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

Volume I
in EU Member States

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Directorate E
Biotechnology, Agriculture and Food

EUROPEAN COMMISSION
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Directorate E – Biotechnology, Agriculture and Food
The Director

INTRODUCTION

An intense debate is taking place in many countries concerning the future of stem cell research and therapy, adding to the European perspective of the opinion issued by the European Group on Ethics on 14 November 2000 and DG Research working paper on Human Stem Cell Research published on 3 April 2003 (website: http://europa.eu.int/comm/research/conferences/2003/bioethics/pdf/sec2003-441report_en.pdf)

In particular human embryonic stem cell research raises complex ethical questions. The national ethics committees or similar bodies in the different countries have provided an opinion on this issue. Discussions on the need or in some cases preparation and implementation of new legal and / or regulatory frameworks for human embryonic stem cell research have been initiated across Europe and worldwide.

In order to contribute to a structured debate, the European Commission, DG Research, initiated in spring 2001 a survey concerning the opinions from national ethics committees and current national legislation in relation to human embryonic stem cell research.

In the context of the Commission's Communication on 23 January 2002 on Life Science and Biotechnology – a strategy for Europe (http://europa.eu.int/eur-lex/en/com/cnc/2002/com2002_0027en01.pdf)), the Council of Ministers invited among others the Commission to monitor the societal dialogue, the ethical concerns and the legal framework for biotechnology. In response to this invitation, we have updated the survey on a regular basis and this effort will be continued.

National Ethics Committees and/or Ministries of Health in the EU Member States, candidate countries, Iceland, Israel, Norway, Switzerland as well as members of the Council of Europe, Canada and United States, etc have been contacted.

I would like to thank sincerely the contact persons in each country for providing this information.

The survey has been largely distributed and following several requests, we have now prepared the survey in an electronic format. Volume I includes information regarding EU Member States and Volume II covers non-EU Member States. A paper version including the different opinions etc is still available from Dr. Line Matthiessen-Guyader (e-mail: line-gertrud.matthiessen-guyader@cec.eu.int; fax: +32.2.299.18.60) who has been responsible for collecting and updating the information.

We would like to invite you to provide any new information you may have to Dr. Line Matthiessen-Guyader.

Christian Patermann
Director

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EU MEMBER STATES

UPDATE JULY 2004

Regulation of human embryonic stem cell research in EU Member States

Opinions on the legitimacy of experiments using human embryos are divided according to the different ethical, philosophical, and religious traditions in which they are rooted. EU Member States have taken very different positions regarding the regulation of human embryonic stem cell research.

Taking into account the situation, as of July 2004, the following distinctions can be made:

- **Allowing for the procurement of human embryonic stem cells from supernumerary embryos by law under certain conditions:** Belgium, Denmark, Finland, France, Greece, the Netherlands, Spain, Sweden and the United Kingdom.

- **Countries which have enacted legislation on human embryo research allowing some research activities on supernumerary embryos, but without specific reference to human embryonic stem cell research**: Estonia, Hungary, Latvia and Slovenia.

- **Prohibiting the procurement of human ES cells from supernumerary embryos but allowing by law for the import and use of human embryonic stem cell lines under certain conditions**: Germany. The import and use of human ES cell lines is not explicitly prohibited in e.g. Austria and Italy.

- **Prohibiting the procurement of human ES cells from supernumerary embryos**: Austria, Ireland Lithuania, Poland and Slovak Republic.

- **No specific legislation regarding human embryo research or human ES cell research**: Czeck Republic, Luxembourg, Malta, Portugal and the republic of Cyprus.

- **Allowing by law for the creation of human embryos for research purposes**: UK and Belgium are for the moment the only Member States, which allow by law for the creation of human embryos either by fertilisation of an egg by a sperm, or by somatic cell nuclear transfer (SCNT, also called therapeutic cloning) for stem cell procurement. The Dutch Embryo Act of 2002 includes a five-year moratorium for the creation of embryos for research purposes including by SCNT.

- **Prohibiting the creation of human embryos for research purposes and for the procurement of stem cells by law or by ratification of the Convention of the Council of Europe on Human rights and Biomedicine signed in Oviedo on 4 April 1997**: Austria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Ireland, Netherlands, Lithuania, Portugal, Slovak Republic, Slovenia and Spain.

Current discussions in EU Member States

Austria
In the course of the planned amendment of the Austrian Act for Reproductive Medicine (Fortpflanzungsmedizingesetz, FMedG) the regulation of human embryonic stem cells research is currently under discussion. Due to the difficult ethical, social and scientific questions in context with this matter the amendment of this Act is not finished yet and the discussion will continue.

