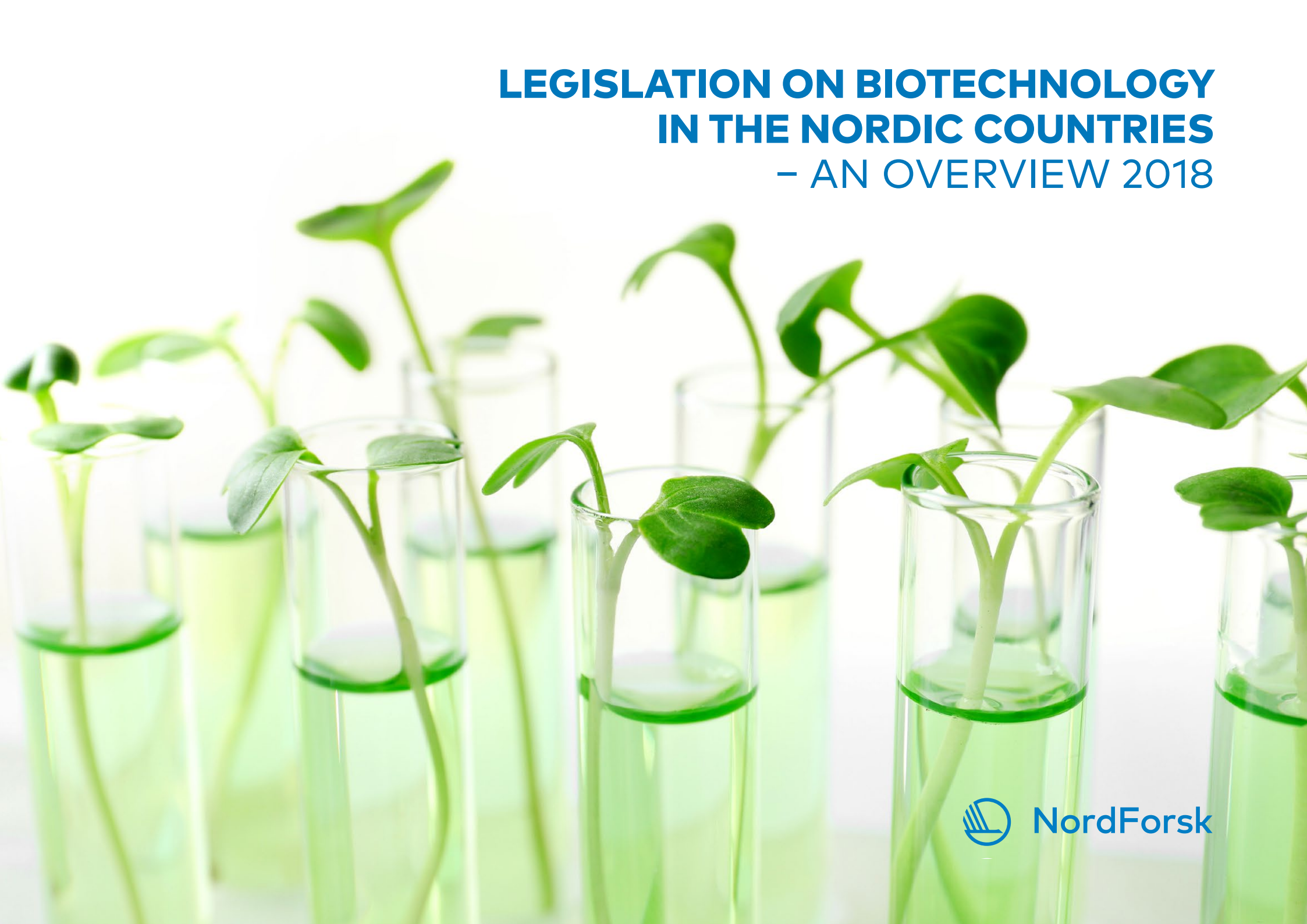
LEGISLATION ON BIOTECHNOLOGY IN THE NORDIC COUNTRIES – AN OVERVIEW 2018



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Legislation on biotechnology in the Nordic countries
– an overview 2018

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Preface

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

Ethics is a field of importance to NordForsk, and the Nordic Committee on Bioethics adds new perspectives to the ongoing activities within NordForsk.

