceptional cases.	The person responsible for the biobank considers applications for access to specimens but the final decision is made by the care provider. Care providers must have routines in place to ensure that applications for access to tissue samples, and for breaking codes in order to access personal information, are dealt with in accordance with the Act. Information that the tissue samples have been released must be documented. The receiving biobank must be registered with the Health and Social Care Inspectorate. As regards applications for the breaking of codes, the National Board of Health and Welfare Guidelines state that this should only be approved in exceptional cases, e.g. when the tissue samples are to be released to a research project and it is not possible to gain any scientific value from the project without access to personal information about the donor.

Table 10 continued	Denmark	Finland	Iceland	Norway	Sweden
Delivery of samples and data abroad for research		Allowed.	Transportation out of the country of clinical samples is subject to the approval of the National Bioethics Committee and the Data Protection Authority and on the conditions they lay down. Samples should be sent without personal identification. The responsible party of the research at hand shall ensure that no personally-identifiable information follows the samples and that all residues are sent back when the research is done. Transportation out of the country of research samples is subject to the approval of the responsible party of the research at hand. The approval of the National Bioethics Committee and the Data Protection Authority is also needed and is granted on the conditions which they lay down.	On approval of a Regional Committee for Medical and Health Research Ethics and according to the laws of consent. The Ministry of Health and Care Services may via regulations allow exemption from the approval requirement for transfer of biobank material that is part of an "ordinary international collaboration".	Only possible if a Swedish research institution submits an application. The application is subject to ethical review. If approved, a condition is placed on the recipient in the foreign country that the specimens are to be returned or destroyed when they are no longer needed for the purpose for which they were released.
Transfer of samples and data abroad permanently		Subject to permission by Valvira.	A biological sample may be sent out of the country in the interests of the donor of a biological sample for diagnosis or quality control.	In most cases subject to permission by the Ministry of Health and Care Services.	Re. samples, see above. A biobank, or parts of it, may not be transferred to a recipient in another country.
Ethical review	See general rules on biomedical research in item 9 above.	Establishment of a biobank is subject to ethical approval by Tukija. Use of biobank samples for research will be assessed as a part of an overall ethical review of the research protocol.	The establishment and operation of a biobank is permissible only for those who have been granted a licence from the Minister of Health, following receipt of recommendations from the Directorate of Health and the National Bioethics Committee. The use of samples for research will be assessed as a part of an ethical review of a research protocol.	Establishment of a research biobank subject to approval by a Regional Committee for Medical and Health Research Ethics.	Establishment of a biobank itself is not subject to ethical review; see above. The decision to use a biobank for the purpose of research or clinical trials is subject to ethical review and must be approved by a research ethics committee. Ethical review is also required before samples and data may be released and transferred abroad, above.

11. Ethical committees

	Denmark	Finland	Iceland	Norway	Sweden
Law	Act on Biomedical Research (593/2011) Act on the Ethical Council (440/2004)	The Medical Research Act governs ethical committees and their composition. Specific tasks are also set out in the Biobank Act and the Tissue Act.	Acts of Law: Patient's Rights Act No 74/1997 Medical Devices Act No 16/2001 Biobanks Act No 110/2000 Act on Patient Insurance No 111/2000 Act on Artificial Fertilisation and Use of Human Gametes and Embryos for Stem-Cell Research No 55/1996, (in particular Articles 2, 12 and 13) Act on the Protection of Privacy as regards the Processing of Personal Data, No 77/2000 Regulations Scientific Research in the Biomedical Sector, No 286/2008 Storing and Utilising Biological Samples in Biobanks, No 1146/2010 (Icelandic only) Clinical Trials of Medicinal Products in Humans, No 443/2004 Manufacture of Medicinal Products, No 893/2004 Informed Consent and Biological Samples in Genetic Research, No 1100/2008, (Icelandic only) Rules: On security of personal data No 299/2001 On the obligation to notify and processing which requires permit No 698/2004 On obtaining informed consent in scientific research in the field of biomedicine No 170/2001 (Icelandic only) Notification concerning the transfer of personal data to a foreign country No 228/2010 (Icelandic only)	Act on ethics and integrity in research (30.6.2006/56) Act relating to the application of biotechnology in human medicine, etc. (5.12.2003/100)	Act on ethics review of research involving humans (5.6.2003/460)[52] Ordinance concerning the ethical vetting of research involving humans (9.10.2003/615)[53] Ordinance containing instructions for the Central Ethical Review Board (22.11.2007/1068)[54] Ordinance containing instructions for regional ethical review boards (22.11.2007/1069)[55]

52 Lag (2003:460) om etikprövning av forskning som avser människor.
53 Förordning (2003:615) om etikprövning av forskning som avser människor.
54 Förordning (2007:1068) med instuktion for Centrala etikprövningsnämden.
55 Förordning (2007:1069) med instuktion for regionala etikprövningsnämder.