Finland
Permission to allow the transfer somatic cell nuclei into egg cells is under discussion.

Portugal
A committee has been established in Portugal for the preparation of a law on human embryo and human ES cell research.

Sweden
A revision of the current legislation is under discussion. The Swedish government adopted in June 2004 a new bill which has been sent to the parliament for discussion in autumn.

In short, the bill proposes:
- No general prohibition of producing fertilised eggs for research purposes
- That donation of human ova for research purposes should be allowed
- That transfer of somatic cell nuclei should not be prohibited, but subject to limitations corresponding to those that apply to research on fertilized eggs
- That reproductive cloning should be unequivocally forbidden

Line MATTHIESSEN-GUYADER

TABLE 1

Regulations in EU Member States regarding hES[1] cell research

	AT	BE	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HU	IE	IT	LT	LU	LV	MT	NL	PL	PT	SE	SI	SK	UK
Allowing procurement of hES cells from supernumary embryos by law		X				X		X	X	X	X								X			X			X
Specific legislation for human embryo research incl. supernumerary embryos but without specific reference to hES cells							X					X					X						X		
Prohibiting procurement of hES cells from human embryos but allowing importation of hES cell lines					X									X											
Prohibiting procurement of hES cells from human embryo	X												X		X					X				X	
No specific legislation regarding human embryo research			X	X												X		X			X				
Allowing creation of human embryos for procurement of hES cells by law		X																							X
Prohibiting creation of human embryo for research purpose and for procurement of hES cells by law or by ratification of the Convention of the Council of Europe on Human rights and Biomedicine signed in Oviedo on 4 April 1997	X		X	X	X	X	X	X	X	X	X	X	X	X	X				X		X		X	X	

1) hES cells = human embryonic stem cells

COUNTRY CODE KEY:

AT : Austria	DK : Denmark	FR : France	LU : Luxembourg	PT : Portugal
BE : Belgium	EE : Estonia	HU : Hungary	LV : Latvia	SE : Sweden
CY : Cyprus	EL : Greece	IE : Ireland	MT : Malta	SI : Slovenia
CZ : Czech Republic	ES : Spain	IT : Italy	NL : Netherlands	SK : Slovakia
DE : Germany	FI : Finland	LT : Lithuania	PL : Poland	UK : United Kingdom

Survey on Human Embryonic Stem Cell Research and Use

AUSTRIA

1. Has your National Ethics Committee or similar body provided an opinion on human embryonic stem cells research and use?

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

A commission on bioethics ("Die Bioethikkommission") was established at the Federal Chancellery in June 2001. It has provided an opinion on "Human embryonic stem cell research in the context of FP6" on 3 April and 8 May 2002. (www.bka.gv.at/bioethik/). This document does not provide an unanimous opinion, in fact there are two groups of members with different points of view. This situation shows the difficulty of the matter as such.

Contact person:
Dr. Robert Gmeiner
Geschäftsstelle der Bioethikkommission, Bundeskanzleramt
Hohenstaufengasse 3
A – 1010 Wien
Tel.: +43.1.53115-4319; Fax: +43.1.53115-4307
Email: robert.gmeiner@bka.gv.at

2. Will (or has) a public debate take(n) place on human embryonic stem cells?

☒ yes

If yes, how was / will it be organised, what were the conclusions; who is the contact person?

The public debate on this topic has already begun. A good insight into the situation gives a publication by Univ. Prof. Dr. Ulrich Körtner "Forschung an embryonalen Stammzellen – zur Diskussion und Gesetzeslage in Österreich" (www.bka.gv.at/bioethik, „Beiträge")

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3. Could you please describe the current legal and/or regulatory framework for human embryonic stem cells research and use in your country and indicate a contact person?

The Austrian Reproductive Medicine Act (Fortpflanzungsmedizingesetz, FMedG) states, that cells capable of development may only be used for medical assisted reproduction; stem cells as such are not included.

Contact person: Dr. Meinhild Hausreither, Federal Ministry of Health and Women, Department I/B/5, Radetzkystr.2, A-1031 Vienna, Phone: +43 1 71100 4387.
Concerning processing: Austrian Pharmaceuticals Act (AMG) and the regulations on blood safety.
Contact person: Dr. Hans Kurz, Federal Ministry of Health and Women, Department III/A/4, Radetzkystr.2, A-1031 Vienna, Phone: +43 1 71100 4643
There is no current legal and / or regulatory framework for human embryonic stem cells research in Austria.