The report Legislation on biotechnology in the Nordic countries has been published annually since 2014. We are pleased to publish this updated version, and hope it serves its purpose of enhancing the understanding for each other's regulatory framework within biotechnology in the Nordic countries.

Oslo September 2018

Arne Flåøyen

Director of NordForsk

Introduction

The Nordic Committee on Bioethics has published an overview on the legislation of biotechnology since 2014 both in a printed booklet and on its webpage www.ncbio.org and www.nordforsk.org/en/publications. The publication has been popular because it provides an easy glance over the core biomedical legislation in the Nordic countries, thus facilitating management of cross-border activities. Given the clear the need for such a publication, NordForsk decided to update the tables regularly to maintain current and accurate information.

Nordic collaboration in the biotechnological arena started as early as in 1987.* The Nordic Committee on Bioethics was established in 1996. One of the tasks of the Nordic Committee on Bioethics is to follow legislative developments in the sphere of biotechnology in the Nordic countries and globally.

The European Union is increasingly introducing regulation in various areas of biotechnology, but its mandate basically only encompasses the health field. However, to meet common safety concerns, the EU may adopt measures that set high standards for quality and safety of organs, tissues, blood and medicinal products and devices. In addition, the EU's General Data Protection Regulation (GDPR) imposes strict conditions on the processing of health data. EU legislation is binding for all the Nordic countries; Denmark, Finland and Sweden are members of the EU, while Norway and Iceland follow EU legislation as part of the EEA cooperation. Tables have references to key union regulation in the respective fields.

In addition to EU legislation, other supranational legislation may affect the legal landscape too. The most important international biomedical document is the Council of Europe 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 supplementary protocols. The legal status of the Convention and its protocols are listed in Table 16.

It is a great pleasure to present readers with the updated tables, based on the legal situation as from 1 April 2018. However, it should be noted that a table such as this cannot provide fully comprehensive information regarding all the necessary details. I foresee many changes happening within the next year, and I therefore recommend contacting the respective country rapporteurs listed in the end for the most current information.

I would like to thank all my colleagues for their efforts in updating their portions of the tables.

Helsinki, June 2018
Sirpa Soini

Links to legislation in force in the respective countries:

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

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

1. Assisted reproduction

	Denmark	Finland	Iceland	Norway	Sweden
Law	Consolidated Act on Assisted Reproduction (93/2015)[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, but it is recommended that the woman is between 25 and 40 years, and that the age difference to her partner is "reasonable".	Ability to carry out parental responsibilities throughout childhood.
Relevance of family status/relationship of the applicants (single, same-sex, marriage)	Single women, married couples. Cohabiting 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. Concept of single women defined as a woman who is not married or cohabite with a man. 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. If the man or the woman in a heterosexual couple is a carrier of a serious and chronic sexually transmitted disease (such as HIV), insemination may be performed even when the couple does not qualify as having medical fertility problems.	Single women, heterosexual couples and female couples (married or in a registered cohabitation) have access to fertility treatment. Because one of the applicants for treatment must be the woman being treated, single men and male couples are excluded from accessing ART.

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. For some of them, 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.

Table 1 continued	Denmark	Finland	Iceland	Norway	Sweden
Is assisted reproduction allowed after change of gender?	Yes – provided the person in question falls into one of the two categories (man or woman): a woman is a person with an uterus or ovarian tissue and a man is a person with at least one testicle.	Issue is not stipulated by law or regulation. Change of legal gender requires approved infertility or sterilization.	Issue is not stipulated by law or regulation.	Since 2016, sterilization or medical treatment is no longer required for legal change of gender. The legal details concerning assisted reproduction after change of gender are not yet stipulated, but will be part of the ongoing evaluation of the Act relating to the application of biotechnology in human medicine, etc.	Access to assisted reproduction after change of gender is neither expressly permitted nor expressly prohibited by law. The Swedish Government has, however, declared that existing rules and principles can be applied analogously without causing legal uncertainty for children born in families where one or both parents have changed legal gender, indicating that access to assisted reproduction cannot be ruled out following change of gender.[7]
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.
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, based on physical characteristics (height and the color of skin, hair and eyes). For same-sex female couples, the couple decides, after consulting with the physician, which physical characteristics should be the basis for selecting the donor	The physician performing the treatment selects a suitable donor.
Written consent of the participants	From the woman, and in the event the woman is not single, from her spouse, registered partner or partner. In cases where eggs or semen are donated, written consent from the donating man or woman must also be obtained.	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.

