

# Human stem cells, cloning and research



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National Advisory Board on Research Ethics	The National Advisory Board on Health Care Ethics	Sub-committee on Medical Research Ethics	Cooperation Group for Laboratory Animal Sciences	National Advisory Board on Biotechnology	Board for Gene Technology

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*Research on human stem cells and the related ethics are being widely discussed not just in Europe but worldwide. The importance of this research and the medical applications that may result from it are recognized, but at the same time ethical aspects are much to the fore, as stem cell research is closely connected with embryo research. The research is regulated, but in some countries more strictly than others.*

*In the United States, the federal government only provides research funding for certain embryonic stem cell lines. In some European countries research on human embryos is forbidden, which also limits research on embryonic stem cells. In Finland, human embryo research is subject to certain provisions. However, there are points in the legislation which require clarification and interpretation. The formation of an embryo exclusively for research purposes is forbidden, as is research aimed at the cloning of human beings. The lack of clarity in the legislation results from the fact that, according to the Medical Research Act, the cell mass formed by nuclear transfer is not considered to be an embryo as defined in the same Act.*

*Finland should clarify its national legislation to define the embryo unambiguously. At the same time Finland should clearly state its views on therapeutic cloning.*

Stem cell therapy may be useful in many serious illnesses. Research conducted on experimental animals, where stem cells have been used to treat different disorders, has yielded promising results. However, the results of animal experiments are not directly applicable to humans, and research on human stem cells is therefore necessary. The research is basic in nature, and results in the form of treatment cannot be expected for many years. Some of the results reported have also been conflicting. Research on stem cells is needed to establish their real potential. It is therefore important that stem cell research has the support and trust of society.

Nuclear transfer offers an opportunity to produce stem cells that the human body does not reject. Research aimed at therapeutic cloning will considerably increase the potential of stem cell therapy but is currently only in its infancy. The crucial question at the moment is whether Finland will approve research aimed at therapeutic cloning. The Medical Research Act (488/1999) does not define the cell mass produced by nuclear transfer unambiguously as an embryo, and clarification of the wording is therefore necessary. The Act defines an embryo as “a living group of cells resulting from fertilization not implanted in a woman’s body” (s. 2). Fertilization refers to the fusion of ovum and sperm.

Finland's national advisory boards on ethics have written this report in order to stimulate discussion on human stem cells, their potential uses, ethical issues and the lack of clarity in their regulation. The report is intended as a source of information for anyone interested and for those working in health care and research sectors, for the media and for national decision-makers to aid them in political and administrative decisions.

## What are stem cells?

Stem cells are undifferentiated cells from which other cells originate. Stem cells have the ability either to divide indefinitely or to differentiate into other cell types. Their ability to differentiate varies. Some stem cells differentiate only into cells of certain tissues, while others can differentiate into many cell types. Stem cells are grouped according to their ability to differentiate and their origin. The stem cell that is most able to differentiate is the fertilized ovum. It is the origin of all tissue types and the developing human body. Other stem cells – embryonic, fetal and adult stem cells – are much more limited in their ability to differentiate.

Embryonic stem cells are obtained from the embryos remaining after fertility treatment. The fertilized ovum is allowed to divide for 6–7 days, at which point it consists of about one hundred cells. An inner cell mass of 20–30 cells can be recognized. All these cells are undifferentiated stem cells and have unlimited scope for division under cell culture conditions. In principle they can differentiate into any cell or tissue type, but they cannot create an embryo and thus an individual.

There are quite a large number of stem cells in the developing fetus. Fetal stem cells can be isolated from fetuses obtained from terminated pregnancies, provided the woman concerned gives her written consent for their use in research. In Finland a lot of research is being done with fetal neuronal stem cells.

Stem cells are also present in the different organs of fully developed individuals, in which case they are regarded as adult type stem cells. These cells have a limited ability to differentiate. The best known source of adult stem cells is bone marrow, from which blood stem cells can readily be isolated. Certain growth factors prompt bone marrow stem cells to divide and to be released into the blood stream, where they can be collected. Many other tissues have stem cells, for example skin and neural tissue, but these are individual cells and not easy to isolate. Stem cell numbers vary between different tissues and also according to the age of the individual: the younger the person the greater the proportion of stem cells and the greater the tissue's capacity for regeneration. The blood of newborn babies contains large numbers of blood stem cells. After delivery they can be isolated from the placenta, which otherwise is waste. The Finnish Red Cross blood service maintains a bank of blood stem cells obtained from placentas.