4. Could you please indicate if any new legal and/or regulatory framework for human embryonic stem cells research and use is under preparation

The main competent authority for the regulation of this matter is the Federal Ministry for Justice.
In the course of the planned amendment of the Austrian Act for Reproductive Medicine (Fortpflanzungsmedizingesetz, FMedG) the regulation of human embryonic stem cells research is currently under discussion. Due to the difficult ethical, social und scientific questions in context with this matter the amendment of this Act is not finished yet and the discussion will continue.

Survey on Human Embryonic Stem Cell Research and Use

BELGIUM

1. Has your National Ethics Committee or similar body provided an opinion on human embryonic stem cells research and use?

X yes

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

The Comité Consultatif de Bioéthique de Belgique. An opinion regarding human embryo research was given on 16.09.2002 (http://www.health.fgov.be/bioeth/)

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2. Will (or has) a public debate take(n) place on human embryonic stem cells?

☐ yes X no

If yes, how was / will it be organised, what were the conclusions; who is the contact person?

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3. Could you please describe the current legal and/or regulatory framework for human embryonic stem cells research and use in your country and indicate a contact person?

No specific legislation related to research on human embryos.

4. Could you please indicate if any new legal and/or regulatory framework for human embryonic stem cells research and use is under preparation

A bill on research on human embryos *in vitro* was approved by the Belgian Senate in 2002 and was adopted by the Parliament on 3 April 2003. The legislation authorises the procurement of embryonic stem cells from supernumerary embryos under certain conditions and the creation of a "Federal Commission for scientific medical research on embryos *in vitro*".
The bill also allows for the creation of human embryos for research purposes including by means of somatic cell nuclear transfer.

Article 3 allows research on human embryos *in vitro* under the following conditions:

- research for therapeutic purposes
- based on recent scientific knowledge
- carried by a registered laboratory
- carried under control of a specialist
- embryos up to 14 days of development
- no alternative method of research as effective

The consent of the donors must be given (article 8)
In addition the research is controlled at the local and federal levels.

See http://www.senat.be and http://www.lachambre.be

Survey on Human Embryonic Stem Cells research and use

THE REPUBLIC OF CYPRUS

1. Has your National Ethics Committee or similar body provided an opinion on human embryonic stem cells research and use?

no

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available: The Cyprus National Bioethics Committee has not provided an opinion on human embryonic stem cells research and use. It is a newly established (3 months only) committee.

2. **Will (~~or has~~) a public debate take (~~n~~) place on human embryonic stem cells?**

yes

If yes, how ~~was~~ / will it be organised, what were the conclusions, who is the contact person?

It is among the public debates that the Cyprus National Bioethics Committee will include in its future activities.

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3. Could you please describe the current legal and / or regulatory framework for human embryonic stem cells research and use in your country and indicate a contact person?

The research on embryo in vitro is prohibited by the provisions of the ratified European Convention on human rights and biomedicine L. 31(III)/2001 article 38. There is no legislation up to now, in Cyprus, permitting the research on the embryo under any conditions which will adequately be safeguarded the embryo from such research. The L. 31(III)/2001 gives this possibility to the legislator as an exeption, from the general rule prohibiting the research, if the conditions previously stated are being fulfilled..

4. **Could you please indicate if any new legal and / or regulatory framework for human embryonic stem cells research and use is under preparation?**

Survey on Human Embryonic Stem Cells research and use

CZECH REPUBLIC

1. Has your National Ethics Committee or similar body provided an opinion on human embryonic stem cells research and use?

X☐ no

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

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2. Will (or has) a public debate take(n) place on human embryonic stem cells?

X☐ yes

If yes, how was / will it be organised, what were the conclusions; who is the contact person?

There is a debate on embryonic stem cells going on at the public level (mostly in media), the debate in ethical and scientific bodies has just started (Masaryk University in Brno, The Czech Christian Academy in Prague, Goethe Institute in Prague). A public hearing in the Senate of the Parliament will take place soon. The research on stem cells is in the Czech Republic very advanced; there is a Center for Cellular Therapy with well-equipped laboratories. Most of the trials are performed on animals - mouse, rats, pigs. The Ethics Committee of the Ministry of Health has not yet approved these trials, because they are not performed on humans.

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3. Could you please describe the current legal and/or regulatory framework for human embryonic stem cells research and use in your country and indicate a contact person?

There is no regulatory framework. The proposal of the new Act on Health Care contains one chapter dealing with genetic tests and assisted reproduction. The proposed provisions could be subject of amendments during the whole preparatory period and legislative procedure as well. Essential normative standards are laid down in the European Convention on Human Rights ad Biomedicine that precedes statutory legislation in the Czech legal ordre.

4. Could you please indicate if any new legal and/or regulatory framework for human embryonic stem cells research and use is under preparation

The debate is going on. It was a theme for the conference of the Bioethics Commission of the Czech Government in March 2004.