7 See Government Bill (Upphävande av kravet på sterilisering för ändrad könstillhörighet), prop. 2012/13:107 pp 19-20.

Table 1 continued	Denmark	Finland	Iceland	Norway	Sweden
Limits to the no. of offspring using the same donor	Maximum 12 pregnancies in Denmark from same donor.	Yes, donor can contribute to the birth of children for 5 recipients.	No.	Sperm from one donor can be used for conceiving up to eight children in no more than six families.[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.
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. Man can consent to that his semen or embryo fertilized with his semen to be used by the woman for assisted reproduction after his death.	Germ cells or embryos can be stored for 15 yrs after donation. Germ cells must be destroyed if the donor is diseased. Embryos shall be destroyed, if the other donor is deceased.	10 years for sperm, oocytes and embryos.	Yes. Sperm from a deceased donor may not be used for assisted reproduction. Yes, but only if the woman qualifies for assisted reproduction or risks infertility due to medical treatment. Eggs from a deceased woman must be destroyed. 5 years.	 Yes.[9] Yes.[10] 5 years.[11]
Donation - sperm - oocytes - embryos	Law. No.1688 of 26/12/2017: Double donation is allowed only if it based on health-related reasons. Either the egg-cell or the semen must be donated in a non-anonymised form.	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.	Not allowed. [12]	Not expressly prohibited by law.[13]

8 Specified in directive IS-2418, Veileder om assistert befruktning med donorsæd: https://helsedirektoratet.no/Documents/Bioteknologi/Veileder%20om%20assistert%20befruktning%20med%20donors%C3%A6d%20-%20oppdatert%20november%202015%20-%20IS-2418.pdf
9 Sperm from a deceased donor may not be used for insemination or IVF.
10 Ova from a deceased donor may not be used for fertilisation.
11 If there are exceptional grounds, the National Board of Health and Welfare may consent to the extension of the storage time.
12 Surrogacy is not regulated in a specific paragraph, but is forbidden.
13 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 co-habitation 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 Assisted Reproduction (93/2015)[14]	Act on Fertility Treatments (1237/2006)[15]	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)[16]	Genetic Integrity Act (1.7.2006/351)[17]
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. Serious autosomal or chromosomal disease. PGD/HLA tissue typing allowed to select embryo that can be stem cell donor for a sibling who requires a haematopoietic stem cell transplant. Sex testing only allowed to detect sex-linked serious disease.	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.

14 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.
15 For a Swedish version or English translation, see www.finlex.fi.
16 PGD is regulated in chapter 2A, which came into force on Jan. 1. 2008. This chapter is not yet included in the translation of the act online.
17 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.	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.[18]
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. The couples are referred to hospitals abroad for treatment.	No.

18 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 Assisted Reproduction (93/2015) § 7 allows genetic testing in connection with IVF treatment in order to detect or rule out significant chromosomal abnormalities.	Act on Fertility Treatments (1237/2006)[19] 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, not PGS.[20]	Genetic Integrity Act (1.7.2006/351)[21]
Indications	Not practiced.	No legal criteria.			PGS is only permitted in relation to research projects approved by research ethics committees.

19 For a Swedish version or English translation, see www.finlex.fi.
20 PGD is regulated in chapter 2A, which came into force on Jan. 1. 2008. This chapter is not yet included in the translation of the act online.
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.