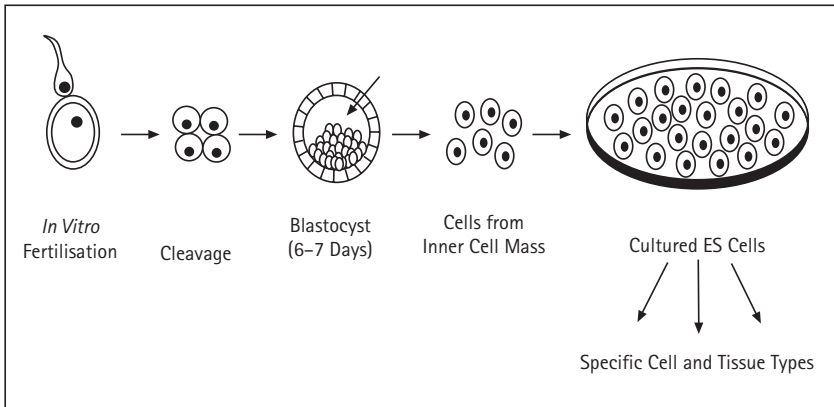


Figure 1. The production of stem cells from embryos remaining after fertility treatment (According to National Bioethics Advisory Commission: *Ethical Issues in Human Stem Cell Research, Volume I, 1999, p. 11*).

## The use of stem cells in medicine

Stem cells can divide an unlimited number of times as long as they are undifferentiated. Differentiation can be regulated under cell culture conditions. As soon as stem cells differentiate, they start to act as differentiated cells: nerve cell starts to mediate nervous impulses, the heart muscle cells contract, and cells of the endocrine system start to produce hormones. Functioning tissue cells undergo virtually no division. Several factors in the human body are known to influence the differentiation and growth of stem cells. Stem cells have a strong tendency to differentiate into certain cell types, and preventing them from differentiating requires special conditions and expertise. Controlled growth and differentiation result from several factors, not all of which are known.

Stem cells may help to treat disorders arising from tissue destruction. Juvenile diabetes is a disorder in which insulin-producing cells in the pancreas have been destroyed. If these cells could be produced from stem cells and transferred to the patient, the disorder could be cured. Stem cells have been used to study Parkinson's disease and its treatment.

Blood stem cells derived from placenta and blood marrow are used routinely to replace bone marrow cells that have been destroyed in cancer treatment. Blood stem cell transplantation is preceded by cytostatic treatment, which destroys not just the cancer cells but also the patient's bone marrow cells. The transplanted blood stem cells find their way into the bone marrow and start to act as bone marrow cells, producing red blood cells, various kinds of white blood cells and platelets.

The usefulness of stem cell therapy is restricted by the body's rejection of cells and tissues. Structures present on cell surfaces cause the cells to be rejected when transplanted into another body. The use of stem cells in cell and tissue transplantations thus requires donor and recipient tissues to be compatible. If stem cells obtained from another individual are used in the treatment of a disorder, thousands of cell lines would be needed from which to select suitable ones for the recipient.

The therapeutic use of stem cells is also restricted by the fact that their differentiation is somewhat unpredictable. Stem cells have the ability to divide indefinitely, a characteristic they share with cancer cells. The fear of uncontrolled growth and cancer limits the use of stem cells. On the other hand, if stem cells could be made to differentiate into certain cell types, such as insulin-producing islets of Langerhans cells or nerve cells, they would not be expected to revert to dividing cells.