Table 11 continued	Denmark	Finland	Iceland	Norway	Sweden
Official status	The Ethical Council is an independent body which advises parliament, ministers and public authorities on ethical issues. The council consists of both experts and laypersons. Some members are appointed by parliament, and some by specific ministers. It is the responsibility of the research ethics committee system to ensure that, from a research ethical point of view, health research projects are carried out in a responsible manner, and that the rights, safety and wellbeing of trial subjects participating in such biomedical research projects are protected, while at the same time possibilities are being created for the development of new, valuable knowledge.	The National Committee on Medical Research Ethics (Tukija) is appointed by the Government for four years at a time. Each hospital district with a university providing medical education in its region must set up at least one ethics committee (regional ethics committee).	The National Bioethics Committee is appointed by the Government. The institutional ethics committees (IRBs) are appointed by the executive committees at the relevant institutions.	A National Committee for Medical and Health Research Ethics (NEM) as well as Regional Committees for Medical and Health Research Ethics (REK) are appointed by the Government. The Norwegian Biotechnology Advisory Board is an independent body appointed by the Government for a four-year term.	One central ethical review board and six regional ethical review boards appointed by the Government.
Functions	The Ethical Council: Advise and create debate and awareness. The National Committee on Health Research Ethics: 1) coordinate activities in the regional committees; 2) lay down guidelines; 3) give opinions on issues of a fundamental nature, if this is not related to the approval of a concrete research project; 4) serve as a board of appeal in connection with findings in the regional committees; 5) monitor the development of research within the health sector and promote the understanding of the ethical problems resulting from development in relation to the health services and the biomedical research environments; and 6) consider whether the National Committee on Health Research Ethics is to make recommendations to the Minister for the Interior and Health. These provisions deal with specific, new fields of research. 7) The National Committee provides consultative statements on biomedical research projects planned by Danish researchers for implementation in developing countries.	Prior evaluation of research projects and delivering opinions on them. The National Committee on Medical Research Ethics shall: 1) act as an expert in issues pertaining to research ethics; 2) monitor, guide and coordinate the handling of issues pertaining to research ethics; 3) take part in international cooperation among the relevant authorities; The National Committee on Medical Research Ethics shall deliver an opinion on clinical drug trials, unless it has delegated the task to a regional ethics committee. The regional ethics committee shall monitor, guide and evaluate the handling of matters pertaining to research ethics in its region.	The National Bioethics Committee (NBC) shall consider collaborative projects, multi-national research projects, clinical pharmaceutical research projects subject to the provisions of the Regulation on Clinical Pharmaceutical Research on Human Beings, No. 443/2004, and other planned scientific studies in the biomedical field, which are not within the mandate of the institutional ethics committees. In addition the National Bioethics Committee shall participate in public and scholarly debate on bioethics, and issue guidance on matters within its mandate. The institutional ethics committees (IRBs) consider research projects at their respective institutions.	The National Committee for Medical and Health Research Ethics serves as an advisory body to the government within the field of medicine. Research projects in Norway that involve experiments on human subjects must submit an application to a Regional Committee for Medical and Health Research Ethics for approval. The Norwegian Biotechnology Advisory Board is appointed to evaluate and promote debate on the social and ethical consequences of modern biotechnology and to discuss use that promotes sustainable development.	In line with the purpose of the Act, i.e. to protect individuals and human dignity when research is conducted, the functions of the ethical review boards are to review research applications in an ethical context and to give opinions. The central board reviews appeals and referrals, and also has a supervisory function.

Table 11 continued	Denmark	Finland	Iceland	Norway	Sweden
Composition	Ethical Council: 17 members appointed by parliament/ministers. National Committee on Health Research Ethics: 13 members appointed by the Minister for Health and Prevention.	Chairperson and at least six other members, one of whom will be the deputy chairperson. There must be an appropriate number of deputies for the members. The committees must include representatives of research ethics, medicine, health science or nursing science, and science of law. At least two members must be laypersons. When dealing with a clinical trial on medicinal products to be conducted on minors, ethics committees must have as a member or consult a specialist in paediatrics. When dealing with a clinical trial on medicinal products to be conducted on an incompetent adult, ethics committees must have as a member or consult a specialist in the illness and patient group concerned, or may request a written opinion from a specialist representing the area in question.	The NBC is an interdisciplinary committee of seven members, including specialists in biomedical science, ethics of research, human rights and social science. The IRBs are also interdisciplinary and consist of seven members, appointed by the board of directors of the hospitals concerned.	The Ministry of Health and Care Services establishes the national and regional committees, determines the committees' fields of responsibility and appoints members. Both the National Committee and the Regional Committees must have expertise in relevant research disciplines, ethics and law. Members must also include laypersons. Each member of the Biotechnology Advisory Board has a background and/or education that makes him/her competent to discuss questions regarding modern biotechnology.	Six regional boards for ethics review, and one central board. Regional boards must have a minimum of two divisions. Each division vets cases within certain areas of research. Each division must consist of 16 members: one chair and 15 other members (10 researchers, 5 laypersons). Deputies are appointed for the members. The chair and the deputy chair must be a judge or former judge. All members are appointed by the Government for a fixed period of time. The Central Board for Ethics Review comprises 7 members: one chair and 6 other members (4 researchers, 2 laypersons). Deputies may be appointed for the members. The chair and the deputy chair must be a judge or former judge. All members are appointed by the Government for a fixed period of time.