4. Abortion

	Denmark	Finland	Iceland	Norway	Sweden
Law	Consolidated Act No. 191 of 28/02/2018	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.[22]	Act on abortion (13.6.1975/50)	Abortion Act (12.6.1974/595)[23]

22 "The revision of Act on Counselling and Education regarding Sex and Childbirth and on Abortion and Sterilisation Procedures, No 25/1975 is ongoing."
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	Danish National Board of Health Guidelines, January 2017. [30]	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)[31]
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.[32]	Blood test offered to pregnant women from week 9; ultrasound offered between weeks 11 – 14. Certain county councils offer Nuchal translucency ultrasound and blood test only to pregnant women over 35 years of age, while others offer the investigation to all pregnant women. Some regions do not offer the investigation at all.[33]
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 The updated Guidelines: two new diagnostic methods: Non-Invasive Prenatal Test (NIPT) and chromosome micro-array. The guidelines prescribe qualitative assurance and a harmonised use of these techniques and stress the need for ethical deliberation on the use of methods of prenatal diagnosis. Note: ISBN 978- 87- 7104- 815

31 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.

32 Specified in directive IS-23/2004 from the Norwegian Directorate of Health: https://helsedirektoratet.no/publikasjoner/veiledende-retningslinjer-for-bruk-av-ultralyd-i-svangerskapet

33 See http://www.1177.se/Fakta-och-rad/Undersokningar/KUB---kombinerat-ultraljud-och-blodprov/

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: [34] -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.[35]
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.

34 SOSFS 2012:20, Chapter 3, Section 3.
35 Lag (1995:831) om transplantation mm; Regulations on Donation and safeguarding of organs, tissues and cells (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[36]	Consolidated Act No. 191 of 28/02/2018	Act of the Medical Use of Human Organs and Tissues (101/2001)	Act on the procurement of organs, No 16/1991	Act on donation and transplantation of organs, cells and tissue[37]	Law on Transplantation etc. (8.6.1995/831) Genetic Integrity Act (1.7.2006/351)[38]
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 only when the procedure does not involve any immediate risk to the donor's physical or mental 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.

36 Directive 2010/45/EU (corrigendum: read 2010/53/EU) on standards of quality and safety on human organs intended for transplantation; 2012/25/EU Implementation Directive.
37 https://lovdata.no/dokument/NL/lov/2015-05-07-25 (Norwegian)
38 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.	Removal of organs, cells and tissue from persons between 12 and 18 years of age may only take place when there are compelling reasons. More stringent rules for minors below 12 years of age, including mandatory demand that the donation must be life-saving, the recipient must be a close relative and the tissue donated must be renewable.	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.	Persons above 16 years of age can consent to having organs, cells and tissue donated after their death. If the diseased has consented to donation, relatives cannot decline. If consent is not given, donation may be performed unless there is reason to believe the deceased would have opposed it, or one of the closest relatives declines.	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 string-ent rules for persons below 12 years of age. Treatments depending on use of embryonic cells must have approval from The Ministry of Health and Care Services.	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 Assisted Reproduction (93/2015)	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)[39]	Genetic Integrity Act (1.7.2006/351)[40]
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.	After five years, eggs fertilized for IVF treatment must be destroyed, donated for training or quality assurance purposes, or donated to research. The research must be performed no more than 14 days after fertilization, cryopreservation time not included.	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.

39 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.
40 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)[41]
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).[42]
Is human germline genetic modification allowed for research purposes?	Yes - but the there are restrictions to the character of the research. It is not allowed to do research with the aim of developing techniques of human cloning, techniques of producing human beings by merging genetically different embryos or parts of embryos and techniques with the aim of producing living humans that are hybrids with a genome containing parts of the genomes of other species.	Research on embryos and gametes for germ line modification is prohibited, save for research to cure or prevent a heritable serious disease.	Issue is not stipulated by law or regulation.	Research entailing genetic modification that may be inherited in people is prohibited. This is interpreted as a ban on all human germline genetic modification, also for research purposes (even though embryos used for research must be destroyed after use).	Human germline genetic modification is prohibited for research purposes.[43]

41 Covers somatic cell nuclear transfer (SCNT) embryos.
42 Lag (2003:460) om etikprövning av forskning som avser människor.
43 Genetic Integrity Act (2006:351), Chapter 2, Section 3.