Survey on Human Embryonic Stem Cell Research and Use

DENMARK

1. Has your National Ethics Committee or similar body provided an opinion on human embryonic stem cells research and use?

yes

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

Please see English translation of the Danish Council of Ethics' statement on cloning on the Council's homepage: http://www.etiskraad.dk/sw329.asp or send email: info@etiskraad.dk

The statement on cloning is included in the English version of the Danish Council of Ethics' annual report for 2001. This can be requested free of charge, while stock last, by using the ordering page on the Councils' homepage at www.etiskraad.dk.

2. Will (or has) a public debate take(n) place on human embryonic stem cells?

Yes

If yes, how was / will it be organised, what were the conclusions; who is the contact person?

In January 2003 The Danish Council of Ethics, The Board of Technology and The Central Scientific Ethical Committee arranged a hearing on the use of embryonic stem cell research. The hearing targeted the Danish politicians and intended to contribute to a political decision on the extent to which it should be permitted to use embryonic stem cells in research.
On May 27 2003 the Parliament implemented a change in the act on Medically Assisted Reproduction, there after allowing for research in embryonic stem cells with the aim of obtaining new knowledge, that will improve the possibilities of curing diseases in humans (Official Danish title: Lov om ændring af lov om kunstig befrugtning i forbindelse med lægelig behandling, diagnostik og forskning m.v. (Forskning på embryonale stamceller). Lov nr. 427 af 10/06/2003). Up until then, it was allowed to use embryonic stem cells in research only if the aim was to improve techniques for in vitro fertilisation in order to induce pregnancy or if the aim was to improve techniques of preimplantation diagnosis (see below).

Contact person at The Dansih Council of Ethics: Head of Secretariat Berit Andersen Faber (berit.faber@etiskraad.dk) or Head of Section Anne Lykkeskov (anne.lykkeskov@etiskraad.dk)

3. Could you please describe the current legal and/or regulatory framework for human embryonic stem cells research and use in your country and indicate a contact person?

The question of Research on human stem cells/human embryos is regulated by § 25-28 in the act on Medically Assisted Reproduction:

Biomedical research on fertilized ova and stem cells intended for reproduction can only be undertaken in the following cases:

- If the aim is to improve techniques for in vitro-fertilisation in order to induce pregnancy,
- If the aim is to improve techniques of preimplatation diagnosis.

The Danish Parliament amended in spring 2003 par. 25 of the act as follows: « Research on fertilized ova and stem cells intended for reproduction is furthermore allowed, if the research has the aim to get knowledge, which can improve treatment concerning human diseases. ». The amendment entered into force September 1, 2003.

According to §28 it is forbidden to undertake research with the following aims:

* Research where the aim is to develop human reproductive cloning;
* Research where the aim is to facilitate the creation of a human identity by melting together genetically unidentical embryos or parts of embryos before the implantation in the womb,
* Research where the aim is to create human individuals that are hybrids with a gene-pool that is a mixture of different species,
* Research with the aim of developping a human individual inside a non-human womb.

In addition to the Act on Medically Assisted Reproduction, the Act on a Scientifical Ethical Committee-system lays down provisions on how to carry out research projects in general - no research project involving humans or stem-cells and fertilized ova can be initiated without permission from a scientific ethical committee. (Act no. 503 of 1992 on Scientifical Ethical Committes and the handling of biomedical research projects.)

Reproductive cloning of humans is prevented by law in Denmark. The Danish Law on Medically Assisted Reproduction (Act no. 460 of June 10. 1997 § 4) states that it is forbidden to implant identical unfertilized or fertilized ova in one or more women.

Penalty: According to this legislation, the doctor and the authorized health persons that violates the provisions of the act can be punished with fine and with imprisonment in the form of presence. The persons donating eggs and semen and the couple consenting to artificial procreation cannot be punished according to this legislation.

Furthermore, research on humans is regulated by The Act on a Scientific Ethical Committee System and the Handling of biomedical Research Projects. The system of scientific ethical committees consists of The Central Scientific Ethical Committee and 7 regional scientific ethical committees. All committees have representation of laymen and scientists. All research projects must be approved by a scientific ethical

committee and projects on fertilized human eggs and human germ cells with the intention of procreational use must be put before the Central Scientifical Ethical Committee.

The scientifical-ethical committees are working on two levels -a regional level (8 regional committees) and one central committee working on national level
Penalty: According to this legislation anyone the initiates a project against the regulations can be punished with fine or ordinary imprisonment.

The Ministry of Health is responsible for the legislation dealing with human stem cells: The Danish Ministry of Health, Holbergsgade 6, 1057 Copenhagen K, email. im@im.dk

4. Could you please indicate if any new legal and/or regulatory framework for human embryonic stem cells research and use is under preparation?