Table 11 continued	Denmark	Finland	Iceland	Norway	Sweden
Criteria for decision-making	Permission is granted by the research ethics committees on condition that: 1) The extent of the risks that the trial may involve is not unjustifiable, either as such or in relation to the foreseeable benefits of the trial. 2) The expected benefits from a therapeutic perspective as well as from a public health perspective may justify the project. 3) The project's scientific standard meets the requirement that the project should lead to new knowledge or investigate existing knowledge, which justifies the implementation of the research project. 4) There is sufficient reason to undertake the project, and expectations as to the project's conclusions are justified. 5) The competent committee must balance the foreseeable risks and drawbacks in relation to the benefit for the individual trial subject and for other present and future patients, including whether pain, discomfort, fear and other foreseeable risks are minimised in relation to the trial subject's disease and stage of development. This balancing must take into account whether the trial subject is able to give informed consent or whether informed consent must be obtained in the form of proxy consent.	The research plan must comply with provisions and regulations regarding medical research. Criteria: 1) Appropriateness of the trial and its planning; 2) Appropriateness of the assessment of its benefit and risks and justifiability of any conclusions regarding them; 3) The research plan; 4) Suitability of the researcher and staff; 5) The researcher's information package containing clinical and other information on the medicinal product or products used in the trial that is of significance when testing the medicinal products on people; 6) Quality of the premises and equipment to be used in the trial; 7) Sufficiency and scope of the written information given to obtain informed written consent and the procedure for obtaining consent, and grounds for trials to be carried out on persons not able to give their consent; 8) The grounds on which damages possibly caused by the trial are compensated and insurance policies and other arrangements for covering a compensation payable on account of damages or death; 9) The amount of the fee or remuneration to be paid to researchers and research subjects, or the criteria for determining this and procedures potentially related to the matter, as well as the main content of the agreement to be concluded between the commissioning party and the research site; 10) Detailed procedures relating to choosing the research subjects.	The NBC and IRBs operate on the basis of the legal acts and regulations referred above. Regulation No 286/2008 on biomedical research involving humans, based on the Patients Act from 1997, is the most important one. Furthermore, international agreements have an important impact and contribute to defining the mode of operations and the criteria applied by the NBC. These are to a variable degree legally binding for the parties concerned. Important instruments include the Council of Europe's "Convention on Human Rights and Biomedicine (Oviedo)" and "Additional Protocol on Biomedical Research." The CoE has also published the "Guide for Research Ethics Committee Members" and Directives of the European Union.	The Regional Committees for Medical and Health Research Ethics will assess whether the ethical aspects of proposed research projects comply with the Act on medical and health research, and are organised and performed in a responsible manner. The National Committee for Medical and Health Research Ethics will, based on the shared values of the population, act as a national observation post, enlightener and advisor within research ethics. The Biotechnology Advisory Board makes recommendations and promotes public debate on the social and ethical consequences of modern biotechnology on its own initiative and at the request of the Government.	The research may only be approved if it can be conducted with respect for human dignity. Criteria: 1) With respect to human rights and fundamental liberties, the welfare of people should be given precedence over the needs of society and science. 2) The risks to which the research subject is exposed must be counterbalanced by the scientific value of the research. 3) The anticipated result may not be achievable by some other means that entails fewer risks for the health, safety and personal integrity of the research subject.

Table 11 continued	Denmark	Finland	Iceland	Norway	Sweden
Is the decision final? Right to appeal? If so, which body?	National Committee on Health Research Ethics acts as a Board of Appeal for the Regional Research Ethics Committees.	No factual appeal, but the decision may be submitted for re-evaluation to the ethics committee, which has to ask for a second opinion from the National Research Ethics Committee.	An IRB decision may be appealed to the NBC. An NBC decision may be appealed to the minister. (However, the bioethical content of the NBC's decision is excluded from the scrutiny of the minister.)	Appeals against decisions made by the Regional Committees for Medical and Health Research Ethics may be filed with the National Committee for Medical and Health Research Ethics. The decision of the National Committee is final and may not be further appealed. The Biotechnology Advisory Board's recommendations are only advisory.	A decision made by a regional board concerning ethical vetting may be appealed to the Central Board if the regional board has determined the matter and the decision is not in favour of the responsible research body. The decisions of the Central Board in matters concerning ethical vetting may not be appealed. Where it concerns matters of supervision, directives or prohibitions issued by the Central Board may be appealed to the Administrative Court. Other decisions of the Board concerning matters of supervision may not be appealed.

12. Genetic testing (prenatal testing, see Tables n & m)

	Denmark	Finland	Iceland	Norway	Sweden
Law[56]	No special law (i.e. the general regulation in the Health Act etc. applies), except in relation to employment, pension and insurance where special regulations are in place: Act on Health Information in Employment (286/1996) Consolidated Act on Company Pensions (1561/2007) Consolidated Act on Insurance Policies (999/2006)	No special law. The general provisions in the Act on patients' rights and position apply. Act on Health Care Professionals; licenced physician decides on diagnostics and applies generally accepted, proven practices.	No specific legislation. The Patients' Rights Act No 74/1997 applies.	Act relating to the application of biotechnology in human medicine, etc. (5.12.2003/100)	Genetic Integrity Act (1.7.2006/351)
Scope of field	Employment, insurance and pension, respectively.			Genetic testing, consent, genetic counselling, data regarding patients' genetic diseases and predispositions.	
Definition of a genetic test				Genetic testing is defined as: all types of analyses of human genetic material at both nucleic acid and chromosome level, analyses of genetic products and their function, and examination of organs to obtain information on human genetic constitution. Postnatal genetic testing is defined as: a) genetic testing to diagnose a disease; b) presymptomatic genetic testing, predictive genetic testing and testing to determine whether or not a person is a carrier of hereditary disease that will only be expressed in later generations (carrier testing); c) laboratory genetic testing to determine sex, with the exception of laboratory genetic testing for identification purposes.	An investigation in health and medical care or medical research for the purpose of providing data concerning the genome of a human being through molecular genetic, microbiological, immunological, biochemical, cytogenetic or comparable method of analysis or through collecting data on his or her biological relatives.