8. Cloning

	Denmark	Finland	Iceland	Norway	Sweden
Law[44]	Consolidated Act on Assisted Reproduction (93/2015) 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.

44 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 Research Ethics Review of Health Research Projects (593/2011).[45] Act on clinical trials of medicinal products (620/16).[46] Medicines Act (506/2013) EU Regulation 536/2014* Act No. 1083 of 15/09/2017	Medical Research Act (488/1999) and Decree Pharmaceutical Act (395/1987) (complementary on clinical drug trials) EU Regulation 536/2014*	Act on Scientific Research in the Health Sector No 44/2014. Clinical trials of medicinal products are in addition subject to the provisions of the Medicinal Products Act No 93/1994 and clinical trials of medical equipment are subject to the provisions of the Act on Medical Devices No 16/2001. The use of human gametes and embryos for stem-cell research is subject to the provisions of the Act on Artificial Fertilisation and use of Human Gametes and Embryos for Stem-Cell Research.	Act on medical and health research (20.6.2008/44) Act on organizing work on research ethics (28.4.2017/23) Some clinical trials that involve both research and treatment also fall under the Act relating to patients' rights (2.7.1999/63). The Norwegian National Research Ethics Committees issued new guidelines for genetic research in April 2016.**	Act on ethics review of research involving humans (5.6.2003/460)[47] 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 scientific research in the health sector. It applies to scientific studies carried out, in whole or in part, in Iceland. Covers both Scientific research project on human subjects (a study in which the individual takes an active part in scientific research, for instance by undergoing tests, or providing samples or information for the study) and Retrospective study (a study which makes use of existing health information materials. The individual from whom the data or materials originate takes no active part in the study).	The Act on medical and health research applies to 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. Act on organizing work on research ethics applies to all research and researchers.	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.	Written, informed consent and freely given. Broad consent is possible for human biological material and personal health data being used later in research projects.	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. The timetable for application is still open.

**https://www.etikkom.no/forskningsetiske-retningslinjer/Medisin-og-helse/retningslinjer-for-bruk-av-genetiske-undersokelser-av-mennesker-i-medisinsk-og-helsefaglig-forskning/

45 Link to English translation of Act on Biomedical Research (593/2011) http://www.nvk.dk/english/act-on-research
46 The act is planned to enter into force when the EU regulation 536/2014 comes into force. As of July 1 2016, however, the sponsor, monitor and the Danish Medicines Agency's GCP inspectors have direct access to trial subjects' patient records.
47 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. In clinical emergencies under certain conditions, including insignificant risk to the patient (Article 24 of Act No 44/2014). 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 (Article 20 of Act No 44/2014). 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 (Article 18 of Act No 44/2014).	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.	A 18-year-old person is capable of giving consent him-/herself. A study on human subjects with participants who are not competent to grant consent is permissible only where all the following conditions are met: a) there is reason to believe that the findings of the study may lead to enhancement of the participants' health, b) research of comparable effectiveness cannot be carried out on individuals competent to give consent, c) the individuals in question have been informed about the study in so far as that is possible, and are not opposed to participation, d) the guardian of a child has granted consent.	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 on minors between 16 and 18 years of age that entails bodily interventions or testing of medicinal products. 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.	Similar to minors. Consent by close relative or the legal guardian of an individual who has been deprived of legal competence.	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.	No specific regulations.	No specific regulations.	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. National Committee on Health Research Ethics: Guidelines 2017.[48]	Biobank Act (688/2012)	Act 110/2000 on Biobanks and health-data banks, as amended by Act No 45/2014, and Regulation No 1146/2010, on the storage and utilisation of biological samples in biobanks.	Act on medical and health research (20.6.2008/44) Act relating to treatment biobanks (21.2.2003/12)	Act on biobanks in health care (23.5.2002/297)[49]
Scope of field (e.g. clinical/ research/both)	Clinical and research	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". Right to ask for own information that is registered and how it has been used.	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 facilitate collection of and other uses of health data, in order to promote health, prevent illness and harm, and provide better health and care services.	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).
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.