## Nuclear transfer and cloning

Somatic cell nuclear transfer (SCNT) is a procedure in which the nucleus of an unfertilized egg is replaced by a somatic cell nucleus, either a nucleus from the ovum donor, or a nucleus from a cell of another person. The somatic cell nucleus contains 46 chromosomes, i.e. the complete genotype. The egg contains only 23 chromosomes, half of the genotype. When the ovum gets a nucleus that has the complete genotype it starts to divide like a fertilized egg and to differentiate like an embryo. According to Finnish legislation this is not an embryo, as the Medical Research Act defines an embryo as "a living group of cells resulting from fertilization not implanted in a woman's body", and makes no mention of cell mass produced by nuclear transfer<sup>1</sup>.

SCNT has been used in cloning animals. It was first used to clone Dolly the sheep, which is why it is often called the Dolly technique. Several animal species have been cloned in this way.

This type of technique is called reproductive cloning, i.e. cloning for reproductive purposes, when the aim is to produce a new individual. Reproductive cloning is forbidden by law in Finland<sup>2</sup>.

## Therapeutic cloning and stem cells

In therapeutic cloning, the ovum to which the somatic cell nucleus has been transferred starts to divide like a fertilized egg. In the early blastocyst stage, the stem cells are isolated in the same way as embryonic stem cells. The exception is the origin of these cells: the genotype of these stem cells is identical to the genotype of the nucleus of the donor.

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<sup>1</sup> Medical Research Act s. 2.

<sup>2</sup> Medical Research Act 26 s.

The aim of therapeutic cloning is to produce cell lines that are compatible with the recipient of the tissue or cells. This would avoid rejection and failure of tissue and organ transplantations. Neither would it then be necessary to establish large stem cell lines of many histocompatibility types, which otherwise would be needed to ensure suitable stem cell transplants for different patients.

Stem cells have been produced by SCNT only using animal cell lines. There have been no reports of the production of stable human stem cell lines using SCNT.

The legal status of therapeutic cloning is not clear. While the Medical Research Act forbids the formation of an embryo solely for research purposes, the cell mass produced by nuclear transfer is not an embryo as defined in the same Act.

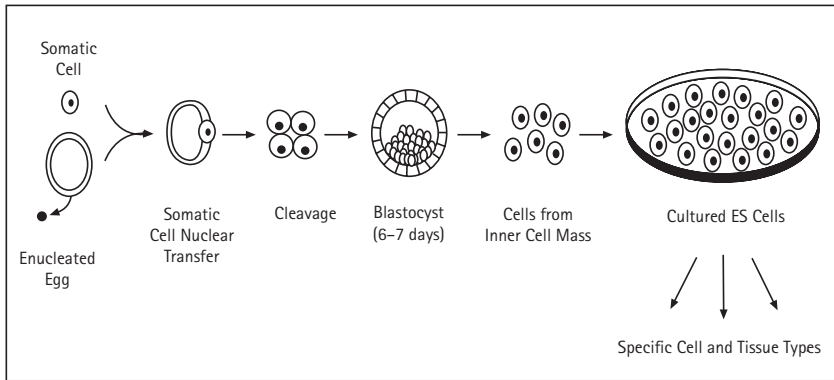


Figure 2. Therapeutic cloning (According to National Bioethics Advisory Commission: *Ethical Issues in Human Stem Cell Research, Volume I, 1999, p. 12*).

# Ethical issues concerning the use of stem cells

There are some problematic issues relating to research on stem cells that mainly concern the origins and methods of stem cell production.

Small numbers of adult stem cells can be found in the human body, but sufficient quantities of adult stem cells for therapeutic purposes can only be isolated from bone marrow. Research in this area is at an early stage, and it is not clear whether reasonable numbers of stem cells can be derived from other sources for treatment and research purposes, or whether these cells are sufficiently capable of differentiating. In some animals, stem cells from somatic tissues have been reported to function in the same way as embryonic stem cells, but it has not been possible to repeat these results.

The best sources of stem cells are fetuses and embryos. Fetal stem cell lines can be cultured from cells isolated from aborted fetuses. Stem cells from embryos can be isolated from 5–7 day-old blastocysts. The collection of stem cells of both fetal and embryonic origins involves destruction of the “donor” – the fetus or embryo – and this is ethically problematic.