56 CoE Biomedicine Convention Article 12 limits the use of genetic tests only for health purposes or for scientific research linked to same, and subject to appropriate genetic counselling. CoE Genetic Testing protocol not ratified in the Nordic countries. See Table n.

Table 12 continued	Denmark	Finland	Iceland	Norway	Sweden
Use in health care	Conditions in the general health law regulation must be met, including the right to know/not to know, information, consent, confidentiality.		Health professionals use genetic testing according to generally accepted criteria.	Must be used for medical purposes only, including medical research.	A genetic investigation that is part of a general medical screening may only be carried out with the permission of the National Board of Health and Welfare. Participants must consent in writing. Permission may only be granted if the genetic investigation is directed at seeking knowledge of serious illness or is otherwise of particular importance to health and medical care.
Use for other purposes - labour - insurance - forensic - determination of descent	Act on Health Information in Employment (286/1996), Consolidated Act on Insurance Policies (999/2006) and Consolidated Act on Company Pensions (1561/2007): information about dispositions for diseases may not be required, used or received.	Act on Privacy in Working Life (759/2004) Article 15: The employer is not permitted to require the employee to take part in genetic testing during recruitment or during the employment relationship, and has no right to know whether or not the employee has ever taken part in such testing.	*Insurance:* See Act on Insurance Contracts No 30/2004; the insurance company may not, prior to or after concluding a personal insurance contract, request, acquire through other means, accept or utilise information on a person's genetic characteristics and the risk that such person will develop or contract diseases. Nor may the company request examinations which may be regarded as necessary in order to be able to obtain such information. *Forensic:* Allowed according to Article 77 of the Act on Criminal Procedure No 88/2008. According to the Biobanks Act No 110/2000 it is prohibited to discriminate against a donor of a biological sample on the grounds of data derived from a biological sample. According to Article 9 of the Biobanks Act the board of the biobank may, with the approval of the Data Protection Authority and the National Bioethics Committee, authorise the use of biological samples for other purposes than those for which the samples were originally collected, provided that exigent interests are at stake, and that the potential benefit outweighs any potential inconvenience to the donor of a biological sample or other parties. This Article has been used to gain access to samples to determine descent.	Prohibited for predictive and presymptomatic genetic information, and carrier diagnostic information. Release of human biological material from biobanks to a prosecuting authority or court of law can only take place by administrative regulation in exceptional cases.	Unless otherwise specified by law, no person may: 1) Stipulate as terms of an agreement that another person must undergo a genetic investigation or provide genetic information about him- or herself (with the exception of matters concerning family law). 2) Enquire into or use genetic information about the other party in connection with an agreement (with the exception of matters concerning family law). No person may unlawfully access genetic information about another person. Regarding risk-rated insurance: An insurance company may enquire into or use genetic information in connection with the entering into, amendment or renewal of an agreement, provided that: The person insured is over 18 years of age and the amount insured that becomes payable in the event of an insurance loss is a lump sum, or a periodic indemnity, in excess of the amounts specified in accordance with Chapter 2, Section 2 of the Act.

Table 12 continued	Denmark	Finland	Iceland	Norway	Sweden
Genetic counselling	Biomedicine Convention Article 12 limits the use of genetic tests only for health purposes or for scientific research linked to same, and subject to appropriate genetic counselling.	Biomedicine Convention Article 12 limits the use of genetic tests only for health purposes or for scientific research linked to same, and subject to appropriate genetic counselling.	No specific laws or regulations other than included in the Oviedo Convention.	Before, during and after predictive, presymptomatic, and carrier diagnostic genetic testing, the person tested will be given genetic counselling. If the person tested is a child under the age of 16, the child's parents or another person who has parental responsibility will also be given genetic counselling.	
Testing minors	General provisions in the Health Act apply.	Analogical provisions as set out in the Act on the Status and Rights of Patients (785/1992) apply.	No specific laws or regulations.	Predictive genetic testing must not be carried out on children under the age of 16 unless the test can detect a condition for which treatment may prevent or reduce damage to the child's health. The ministry may grant exemptions in special cases.	

13. Advanced therapy medicinal products (ATMP, i.e. gene therapy, somatic cell therapy, stem cell therapy, tissue engineering)