48 http://www.nvk.dk/emner/biobanker/vejledning-om-bio-mat
49 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
Purpose of a biobank	According to the Danish National Research Committee there are three types of biobanks: Research biobank: created in relation to a specific biomedical health-research project. Clinical biobank: created primarily for clinical purposes: to prevent, diagnose, or treat illness or with the purpose of administration of healthcare and medical treatment. Biobank for future research: A structured collection of human biological material stored with the purpose of future unspecific research accessible by certain criteria and where the information contained in the samples can be traced to identifiable persons. Act no. 338/2017 amends act no. 955/2014 by revising the definitions of cells and tissue and securing better standards for security and traceability of cells and tissue. (i.e., to Licence/legal oversight).	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	If the biological material is aimed for use in the human body license is needed from the National Board of Health according to consolidated act No.955/2014	Establishment of a biobank requires ethical review by Tukija.[50] Valvira[51] is the supervising authority. A biobank must be registered in Valvira's biobank register to be legally competent to operate.	Licence for biobanks 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 Directorate of Health monitors the activities of research biobanks and 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.[52] 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.

50 Tukija is the acronym for the National Medical Research Ethics Committee, www.tukija.fi .
51 Valvira is the acronym for the National Supervisory Authority for Health and Welfare.
52 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.[53]
Reconsent when reached maturity/ competence	Not required.	Not required.	Not regulated.	Not required.	Yes.[54]

53 SOSFS 2002:11, Chapter 4, Section 4.
54 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. 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	No general time-span but the Danish Data Protection Agency can impose time-frame restrictions according to the principle of purpose (the samples and data can only be stored for relevant purposes[55])	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. The Ministry of Health and Care Services may in some instances allow for human biological material from a research biobank to be transferred to other liable researchers rather than to be destroyed.	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.[56]

55 Act no. 429/2000 on Treatment of Personal Data
56 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 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.	Research biobanks: The liable researcher must provide access to human biological material in a biobank to other researchers with an approved research project, unless the liable researcher needs the material or other particular reasons apply. Treatment biobanks: Access can be given, provided that the donor of the material has given the necessary consent. 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	Samples and data delivered abroad to countries outside the EU for research can as a main rule only be carried out if the receiver can ensure a sufficient level of protection.[57]	Allowed.	Allowed, subject to conditions in the Act on the Protection of Privacy as regards the Processing of Personal Data No 77/2000.	For research biobanks: On approval of a Regional Committee for Medical and Health Research Ethics and according to the laws of consent. For treatment biobanks: On approval of the The Ministry of Health and Care Services, and in accordance with the consent given by the donor of the material. The Ministry´s approval is not needed if the delivery abroad is part of health care treatment given to an individual. The Ministry of Health and Care Services may via regulations allow exemption from the approval requirement for transfer of biobank material and information 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	See above	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, The National Bioethics Committee and The Data Protection Authority. 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.

57 Act on Proteciton of Protection Data no. 429/2000

11. Ethical committees

	Denmark	Finland	Iceland	Norway	Sweden
Law	Act on Biomedical Research (593/2011) Act on the Ethical Council (440/2004) Act No. 1083 of 15/09/2017	The Medical Research Act governs ethical committees and their composition. Specific tasks are also set out in the Biobank Act and the Tissue Act.	Act on Scientific Research in the Health Sector No 44/2014 and Act 110/2000 on Biobanks and health-data banks. Regulation No 1186/2014 on institutional ethics committees. Regulation No 1187/2014 on the communication between The National Bioethics Committee and The Data Protection Authority concerning review of research protocols.	Act on medical and health research (20.6.2008/44) Act on organizing work on research ethics (28.4.2017/23) 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) Ordinance concerning the ethical vetting of research involving humans (9.10.2003/615) Ordinance containing instructions for the Central Ethical Review Board (22.11.2007/1068) Ordinance containing instructions for regional ethical review boards (22.11.2007/1069)