## Ethical issues connected with the use of fetal stem cells

10,000–11,000 terminations of pregnancy are performed in Finland every year. Most are performed for social reasons before the 12<sup>th</sup> gestational week. The fetuses donated from these terminations are studied very rarely. The woman undergoing pregnancy termination will be asked for her consent for the research. The research project must be approved by an ethics committee prior to the start of the research, and it has to have permission from the head of the research unit.

Fetal stem cells are studied at only a few research centers in Finland. When a woman coming for termination of pregnancy is asked for her consent, she will be told why and how the research is to be carried out. Obtaining consent has not been a problem.

Fetal stem cells have been used in connection with other treatments to cure degenerative neurological disorders, such as Parkinson’s disease, especially in Sweden and the United States. The problem has been the low recovery of stem cells, making the treatment rarely available and expensive.



# Ethical issues connected with embryonic stem cells

Embryonic stem cells are able to differentiate into different cell types. Thus they are subject to the greatest expectations. In theory embryonic stem cells can differentiate into any cell type and in this way can replace destroyed tissues.

Embryonic stem cells are obtained from fertilized ova, which are produced in infertility treatments. Hormone treatment in cases of assisted reproduction may sometimes produce only a few single ova, although sometimes tens of ova mature during the same treatment. *In vitro* fertilization is not always successful, and only some of the developing embryos are viable. For this reason several embryos are almost always produced during a course of one treatment, those that are not implanted into the woman's body being deep frozen for future use. Only one fourth of *In vitro* fertilizations are successful. It is therefore also in the interests of the couple concerned that as many hormonally matured ova as possible are collected and fertilized during the same treatment period. This saves money, relieves the burden on the couple involved in the infertility treatment, and spares the woman the procedures she has to undergo, together with the associated risks.

IVF treatment often yields unwanted frozen embryos. Embryos no longer needed by the couple for reproduction can be destroyed, donated to other infertile couples or used in research. Their use for other infertile couples is rare, as many couples that use infertility treatment services wish to use one or both of their own gametes.

Embryonic stem cells are isolated from embryos destroyed during the isolation procedure. In many European countries embryonic stem cells are considered equal to other cultured cell lines. The prerequisite for the use of embryos is the consent of the gamete donors. In other European countries an embryo is regarded as having basic human rights that should be protected. In these countries the life of a person is considered to start at fertilization of the ovum, and interference with the life of an embryo violates the rights of the embryo and developing fetus and thus is against the dignity of life. For this reason research on embryos is often forbidden in these countries. Opponents of research on embryonic stem cells also argue that the interests of another person are put above those of the embryo.

## Ethical issues connected with therapeutic cloning

Therapeutic cloning requires unfertilized ova that can be made to divide and develop like a fertilized ovum through somatic cell nuclear transfer. In this situation the ova are used for the benefit of the somatic cell donor and his/her treatment. Many people who oppose therapeutic cloning say that this procedure exploits both the embryo and the women who donated the ovum. Therapeutic cloning is also opposed because it produces cell masses that can be considered as embryos ultimately for research purposes. In many international conventions and recommendations the formation of an embryo solely for research purposes is forbidden.

Therapeutic cloning is possibly the only means to produce immunologically identical tissues for treatment purposes. Rejection is the main cause of failure in organ and tissue transplantations. In this therapy, rejection must be prevented by long-term, often lifelong, preventive medicine.

SCNT techniques are also opposed because the procedure can be used to clone humans, i.e. to produce an identical individual to the somatic cell nucleus donor, which is forbidden under many international agreements.

## Stem cells and Finnish legislation

The Medical Research Act (Research Act) regulates medical research on humans, human embryos and fetuses.<sup>3</sup> At present, there is no legislation on assisted reproduction, but such legislation is currently under preparation. Other medical use of human organs and tissues – such as the use of stem cells for therapeutic purposes – is controlled by the Act on the Medical Use of Human Organs and Tissues (Tissue Act).<sup>4</sup> Collection of human blood and blood products for medical purposes is regulated by the Act on Blood Services<sup>5</sup> and by the Medicines Act<sup>6</sup>.