	Denmark	Finland	Iceland	Norway	Sweden
Law[57]	Medicines Act (506/2013) Tissue Act 273/2006 (premises)	Pharmaceuticals Act (395/1987) Act of the Medical Use of Human Organs and Tissues (101/2001) (premises)	No specific laws or regulations.	Act relating to the application of biotechnology in human medicine, etc. (5.12.2003/100) Act relating to the production and use of genetically modified organisms, etc. (2.4.1993/38) Regulation on pharmaceuticals (18.12.2008/1839).	Act on quality and safety standards for the handling of human tissue and cells (15.5.2008/286) Ordinance on quality and safety standards for the handling of human tissue and cells (22.5.2008/414)[58]
Scope of field	Scope as defined in EU Regulation 1394/2007 on advanced therapy medicinal products.	Development, research and use of ATMPs.		Gene therapy may only be used to treat serious diseases or to prevent the occurrence of such diseases. Gene therapy on foetuses and embryos and gene therapy that may involve genetic modification of gametes is prohibited.	Development, research and use of ATMPs.
Special regulations regarding clinical trials	All clinical trials on humans must be approved by the Board of Health.	Requires authorisation by the Finnish Medicines Agency (Fimea).	General rules apply, i.e. the Medicinal Products Act, No 93/1994 and Regulation on clinical trials of medicinal products in humans, No 443/2004 (no special regulations).	Requires authorisation by the Norwegian Directorate of Health and the Norwegian Medicines Agency.	Requires authorisation by IVO.[59]
Licence for production	Yes, by Board of Health.	Yes, by Fimea.	General rules apply.	Yes, by the Norwegian Medicines Agency.	Requires authorisation by the Medical Products Agency.
Authorisation for use in health care (in-house vs. market authorisation)	Authorised centrally by the European Medicines Agency (Committee for Advanced Therapy).	Yes, by Fimea.	Authorisation for licensed medicine, including ATMP, is given by the Price and Reimbursement Committee, cf. Amendments to the Act on Health Insurance No 45/2012, which came into force 4.5.2013.	Hospital exemption administered by the Norwegian Medicines Agency. The Norwegian Directorate of Health must approve the condition.	Production of pharmaceutical preparations covered by the hospital exception (e.g. concerning products used for a single patient) requires the authorisation of the Medical Products Agency.

57 EU Regulation 1394/2007 on advanced therapy medicinal products is directly binding in Denmark, Finland and Sweden. Norway has adopted the regulation as part of the EEA cooperation.
58 Lag (2008:286) om kvalitets- och säkerhetsnormer vid hantering av mänskliga vävnader och celler; Förordning (2008:414) om kvalitets- och säkerhetsnormer vid hantering av mänskliga vävnader och celler. The Act and Ordinance are complemented by the Medical Products Agency's Regulations on the handling of human tissue and cells intended for the production of pharmaceutical preparations (24.11.2008/12), and Regulations on pharmaceutical preparations covered by the hospital exception (19.5.2011/3). (Läkemedelsverkets föreskrifter om hantering av mänskliga vävnader och celler avsedda för läkemedelstillverkning (LVFS 2008:12); and Läkemedelsverkets föreskrifter om läkemedel som omfattas av sjukhusundantaget (LVFS 2011:3)). See also Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products, above.
59 The Health and Social Care Inspectorate (IVO: Inspektionen för vård och omsorg).

14. Genetically modified organisms (GMOs; animals, see below)

	Denmark	Finland	Iceland	Norway	Sweden
Law[60], [61]	Consolidated Act 869/2010 on Environment and Gene Technology Aim of the Act: 1) To safeguard nature and the environment; 2) To protect human health in relation to gene technology. Consolidated Act on growth of genetically modified crops (193/2009)	Gene Technology Act (377/1995) Aim of the Act: 1) To promote the safe use and development of gene technology in accordance with the precautionary principle and in a way that is ethically acceptable; and 2) To protect human and animal health and the environment when carrying out the contained use or deliberate release into the environment of genetically modified organisms.	Act No 18/1996 on genetically modified organisms. The aim of the Act is to protect nature, biological diversity, ecosystems, plants and health of humans and animals, against possible harmful and undesirable effects of genetically modified organisms. It shall be ensured that production and use of GMOs is conducted in an ethically and socially responsible way in accordance with the precautionary principle and the principle of sustainable development (Article 1 of the Act on GMOs).	Act relating to the production and use of genetically modified organisms, etc. (2.4.1993/38) Act relating to food production and food safety, etc. (19.12.2003/124)	Regulation (EC) No 1829/2003 on genetically modified food and feed Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms The Swedish National Food Agency has issued “Directions for supervising authorities and others in relation to genetically modified organisms” to complement the EC regulations above. [62]
Scope of field (production/use)	- Fabrication, production, sale, handling and use of GMOs - Commercial growth, handling, sale of GMOs to first buyer in order to limit spread, respectively	Contained use and deliberate release into the environment of GMOs. Risk assessment and risk classification. Launch and operation of installations and premises intended for the handling of GMOs.	Article 2 of the Act on GMOs: All use and activity with GMOs, including research, cultivation, production, storage, waste treatment, release and distribution, and control of premises. The Act covers importation, labelling, marketing (i.e. placing on the market), sale and other delivery of GMOs, and products or parts of products that contain GMOs. The Act also covers transportation of GMOs and products that contain GMOs on land, sea and air. The Act covers dissemination of information to the general public and its right to make comments. The Act does not cover - organisms that come into being with natural breeding or natural genetic modification - products of GMOs. When executing the Act special regard shall be made to the unique position of Iceland in the Arctic.	Contained use and deliberate release into the environment of GMOs. Production of cloned vertebrates and crustaceans. Provisions relating to GMOs also apply to substances and products that consist of or contain GMOs. Risk assessment and risk classification. Launch and operation of installations and premises intended for the handling of GMOs. Foodstuffs containing or deriving from GMOs.	In accordance with the regulations above: -Central approval of GMOs for release in the EU -Environmental assessment -Risk assessment -Marking and traceability of GMOs -Supervision of compliance

60 Regulation (EC) No 1829/2003 of the European Parliament and the Council of 22 September 2003 on genetically modified food and feed.
61 Regulation (EC) No 1830/2003 of the European Parliament and the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.
62 Livsmedelsverket, Vägledning till kontrollmyndigheter m fl: Genetiskt modifierade livsmedel (GMO) 2013-11-22.