Survey on Human Embryonic Stem Cells research and use

ESTONIA

1. **Has your National Ethics Committee or similar body provided an opinion on human embryonic stem cells research and use?**

   ♦ **no**

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

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2. **Will (or has) a public debate take(n) place on human embryonic stem cells?**

   ♦ **no**

If yes, how was / will it be organised, what were the conclusions; who is the contact person?

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3. **Could you please describe the current legal and/or regulatory framework for human embryonic stem cells research and use in your country and indicate a contact person?**

There is still no research on embryonic stem cells, and no plan to discuss ethics on this subject in the future. However, there is an ongoing research on fetal neural stem cells with permission of the Ethics Review Committee on Human Research of the University of Tartu..

Contact person : Prof. Aavo-Valdur Mikelsaar, MD, Ph.D
Head of the Institute of General and Molecular Pathology
University of Tartu
Ravila St. 19, Tartu 51014, Estonia
Phone +372 7 374 211
Fax +372 7 374 212
e-mail valdur@ut.ee

4. **Could you please indicate if any new legal and/or regulatory framework for human embryonic stem cells research and use is under preparation**

At this moment no.

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Survey on Human Embryonic Stem Cell Research and Use

FINLAND

1. Has your National Ethics Committee or similar body provided an opinion on human embryonic stem cells research and use?

☐ yes X no

2. Will (or has) a public debate take(n) place on human embryonic stem cells?

X yes, some not yet

There have been several seminars on stem cells, some journalists have written about stem cells but the topic has not reached wider public attention. The National Advisory Board on Health Care Ethics, its Sub-Committee on Medical Research Ethics, The Advisory Board for Biotechnology, The Advisory Board on Research Ethics, The Board for Gene Technology and the Cooperation Group for Laboratory Animal Sciences organised a public seminar on stem cells in April 2003.

3. Could you please describe the current legal and/or regulatory framework for human embryonic stem cells research and use in your country and indicate a contact person?

The Act on Medical Research (No. 488/1999) covers the preconditions and use of human embryos up to 14 days. The production of human embryonic stem cells from supernumerary embryos is allowed, production of embryos only for research purposes is not allowed. The Act defines also embryo as a fusion of gametes, so the embryo produced by nuclear transfer is not an embryo. Research on reproductive cloning is prohibited in this act. The laboratories that do embryo research need a lisence from the National Authority for Medicolegal Affairs. Written consent from both gamete donors is required.
The Act on Medical Use of organs and tissues 101/2001) contains also articles on research.

4. Could you please indicate if any new legal and/or regulatory framework for human embryonic stem cells research and use is under preparation

There is no specific regulatory framework for stem cells. The Medical Research Act, the Act on Medical Use of Tissues and Organs should cover also research on embryonal stem cells as well as other stem cells.

The Parliamentary Committee for the Future has produced a report and made a statement (8 January, 2003) on Social and legal challenges of human genome and stem cell research. The report is in Finnsh and has an English summary.
Reference: Ihmisen perimän ja kantasolujen tutkimuksen haasteet päätöksenteolle. Eduskunnan kanslian julkaisu 4/2003, ISBN 951-53-2517-X.

Regarding stem cell research the statement declares that a network for stem cells research should be established in co-operation with other Nordic countries. All biocentres should also be equipped with functional stem cell laboratories.
The statement further states that it must be clarified what kind of provisions should be made in the European biomedicine agreement to guarantee basic stem cell research and the possibility to implement them on a sound ethical basis.

Survey on Human Embryonic Stem Cell Research and Use

FRANCE

1. Has your National Ethics Committee or similar body provided an opinion on human embryonic stem cells research and use?

Yes

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

The French Comité Consultatif National d'Ethique has given an opinion on the establishment of collections of human embryo cells and their use for therapeutic or scientific purposes (opinion n°53 – March 11, 1997).

More recently, the Comité Consultatif National d'Ethique concluded in its opinion on the preliminary draft revision of the laws on bioethics No.67 - January 2001 (www.comite-ethique.fr/) that controlled possibilities for the use of spare IVF embryos for research purposes, in particular for research on embryonic stem cells should be allowed. On the subject of "therapeutic cloning ", however, opinions differ but a majority favours controlled authorisation to engage in "therapeutic cloning".

Contact person : Didier Sicard (President), Comité Consultatif National d'Ethique pour les Sciences de la Vie et de la Santé, 71 rue Saint-Dominique - 75007 Paris, website: www.comite-ethique.fr/

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2. Will (or has) a public debate take(n) place on human embryonic stem cells?

yes

If yes, how was / will it be organised, what were the conclusions; who is the contact person?