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. Medical research on human subjects, human biological material or health records must have approval from a Regional Committee for Medical and Health Research Ethics. 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 chosen from a mixture of specialists and lay people. 9 members are chosen by a Parliamentary committee whose task is to follow the work of the council. In addition, 4 members are chosen by the Minister for Health; 1 member is chosen by the Minister for Environmental Affairs; 1 member is chosen by the Minister for Food, Agriculture and Fisheries; 1 member is chosen by the Minister for Science, Technology and Development; and 1 member is chosen by the Minister for Business. When the Minister for Health appoints the members, the minister must ensure that lay-people as well as experts are represented in the council, and that there is equal representation of men and women in the council leaving the possibility for either 9 men and 8 women or 9 women and 8 men as members. National Committee on Health Research Ethics: The National Committee on Health Research Ethics consists of 13 members: The Chairman is appointed by the Minister for Health. 2 members are appointed by the Minister for Health after joint recommendation from the board of The Danish Council for Strategic Research and The Danish Council for Independent Research. 5 members are appointed by the Minister for Health in collaboration with the Minister for Science, Technology and Development after a public call for candidates. 5 members are appointed after recommendation from the county-regions. When recommending candidates for the committee, an equal number of men and women must be recommended. When the committee is appointed, an equal representation of men and women must be ensured – so because of the uneven number of members you can either have 7 women and 6 men as members, or 7 men and 6 women as members. The committee must consist of members representing both biomedical health research areas and lay-members.	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 National Bioethics Committee is an interdisciplinary committee of seven members. It shall be ensured that the committee includes individuals with expertise in the methodology of health sciences, ethics, law and data protection. The institutional ethics committees 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 determines the fields of responsibility of both the National Committee and the Regional Committees, 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 National Bioethics Committee has the task of evaluating scientific research projects in the health sector with the objective of ensuring that they are consistent with scientific and ethical principles. The National Bioethics Committee and the institutional ethics committees operate on the basis of applicable legal acts and regulations. Furthermore, international agreements have an important impact and contribute to defining the mode of operations and the criteria applied by The National Bioethics Committee. 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 Convention) and Additional Protocol on Biomedical Research. The Council of Europe 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 assesses whether proposed research projects comply with the law, and are organised and performed in a responsible manner. The National Committee for Medical and Health Research Ethics serves as an advisory body to the government within the field of medicine, and decides appeals on the decisions from the Regional Committees for Medical and Health 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 (for prenatal, see Tables 2, 3 and 5)

	Denmark	Finland	Iceland	Norway	Sweden
Law[58]	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 (953/2015) Consolidated Act on Insurance Policies (1237/2015)	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.

58 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 16.

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 (1237/2015) and Consolidated Act on Company Pensions (953/2015): 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 must be given genetic counseling. If the person tested is a child under the age of 16, the child's parents or another person who has parental responsibility must also be given genetic counseling.	
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, presymptomatic, and carrier diagnostic 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[59]	Consolidated act on Medicines (506/2013) Consolidated act on Tissue (955/2014) Act no. 338/2017 on tissues and cells. Consolidated Act No. 99 of 16/01/2018	Pharmaceuticals Act (395/1987) Act of the Medical Use of Human Organs and Tissues (101/2001) (premises)	The Medicinal Products Act, No 93/1994, regulation on entering into force of EU regulations in the field of pharmaceuticals (X) No 794/2010.	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 (18.12.2009/1839).	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)[60]
Scope of field	Scope as defined in EU Regulation 1394/2007 on advanced therapy medicinal products.	Development, research and use of ATMPs.	Development, research and use of ATMPs.	Development, research and use of ATMPs.	Development, research and use of ATMPs.
Is human germline genetic modification allowed for therapeutic purposes?	No	No. Human germ line modification is prohibited.	Issue not stipulated by law or regulations.	No. Gene therapy on foetuses and embryos and gene therapy that may involve genetic modification of gametes is prohibited.	Human germline genetic modification is prohibited for therapeutic purposes. [61]
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).	Requires authorisation by the Icelandic Medicines Agency and the National Bioethics Committee	Requires authorisation by the Norwegian Directorate of Health and the Norwegian Medicines Agency.	Requires authorisation by IVO.[62]
Licence for production	Yes, by Board of Health.	Yes, by Fimea.	Yes, by Icelandic Medicines Agency.	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.	Hospital exemption administered by the Icelandic Medicines Agency.	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.