Table 14 continued	Denmark	Finland	Iceland	Norway	Sweden
Prior notification of or licence for GMO cultivation	Authorisation is required from the Minister of Environment. Minister of Food, Fisheries and Agriculture is authorised to set out conditions.	Yes, to the Board for Gene Technology.	Licence from the Environment Agency of Iceland is needed for: - contained use (Article 11 of the Act on GMOs) - deliberate release (Article 16) - placing on the market (Article 19).	Deliberate release of GMOs may only take place with approval from the Ministry of the Environment. Contained use of GMOs must be notified to or approved by the Ministry of Health and Care Services/Norwegian Directorate of Health.	Yes, to the competent authority. Where it concerns food products, to the National Food Agency; where it concerns feedstuff, to the Board of Agriculture. In accordance with the EC regulations above, applications for the approval of GMOs are submitted to a competent authority which ensures that the application is complete before submitting it to the European Food Safety Authority (EFSA).
Information to neighbours regarding cultivation	Public hearing. Minister of Food, Fisheries and Agriculture is authorised to set out conditions in relation to notification of neighbours.	No.	According to Chapter IV of Act 18/1996 the Environment Agency must inform the public about several things regarding the placing on the market as well as the release of GMOs. According to Article 31 of the Act, the Environment Agency shall, after receiving an application for cultivation of GMOs, consult the public, as is relevant, on different parts of the release, circulation and placing on the market of the GMO in question. This can for example be done by hosting a public meeting which shall be advertised specially. This has been done with meetings both in the area where the cultivation is to take place and in the capital.	No, but applications for deliberate release must include an impact assessment setting out the risk of adverse effects on health and the environment and other consequences of the release.	-
Approval of GMO products for use	Authorisation for placement on market is required from the Minister of Environment	Placement on market requires the written consent of the Board for Gene Technology.	Requires a licence from the Environmental Agency of Iceland (Article 19 of the Act on GMOs). If a licence from another competent authority in the EEA area has been obtained for the product, it is not necessary to apply for a licence from the Environmental Agency of Iceland (Article 23).	Placement on market may only take place with the approval of the Government. Contained use of GMOs must take place in laboratories and installations approved by the Ministry of Health and Care Services/Norwegian Directorate of Health.	In accordance with the EC regulations above, applications for the approval of GMOs are submitted to a competent authority which ensures that the application is complete before submitting it to the EFSA. The EFSA carries out an independent risk assessment which is used by the European Commission and Member States in determining whether or not to approve the GMO. When the GMO product is approved by the European Commission it may be sold within the EU.
Authority	Ministry of Environment Ministry of Food, Fisheries and Agriculture	Board for Gene Technology National Supervisory Authority for Health and Welfare (Valvira) – health issues Finnish Environment Institute – environment Finnish Food Safety Authority (Evira) – food and agriculture	The Environment Agency of Iceland	Final decision is made by the Government, based on a recommendation from the Ministry of the Environment. Norwegian Environment Agency Norwegian Biotechnology Advisory Board Norwegian Scientific Committee for Food Safety	National Food Agency Swedish Board of Agriculture

15. Animal experimentation

	Denmark	Finland	Iceland	Norway	Sweden
Law[63],[64]	Consolidated Act on Animal Experimentation (253/2013) Consolidated Act on Cloning and Genetic Modification of Animals (259/2013)	Animal Welfare Act (247/1996) Act on the Protection of Animals Used for Scientific or Educational Purposes (497/2013) and decrees (564 & 565/2013) Pharmaceuticals Act (395/1987) – clinical trials of animal medical products Gene Technology Act (377/1995)	From 1.1.2014: Act No 55/2013 on Animal Welfare, current act is Act No 15/1994 on Animal Welfare (English versions not available). Regulation No 279/2002 on Animal Experimentation (new regulation will be made soon according to the new act on animal welfare).	Animal Welfare Act (19.6.2009/97) Act relating to the production and use of genetically modified organisms, etc. (2.4.1993/38) Regulation of experiments with animals (15.1.1996/23)	Animal Welfare Act (2.6.1988/534)[65] Animal Welfare Ordinance (2.6.1988/539)[66]
Scope of application (species etc.)	Mammals, vertebrates and squids, including foetuses (all foetuses if it is likely that they will suffer pain, anxiety, suffering or lasting injury, otherwise all foetuses in the last third of their development). Experiments on the above require authorisation from the Animal Experimentation Authority.	To protect animals from distress, pain and suffering and to promote good welfare and treatment. Use of animals for scientific and educational purposes only when necessary and important. All vertebrates, keeping and treating, processes, premises, clinical trials (very broad scope).	The purpose of the legislation is to promote animal welfare, i.e. animals are free of distress, hunger, thirst, fear and suffering, pain, injury and diseases, in light of the fact that animals are living creatures. The purpose is also to ensure that animals can behave normally, as far as possible. Vertebrate, decapoda, cephalopoda and bees. Foetuses of animals when senses have reached the same level as those of living animals. Catching of wild fish is excluded.	The Animal Welfare Act applies to conditions that affect the welfare of or respect for mammals, birds, reptiles, amphibians, fish, decapods, squid, octopi and honeybees. The Act relating to the production and use of genetically modified organisms applies to genetically modified and cloned animals. Regulation of experiments with animals applies to experiments with animals, as well as breeding, rearing and husbandry of animals that are to be used in experiments.	The Animal Welfare Act applies to the care and treatment of domestic and laboratory animals, and to other animals if they are kept in captivity. The Act defines “laboratory animals” as animals used, or intended to be used, in animal experiments or animals bred, kept or supplied for animal experiments. Animals comprise mammals, birds, reptiles, amphibians, fish, cyclostomes and octopi. “Animal experiments” means using animals for: scientific research; diagnosis of disease; development and manufacture of pharmaceutical or chemical products; teaching purposes; and other similar purposes. It also includes the production of genetically modified animals, if gene technology, chemical or other similar methods are used.