3. Could you please describe the current legal and/or regulatory framework for human embryonic stem cells research and use in your country and indicate a contact person?

The revision of the Bioethics law of 1994 was adopted in June 2004. It prohibits human embryo research but includes derogation for five years allowing for research on supernumerary human embryos including the procurement of hES cells under the following conditions:

- The research should have the potential to lead to major therapeutic advances and only be undertaken if there is no alternative method of comparable effectiveness available;

- The embryos must derive from an *in vitro* fertilisation, in the context of medically assisted reproduction (supernumerary embryos);
- Written consent of the couple from whom the embryos are issued must be obtained;
- Authorisation by a central body (to be created).

The law allows the import of foetal or embryonic cells or tissues after prior authorisation by the central body.

The creation of embryos or the constitution by cloning, for research purposes as well as for commercial or industrial purposes, is forbidden. Reproductive cloning is now considered by law as a crime against mankind.

4. Could you please indicate if any new legal and/or regulatory framework for human embryonic stem cells research and use is under preparation?

Survey on Human Embryonic Stem Cells research and use

GERMANY

1. Has your National Ethics Committee or similar body provided an opinion on human embryonic stem cells research and use?

yes

Following intensive debate the National Ethics Council (http://www.ethikrat.org/) published its Opinion on the import of human embryonic stem cells for research purposes on 20 December 2001.

In conclusion, the comprehensive document offers the following options:

A The temporary import of pluripotent human stem cells is deemed ethically acceptable under strict conditions (described in detail in the Opinion), as the production of such stem cells using surplus embryos is held to be ethically permissible. Therefore, the production of such stem cells using surplus embryos within Germany would also be acceptable. The import conditions mentioned would have to apply in equal measure to both publicly and privately funded research.

B The Council advocates the provisional and temporary import of human embryonic stem cells under strict conditions as described in the Opinion. All conditions shall apply in equal measure to both publicly and privately funded research, and must be met prior to import.

C A provisional ban (moratorium) should be imposed on stem cell import. The legislator must issue an explicit opinion on imports, yet not before clarifying a number of issues, individually listed in the Opinion. These issues should be examined before the end of 2004.

D Stem cell import is deemed ethically impermissible, mainly due to the basic considerations surrounding the production of stem cells using human embryos. As this is deemed an impermissible instrumentalisation (destruction) of human life, it follows that the import of such stem cells must be rejected. The imported cells carry the stigma of the conditions under which they were produced. Their import will lead to an increase in demand, thereby directly promoting consumption of embryos in the exporting countries. Eventually the level of protection afforded to embryos will be lowered also in Germany.

Bearing in mind that the National Ethics Council is yet to express its opinions on the basic issues surrounding stem cell research, and while decisions regarding the import of embryonic stem cells are still pending, fifteen Members have moved in favour of a tightly restricted temporary import of embryonic stem cells (Option B). Nine among these fifteen also advocated Option A. Ten Members favour a moratorium on stem cell imports for the time being (Option C), among these four who are also in favour of Option D.

The Ad-hoc Commission on Law and Ethics in Modern Medicine of the Deutsche Bundestag (14th election period) was similarly split in its views.

The Deutsche Bundestag (German Parliament) voted in its debate on 25 April 2002 for a law allowing the import of human embryonic stem cell lines under certain restrictive conditions (Gesetz zur Sicherstellung des Embryonenschutzes im Zusammenhang mit Einfuhr und Verwendung menschlicher embryonaler Stammzellen – StZG). The law became effective on 1 July 2002.

The Deutsche Forschungsgemeinschaft (DFG) supports the use of supernumerary embryos from IVF for the generation of human embryonic stem cells (1). A legal opinion - on behalf of the DFG – describes the current limits for human embryonic stem cell research (2).

For the position of the German National Ethics Council see:
http://www.ethikrat.org/stellungnahmen/stell_stammzellen/inhalt.html

For the position of the Ad-hoc Commission on Law and Ethics in Modern Medicine see: http://www.bundestag.de/gremien/medi/index.html

For the position of the Deutsche Forschungsgemeinschaft (German Research Society) see:
(1)http://www.dfg.de/aktuelles_presse/reden_stellungnahmen/2001/redstell/forschung_stammzellen.html
and
(2)http://www.dfg.de/aktuelles_presse/reden_stellungnahmen/2003/redstell/rechtsgutachten_stammzellen.html

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2. Will (or has) a public debate take(n) place on human embryonic stem cells?

X yes ☐ no

If yes, how was / will it be organised, what were the conclusions; who is the contact person?