Because the therapeutic use of stem cells is to a large extent only at the research stage, the key provisions in this field are found in the Medical Research Act. The Act also applies when research is conducted on stored samples taken from humans, gametes and embryos.<sup>7</sup> When stored samples are used, the provisions of the Tissue Act on the change of the original purpose are applied in addition to the Research Act.

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<sup>3</sup> Medical Research Act (9.4.1999/488).

<sup>4</sup> Act on the Medical Use of Human Organs and Tissues (2.2.2001/101).

<sup>5</sup> Act on Blood Services (4.11.1994/968).

<sup>6</sup> Medicines Act (10.4.1987/395).

<sup>7</sup> The Governmental proposition to the Parliament for the Act on Medical Research and Amendment of the Act on the Status and Rights of Patients sections 6 and 9 (HE 229/1998 vp.).

One example of a change of original purpose is when tissue has been originally taken for therapeutic or diagnostic purposes, such as gametes or embryos, and is then used for medical research or the treatment of another person.

## Legislation and research on embryos and fetuses

Medical research on embryos requires that the institution where the research is conducted has obtained permission from the National Authority for Medicolegal Affairs. Permission is given to the institution, not for the research project. In addition, every study on embryos requires the approval of the relevant ethics committee and written consent from both donors of the gametes from which the embryo has been created. The donors can withdraw their consent at any stage. Where research is conducted on an embryo inside a woman's body, the consent must be given by the woman concerned and the relevant ethics committee must give its approval.

The creation of embryos solely for research purposes is forbidden under Finnish law. An embryo that has been used for research cannot be transferred into a human body, and embryos may not be kept alive for more than 14 days from their creation. This time limit excludes the time that the embryo has been kept frozen. Research on embryos and gametes for the purpose of developing methods for modifying hereditary properties is prohibited unless the research is designed to cure or prevent a serious hereditary disease.<sup>8</sup>

## Legislation and stem cell research

Research on stem cells derived from living embryos is regulated by the general provisions on embryo research. Once the stem cells have been removed from the embryo, the embryo perishes, and the 14-day time limit no longer applies. There is no time limit for the life time of the cell lines derived from stem cells.

Research that uses only stem cell lines derived from embryos (as against the embryos themselves) is research on human tissue, and subject to both the Tissue Act and the Research Act. Research on ready-made stem cell lines does not require a separate institutional permit. Neither do other restrictions that specifically concern research on embryos apply to research on stem cell lines. In order to conduct the study, however, the approval of an ethics committee is required, and the consent of the sample donor will be needed if the sample is subsequently to be used for another

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<sup>8</sup> Medical Research Act, s. 11–15.

purpose. If the identity of the donors cannot be ascertained, research on stem cell cultures does not require the donors' consent. In such cases, permission to change the original purpose of the sample (stem cells) is given by the health care unit for whose purposes the sample was originally taken.<sup>9</sup>

If tissue is collected in the connection with termination of pregnancy, permission from the woman or her representative and the National Authority for Medicolegal Affairs is required.<sup>10</sup>

## Therapeutic cloning and Finnish law

The use of somatic cell nuclear transfer (SCNT) to create groups of cells that behave similarly to a human embryo involves not only ethical but also legal issues. Section 2 of the Research Act defines an embryo as "a living group of cells resulting from fertilization not implanted in a woman's body". The core question is then whether a living group of cells created by SCNT must legally be regarded as an embryo, despite the fact that it did not arise through fertilization. The use of SCNT in therapeutic cloning – in which the tissue type of the stem cell culture is identical to that of the recipient – is dependent on the answer to this question. After all, the Research Act – like the Council of Europe Convention on Human Rights and Biomedicine – forbids the creation of embryos solely for research purposes.<sup>11</sup> Up to now, only excess embryos from IVF treatment have been used for research in Finland.

## Cloning and the law

If the group of cells created by SCNT is used only to produce stem cells that are of a certain type, the cell mass is allowed to grow until days 6–7 and then destroyed when the stem cells are isolated. If the same cell mass was to be transferred into a uterus and allowed to grow and develop into an individual, this would be reproductive cloning, the aim of which is to create an individual genetically identical to the donor of the somatic cell nucleus.