59 EU Regulation 1394/2007 on advanced therapy medicinal products is directly binding in Denmark, Finland and Sweden. Norway and Iceland have adopted the regulation as part of the EEA cooperation.
60 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.
61 Genetic Integrity Act (2006:351), Chapter 2, Section 4.
62 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[63], [64]	Consolidated Act on Environment and Gene Technology 840/2015 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) Consolidated act 9/2017 on Environment and Gene Technology. Act no. 646/2016 on the growing of genetically modified crops.	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 of contained use of genetically modified animals (21.12.2001/1602) Regulation of contained use of genetically modified plants (21.12.2001/1603) Regulation of contained use of genetically modified microorganisms (21.12.2001/1600)	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. [65]
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

63 Regulation (EC) No 1829/2003 of the European Parliament and the Council of 22 September 2003 on genetically modified food and feed.
64 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.
65 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. Ministry of Environment and Food 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. Ministry of Environment and Food 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 Ministry of Environment and Food	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).	Products may be placed on market if they are approved by the European Commission or the Norwegian government. The government may, on certain conditions, ban the sale of a GMO approved by the EC. 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 and Food	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[66, 67]	Consolidated Act on Animal Experimentation (474/2014) Consolidated Act on Cloning and Genetic Modification of Animals (478/2014)	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)	Act No 55/2013 on Animal Welfare. Regulation No 460/2017 on the protection of animals that are used for scientific purposes.	[No hyphen in organ-isms]	Animal Welfare Act (2.6.1988/534)[68] Animal Welfare Ordinance (2.6.1988/539)[69]
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).	Live non-human vertebrate animals, including: (i) foetal forms of mammals as from the last third of their normal development; and (ii) independently feeding larval forms; (b) live decapoda and cephalopods. The Regulation applies where animals are used or intended to be used in experimentation, or bred specifically so that their organs or tissues may be used for scientific purposes.	[No hyphen in rep-tiles]	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.

66 EU directive 2010/63/EU on the protection of animals used for scientific purposes.
67 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.
68 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.
69 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 Food Safety Authority. Licence is not required for experiments that only entail killing animals for the purpose of using their organs or tissue.	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 Food Safety 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 Food Safety 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. Care shall be taken so that animals are not subjected to more suffering than is unavoidable. It is not allowed to use endangered species for experimentation or animals captured in nature besides certain exceptions. 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.	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, afraid or be permanently injured. Destruction must be carried out in a manner that does not cause unnecessary suffering, pain or distress.	An animal that has already been used in one or more experiments cannot be used in another experiment if it´s possible to use another animal not previously used. Certain exceptions apply. 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.[70]
Other		Each breeder, supplier and user must set up an animal welfare body.		The Norwegian Food Safety Authority must approve animal research facilities, as well as the breeders, distributors and users. If the animals are genetically modified, approval by the Norwegian Directorate of Health is required.	

70 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.[71]	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.[72]	Signed 4.4.1997.
Protocol on Cloning (ETS No. 168, 1998)	Signed 12.1.1998.	Ratified 26.5.2015 and in force as of 1.9.2015	Ratified in 2004 and in force since 1.2.2005.	Ratified 26 May 2015 and in force since 1.9.2015.	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.	Ratified 26 May 2015 and in force since 1.9.2015.	Signed 25.1.2005.
Protocol on Genetic Testing for Health Purposes (CETS No. 203, 2008)	Not signed.	Signed and ratified 26.5.2015.	Signed 7.7.2009.	Signed and ratified 26 May 2015.	Not signed.

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

LEGISLATION ON BIOTECHNOLOGY IN THE NORDIC COUNTRIES
– AN OVERVIEW 2018

The current report is an update of the reports on Legislation on biotechnology in the Nordic countries published annually since 2014. Given the clear need for such overviews, the Nordic Committee on Bioethics decided to update the tables to reflect recent legal amendments. The aim of this report is to give the reader information on the current status in the different countries and a chance to compare the legal situation. 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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