63 EU directive 2010/63/EU on the protection of animals used for scientific purposes.
64 Council of Europe: European Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes CETS No 123 18.3.1986. Denmark ratified in 2001, Finland, Norway and Sweden in 1991, thus making the Convention legally binding in their jurisdictions. Iceland has not signed the Convention.
65 Djurskyddslagen (1988:534). However, many of the specific provisions on review of animal research are found in Sections 40-55a of the complementary Ordinance on animal protection, Djurskyddsförordningen (1988:539). See also regulations from the National Agency for Animal Protection: Djurskyddsmyndighetens föreskrifter och allmänna råd (DFS 2004:4) om djurförsök m.m.
66 Djurskyddsförordningen (1988:539). The Animal Welfare Ordinance contains many of the specific provisions on review of animal research (Sections 40-57b). See also the Regulations and guidelines concerning animals used for experimental purposes issued by the Swedish Board of Agriculture: Statens jordbruksverks föreskrifter och allmänna råd om försöksdjur (SJVFS 2012:26, Saknr L 150).

Table 15 continued	Denmark	Finland	Iceland	Norway	Sweden
Licence for animal experiment project	A licence can only be granted to named physical or legal persons, in the latter case one or more responsible persons must be named.	Yes, from the Project Authorisation Board.	Yes, from the Icelandic Food and Veterinary Authority.	Yes, from the Norwegian Animal Research Authority.	Authorisation must be granted by the Swedish Board of Agriculture before laboratory animals can be used, bred, kept or supplied. When applications for permission to breed laboratory animals are considered, the need for such animals must be taken into account.
Licence for an establishment to use animals in experiments	Generally, authorisation can only be granted for specified experiments stating the species and number of animals. In special cases authorisation can be granted without these conditions being met. The competent body is the Animal Experimentation Authority.	Yes, from the Regional State Administrative Agency.	Yes, from the Icelandic Food and Veterinary Authority.	Yes, from the Norwegian Animal Research Authority.	Permission must be granted by the Swedish Board of Agriculture.
Ethical review process for animal experimentation	No ethical review process as such; however, the Animal Experimentation Authority assesses on a case-by-case basis if authorisation can be granted based on the criteria set out in the Act and the appurtenant administrative guidelines.	National Animal Experimentation Board. Notification to Fimea in cases of clinical trials.	The Icelandic Food and Veterinary Authority is obligated to consult with the Expert Council on Animal Welfare on application for animal experimentation. The Expert Council is composed of the senior veterinarian and representatives of the Farmers Association of Iceland, the Icelandic Veterinary Association, the Icelandic Association for the Protection of Animals and the Centre for Ethics at the University of Iceland.	Norwegian Animal Research Authority.	Must be examined and approved by an ethical review board before experimentation can commence. There are seven regional boards for ethics review of animal research, appointed by the Swedish Board of Agriculture. Each board has 14 members, including a chair and vice-chair. The decision of the Board is binding but can be appealed to the central ethics review board for animal research.

Table 15 continued	Denmark	Finland	Iceland	Norway	Sweden
Criteria for decision-making	Majority vote. The Animal Experimentation Authority consists of 11 members; the chairperson must be a judge by profession.		Experimentation on living animals is only allowed if other means to achieve comparable results are not known. It is prohibited to use living animals to test cosmetics. As few animals should be used as possible. There must be a realistic possibility that the purpose of the experiment can be reached. Care shall be taken so that animals are not subjected to more suffering than is unavoidable. Only one animal shall be used for each experiment if it entails much distress or suffering. It is not allowed to use endangered species for experimentation, except when the purpose of the experiment is preservation of that species. It is not allowed to use animals captured in nature, except when the use of other animals is not satisfactory. The Icelandic Food and Veterinary Authority shall make sure that those who use animals for experimentation have training and education in the relevant branch of science and finished a course in animal experimentation. Objectives to keep in mind: - Development, production and testing of the quality, effectiveness and safety of medicinal products, foodstuff, chemicals or products: a) to prevent, analyse or cure diseases, poor health or other effects on people, animals or plants; b) to evaluate, analyse, improve or change the biophysical state of humans, animals or plants. The protection of the environment for the health and wellbeing of humans and animals.	Animal welfare and scientific merit of the research project.	An animal experiment application may only be approved if its use can be considered important to the public interest. In addition, the value of the experimentation must be greater than the suffering the animal is exposed to; the goal must be to use as few animals as possible; and the activity must be organised in such a way as to not subject the animals to greater suffering than absolutely necessary. Permission may not be given if there is a sufficiently good alternative that does not require the use of animals.