However, according to present legislation, an embryo used for research may not be implanted in a human body. Additionally, research aimed at cloning human beings is forbidden as an unlawful intervention in the genome, for which a person

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<sup>9</sup> Act on the Medical Use of Human Organs and Tissues, s. 20.

<sup>10</sup> Act on the Medical Use of Human Organs and Tissues, s. 7.

<sup>11</sup> Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine. European Treaty Series 164.

can be fined or imprisoned for a period not exceeding two years. Any intervention seeking to create a human being genetically identical to another human being is also prohibited by the Additional Protocol to the Convention for the Protection of Human Rights and Biomedicine, on the Prohibition of Cloning Human Beings.<sup>12</sup> There are no specific provisions prohibiting therapeutic cloning in Finland.

## Finnish legislation and the Convention on Human Rights and Biomedicine

Finland has signed, but not ratified, the Council of Europe Convention on Human Rights and Biomedicine (Biomedicine Convention) and its Additional Protocol on the Prohibition of Cloning Human Beings. Finland's Medical Research Act is based on the provisions of the Biomedicine Convention. Other legislation has been amended in order to ensure compatibility with the Biomedicine Convention. Finland's ratification of the Biomedicine Convention is expected to take place as soon as legislation on assisted reproduction has been introduced. Before ratification, Finland must consider its final approach to therapeutic cloning. If we accept therapeutic cloning, we must either make a reservation to Article 18 of the Biomedicine Convention or make known the definition of the embryo as defined under Finnish law.

### Outlawed embryos?

If regulation of embryo research is not applied to a living group of cells created by SCNT, because it is not considered as an embryo under the Research Act, which provisions apply? Will the "embryo" created by SCNT be entirely excluded from the protective measures that have been designed for embryos?

Although a group of cells created by SCNT is not legally an embryo, it is nevertheless human tissue to which the provisions of the Research Act and the Tissue Act apply. The Research Act sets conditions for medical research projects, such as the approval of an ethics committee and qualifications in medicine or dentistry from the person in charge of the study. According to both the Research and the Tissue Acts, the donor of the ovum used for SCNT transfer must give her informed consent and must be given information about the nature and purpose of the study. Consent is also needed from the donor of the nucleus of the somatic cell (derived for example from a skin cell). The

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<sup>12</sup> Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regards to the Application of Biology and Medicine, on the Protection of Cloning Human Beings. European Treaty Series 168.

consent must be written and based on sufficient information. If the cells or samples used have been previously stored (for example for medical or diagnostic purposes), and the donor's identity is not connected to the sample in the research project, the study can be conducted without the consent of the donors. In this situation, permission to use the sample will be given by the health care or other unit for whose purposes the sample was originally taken. If the sample is identifiable, a change in the original purpose of the sample generally requires the donor's consent.<sup>13</sup>

## Examples from other countries<sup>14</sup>

### Sweden

In Sweden the Act on the Use of Fertilized Ova (1991:115) also applies to research on stem cells. Research on embryos is allowed for 14 days after fertilization (excluding deep freeze storage for 5 years, which is permitted). After this the embryos must be destroyed. The Act is also considered to apply to the production of embryonic stem cells from fertilized ova. The Act does not regulate the use of embryos for research purposes or the production of embryos through processes other than fertilization. The Swedish Parliament decided at its meeting on 2 February 2005, to amend the Act to allow the use of therapeutic cloning or somatic cell nuclear transfer in research (Act concerning measures for purposes of research or treatment involving human ova 14.3.1991/115, Governmental bill 2003/04:148). The Amendment has come into force on April 1<sup>st</sup>, 2005. Research aiming at reproductive cloning would be forbidden.

In June 2003 Sweden introduced a new Act on Medical Research (2003:460) that regulates both medical research and research on biological material of human origin.

### Norway

Norway's legislation allows research on adult-type stem cells and, in some cases, also on fetal stem cells. Research on fertilized egg cells and embryos and their production for research, research on embryonic stem cells, reproductive cloning and somatic cell nuclear transfer are all forbidden under the Act on the Medical Use of Biotechnology (5.8.1994:56).