There have been countless public discussions on human embryonic stem cells organised by numerous different institutions, i.e. political parties, churches, professional organisations, etc.

3. Could you please describe the current legal and/or regulatory framework for human embryonic stem cells research and use in your country and indicate a contact person?

The Embryonenschutzgesetz (Embryo Protection Law) does not allow the use of human embryos for research purposes, but does not exclude the import of human embryonic stem cells. However, this point was debated on in a very controverse

manner in 2001. Therefore the German Parliament decided to establish a law clarifying specifically this point in the Stem Cell Act.

The Deutsche Bundestag (German Parliament) voted in its debate on 25 April 2002 for a law allowing the import of human embryonic stem cell lines under certain restrictive conditions (Gesetz zur Sicherstellung des Embryonenschutzes im Zusammenhang mit Einfuhr und Verwendung menschlicher embryonaler Stammzellen – StZG). The law became effective on 1 July 2002.
The official text of the law was also published in the electronic version of the Bundesanzeiger. It can be found under the following web site:
http://217.160.60.235/BGBL/bgbl1f/BGBl102042s2277.pdf

See hereafter an extract from the German Act ensuring the protection of embryos in connection with the importation and utilization of human embryonic stem cells (Stem Cell Act) (June 28, 2002):

Section 4
Importation and utilization of embryonic stem cells

(1) *The importation and utilization of embryonic stem cells shall be prohibited.*

(2) Notwithstanding para 1, the importation and utilization of embryonic stem cells for research purposes shall be permissible under the conditions stipulated in section 6 if
1. the competent agency has satisfied itself that

a) the embryonic stem cells were derived before 1 January 2002 in the country of origin in accordance with relevant national legislation there and are kept in culture or are subsequently stored using cryopreservation methods (embryonic stem cell line),

b) the embryos from which they were derived have been produced by medically-assisted in vitro fertilization in order to induce pregnancy and were definitely no longer used for this purpose and that there is no evidence that this was due to reasons inherent in the embryos themselves,

c) no compensation or other benefit in money's worth has been granted or promised for the donation of embryos for the purpose of stem cell derivation and if

2. other legal provisions, in particular those of the German Embryo Protection Act , do not conflict with the importation or utilization of embryonic stem cells.

(3) Approval shall be refused if the embryonic stem cells have obviously been derived in contradiction to major principles of the German legal system. Approval may not be refused by arguing that the stem cells have been derived from human embryos.

Section 5
Research using embryonic stem cells

Research involving embryonic stem cells shall not be conducted unless it has been shown by giving scientific reasons that

1. such research serves eminent research aims to generate scientific knowledge in basic research or to increase medical knowledge for the development of diagnostic, preventive or therapeutic methods to be applied to humans and that,

2. according to the state-of-the-art of science and technology,

   a) the questions to be studied in the research project concerned have been clarified as far as possible through in vitro models using animal cells or through animal experiments and

   b) the scientific knowledge to be obtained from the research project concerned cannot be expected to be gained by using cells other than embryonic stem cells.

Section 6
Approval

(1) Any importation and any utilization of embryonic stem cells shall be subject to approval by the competent agency.

(2) Applications for approval must be submitted in writing. In the documents accompanying the application, the applicant shall provide the following information in particular:

1. Name and official address of the person responsible for the research project concerned,

2. a description of the research project including scientific reasons showing that the research project meets the requirements set forth in section 5 above,

3. a documentation concerning the embryonic stem cells to be imported or used showing that the requirements set forth in no. 1 of para 2 of section 4 above have been complied with or equivalent evidence that

   a) the embryonic stem cells to be imported or used are identical with those registered in a scientifically recognized, publicly accessible registry maintained by government agencies or agencies authorized by the government and that,

   b) by way of such registration, the requirements set forth in no. 1 of para 2 of section 4 above have been complied with.

(3) The competent agency shall immediately acknowledge in writing receipt of the application and the attached documents. At the same time, the agency shall request the opinion of the Central Ethics Commission on Stem Cell Research. On receipt of

the opinion, the agency shall notify the applicant of the content and the date of the opinion adopted by the Central Ethics Commission on Stem Cell Research.

(4) Approval shall be given if

1. the requirements set forth in para 2 of section 4 above have been complied with,

2. the requirements set forth in section 5 above have been complied with and, accordingly, the research project is ethically acceptable, and if

3. an opinion by the Central Ethics Commission on Stem Cell Research has been submitted following a request by the competent agency to this effect.