Table 15 continued	Denmark	Finland	Iceland	Norway	Sweden
Specific criteria for genetic modification	Authorisation can only be given if the aim of the research is: 1. Basic research; 2. Applied research intended to improve health or the environment; 3. The production or breeding of animals intended to produce a substance which benefits health or the environment; 4. Teaching and education at universities and similar higher education institutions.	Use of gene technology for quantitative or qualitative modification of animals is prohibited if it may have harmful impacts on the health or welfare of animals.	Reproduction, including artificial fertilisation or gene technology, is prohibited when it is foreseeable that - it alters characteristics in a way that has negative effects on the health and behaviour of the animal or its offspring or it maintains such defects; - it affects the ability of the animal to behave normally.	Approval is required, with a few exceptions, for genetic modification of vertebrates resulting in heritable genetic alterations, as well as for production and use of genetically modified animals for placing on the market or other commercial use. Experiments with GM animals are regarded as contained use, and must be notified to or approved by the Ministry of Health and Care Services/ Norwegian Directorate of Health.	Same as for other forms of animal experimentation
Fate of animals after research; destruction methods	If at all possible the experimentation should end in early and humane outcomes instead of terminal outcomes. If death is inevitable it must be ensured that as few animals as possible die, that the extent of suffering is limited and that a pain-free death is ensured whenever possible.	Destruction methods must minimise pain and suffering. Methods are listed in Decree 565/2013, Appendix 2. Animals must be destroyed - if suspected to suffer greatly and suffering cannot be alleviated, or - after the intervention, if it is likely to continue suffering. If not destroyed, the animal must be treated and nursed appropriately. A veterinary or other qualified person makes the decision on destruction.	After an experiment, a decision shall be made whether to keep an animal alive or destroy it in a humane way. An animal shall not be kept alive if it is suspected that it will continue to be in pain and afraid, in spite of regaining normal health in other respects. Destruction shall be performed by the supervising veterinarian or licensee who has the proper knowledge.	Animals that have been used in experiments assumed to cause harm must not be used in further experiments causing more than insignificant pain or affliction. Destruction of test animals must be carried out in a manner that does not cause unnecessary suffering.	The destruction of animals used for experimental purposes may only be carried out in an establishment where animals are used, bred, kept or supplied for animal experiments, unless otherwise approved by the Swedish Board of Agriculture. Persons performing the destruction, anaesthetising or sedation of animals must be competent and trained in such methods.[67]
Other		Each breeder, supplier and user must set up an animal welfare body.		The Animal Research Authority must approve animal research facilities, as well as the person responsible for each research project. If the animals are genetically modified, approval by the Norwegian Directorate of Health is required.	

67 Chapter 12 of the Regulations and guidelines concerning animals used for experimental purposes (SJVFS 2012:26, Saknr L 150) sets out the requirements for and processes of destruction.

16. Legal status of the Council of Europe Biomedicine Convention and its additional protocols

	Denmark	Finland	Iceland	Norway	Sweden
Biomedicine Convention (ETS No. 164, 2007)	Ratified in 1999 and in force since 1.12.1999.[68]	Ratified in 2010 and in force since 1.3.2010.	Ratified in 2004 and in force since 1.2.2005.	Ratified in 2006 and in force since 1.2.2007.[69]	Signed 4.4.1997.
Protocol on Cloning (ETS No. 168, 1998)	Signed 12.1.1998.	Ratified in 2010 and in force since 1.3.2010.	Ratified in 2004 and in force since 1.2.2005.	Signed 12.1.1998	Signed 12.1.1998
Protocol on Transplantation of Organs and Tissues (ETS No. 186, 2002)	Not signed.	Ratified in 2010 and in force since 1.3.2010.	Ratified in 2004 and in force since 1.5.2006.	Not signed.	Not signed.
Protocol on Biomedical Research (CETS No. 195, 2005)	Signed 25.1.2005.	Not signed.	Signed 25.1.2005.	Signed 25.1.2005.	Signed 25.1.2005.
Protocol on Genetic Testing for Health Purposes (CETS No. 203, 2008)	Not signed.	Signed 27.11.2008.	Signed 7.7.2009.	Not signed.	Not signed.

68 Reservations, declaration and territorial applications when ratified for Articles 10.2, 20 and 35.
69 Reservations for Articles 20.2 and 36.

NordForsk

Legislation on biotechnology in the Nordic countries – an overview 2014

The legislation on biotechnology varies markedly from one Nordic country to another. The aim of this report is to give the reader information of the current status in the different countries and a chance to compare the legal situations. Sixteen important areas of biotechnology have been chosen for this overview:

- Assisted reproduction
- Preimplantation genetic diagnosis (PGD)
- Preimplantation genetic screening (PGS)
- Abortion
- Prenatal Diagnosis and/or screening
- Organ and tissue transplantation
- Embryo research
- Cloning
- Clinical research on humans
- Human biobanks
- Ethical committees
- Genetic testing
- Advanced therapy medicinal products
- Genetically modified organisms
- Animal experimentation
- Legal status of Council of Europe Biomedicine Convention and its additional protocols

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