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<sup>13</sup> Act on the Medical Use of Human Organs and Tissues, sections 7 and 20.

<sup>14</sup> European Commission, Directorate General: Research. Survey on opinions from National Ethics Committees or similar bodies, public debate and national legislation in relation to human embryonic stem cell research and use, Vol. 1 (EU Member States), Vol. 2 (Accession, associated and third countries). Edited by Line Matthiessen-Guyader, September 2003.

## Denmark

The Act on Medically Assisted Reproduction (10.6.1997:460) regulates research on fertilized eggs and stem cells. Research is allowed provided it seeks to improve *in vitro* fertilization and preimplantation diagnostics. Research on fertilized eggs and embryonic stem cells is also permitted provided it produces information that can be applied to the treatment of diseases. Reproductive cloning is forbidden.

## United Kingdom

The Act on Human Fertilization and Embryology regulates research on embryos. The Act allows research on embryos and stem cells from embryos left over from infertility treatment. In 2001 this Act was amended to allow therapeutic cloning, i.e. the formation of an embryo solely for research purposes. This provoked much public discussion, but the UK's Human Fertilisation and Embryology Authority has since granted several licenses for research aimed at therapeutic cloning.

The Act does not cover isolated stem cell lines. The monitoring committee of the national stem cell bank has been asked to formulate rules for the use of stem cell lines. As the national authority, the Human Fertilisation and Embryology Authority grants licenses and regulates all research aimed at the production and use of human embryos.

## Germany

The Act on the protection of an embryo forbids the use of human embryos in research but does not prevent the import of stem cell lines into Germany. The Act on the import and use of stem cells regulates importation and research. The Act forbids the import and use of embryonic stem cells. However, importation and research are permitted in the case of cell lines verifiably created before 1 January 2002, according to the rules of the country of origin, from superfluous embryos without monetary compensation, provided the embryos were intact and that there is no conflict with present legislation (for example Embryonenschutzgesetz).

All research and importation of stem cells requires the permission of the national authority. Permission is granted on condition that the research is likely to result in substantial benefits and that it cannot be performed in another way.

## France

Research on embryos and stem cells is forbidden by the Act on Bioethics (29.4.2005). The Act is currently being amended. Under the amendment, superfluous embryos and fetal stem cells can be studied under strict regulations for a period not exceeding five provided the donors of the gametes have given their informed consent. Both therapeutic and reproductive cloning are forbidden.

## Belgium

In autumn 2003, Belgium introduced new legislation governing research on *in vitro* fertilized embryos that allows the production of embryos solely for research purposes. The embryos can be produced by somatic cell nuclear transfer. Supernumerary embryos can be used to produce embryonic cell lines.

The research is very strictly regulated and requires a national opinion before it can be started. Any study on embryos must be aimed at the development of treatment methods, it must be performed at an institute licensed for such research under the leadership of an expert, it must not take more than 14 days, and must constitute the most effective way to conduct the research. The consent of the donors of the gametes is also required.

## USA

There is no legislation on stem cell research or cloning in the USA. Government rules state that the US funds research only on embryonic cell lines that have existed since August 2001. There is a lot of discussion in the US Senate about the ban on both therapeutic and reproductive cloning.

## In conclusion

Research provides increasing scope for the application of new knowledge. International agreements and national legislation should anticipate developments and respond quickly to the challenges of the time.

Finland, like many other countries, has opposed reproductive cloning, but our legislation on therapeutic cloning is unclear. Sooner or later Finland will have to state its views and formulate rules concerning embryonic stem cell research. It would be good if these views could be clearly stated before ratification of the Convention on Biomedicine of the Council of Europe. The issue should first be opened for public debate so that the decisions that are eventually taken are based on adequate information and properly balanced consideration.



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### **Advisory Board on Biotechnology (BTK)**

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• National Advisory Board on Research Ethics (TENK) • National Advisory Board on Health Care Ethics (ETENE) • Sub-committee on Medical Research Ethics (TUKIJA)  
• Cooperation Group for Laboratory Animal Sciences (KYTÖ) • National Advisory Board on Biotechnology (BTNK) • Board for Gene Technology (GTLK)