(5) If the application, complete with documentation, and the opinion of the Central Ethics Commission on Stem Cell Research have been received, the agency shall decide in writing on the application within a period of two months. In doing so, the agency shall consider the opinion adopted by the Central Ethics Commission on Stem Cell Research. If the competent agency‘s decision differs from the opinion adopted by the Central Ethics Commission on Stem Cell Research, the agency shall give its reasons in writing.

(6) Approval can be limited in time or by imposing obligations to the extent necessary for complying with or continuing to meet the approval requirements pursuant to para 4 above. If, following approval, events occur which conflict with the granting of approval, approval can be withdrawn wholly or in part with effect in the future or be limited in time or be made dependent on the fulfilment of conditions to the extent necessary for complying with or continuing to meet the approval requirements set forth in para 4 above. Any objection to or action for rescission of withdrawal or revocation of approval shall not suspend the effect of the decision.

For the Parliamentary Debate see: http://dip.bundestag.de/btp/14/14214.pdf

4. Could you please indicate if any new legal and/or regulatory framework for human embryonic stem cells research and use is under preparation?

On 1 July 2003 (Drucksache 15/1310) Members of the German Bundestag from the Christian Democratic Party, the Social Democratic Party and Alliance 90/The Greens introduced a motion asking the government to ensure that research projects prohibited under German law will not receive funding from the EU. On 2 July 2003 (Drucksache 15/1346) the parliamentary Free Democratic Party introduced a motion to the contrary. A final debate is scheduled for the end of September 2003.

The German Parliament has decided in February 2003 to establish a new Ad-hoc Commission on Ethics and Law in Medicine to discuss bioethical issues.

Survey on Human Embryonic Stem Cells research and use

GREECE

1. Has your National Ethics Committee or similar body provided an opinion on human embryonic stem cells research and use?

Yes, there is a relevant opinion of the National Bioethics Commission.

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

1. Here is a summary of the recommendations adopted (not always by unanimous decision – see the extended version of the opinion)

- *Stem cell removal from embryonic tissue after abortion*. This practice is legitimate, on condition that the donors of the gametes have given their consent following appropriate information about the specific use. Antecedent or posterior to conception agreements resorting to abortion and stem cell derivation should be prohibited. The relevant penalties should be more severe in cases where such agreements comprise financial compensations.

- *Stem cell removal from embryos in vitro*. The general principle of the article 18 of the Convention on Human Rights and Biomedicine, according to which research under specified conditions on embryos in vitro is allowed, is accepted, though it needs further clarification concerning, in particular, the conditions for stem cell research.
The authentic and informed consent from the donors of the gametes is required, in order to derive stem cells from an embryo in vitro.
Many members of the Commission consider that financial agreements for stem cell derivation from embryos in vitro should be precluded, in order to prevent donors' exploitation from third parties. However, other members consider that absolute prohibition of such agreements does not guarantee lack of exploitation.
Embryo production for therapeutic purposes, via cloning, and derivation of stem cells from such embryos should not be precluded, in condition that there is not an alternative cure.

- *Stem cell removal from individuals*. Removal of somatic stem cells from an adult person presupposes his/her authentic consent, under the same guarantees as previously mentioned. It should be appropriate to preclude removal of somatic stem cells from a minor for research purposes.
- The rule of the donor's anonymity should be maintained, in the exception of therapeutic use on him/herself.
- The recipient of stem cells – or tissue and graft that might be derived in the future from stem cells- should be protected against the odds of becoming a research "means".
- The State should elaborate a funding policy of research projects based, among others, on the above-mentioned deontological principles. All research projects should

be accompanied by a report of ethical adequacy. Research ethics committees that would function in the frame of the funding and research institutions should assess the project based on this report.

2. See the extended version of this opinion, the report on which it is based, and the previous opinions of the Commission in http://www.bioethics.gr

3. Contact: K.Manolakou@bioethics.gr, T.Vidalis@bioethics.gr

2. Will (or has) a public debate take(n) place on human embryonic stem cells?

No

3. Could you please describe the current legal and/or regulatory framework for human embryonic stem cells research and use in your country and indicate a contact person?

Two legal documents are in force currently: a) The Convention on Human Rights and Biomedicine and its additional protocol on the prohibition of cloning human beings, and b) The recent law 3089/2002 on medically assisted human reproduction, according to which the use of surplus embryos for therapeutic and research purposes is permitted on condition that there is a prior informed consent of the concerned persons or that they have not stated their common will during the maximum storage period of 5 years. Furthermore, this law prohibits explicitly only reproductive cloning.

4. Could you please indicate if any new legal and/or regulatory framework for human embryonic stem cells research and use is under preparation

There is not available official information

Survey on Human Embryonic Stem Cells research and use

HUNGARY

1. Has your National Ethics Committee or similar body provided an opinion on human embryonic stem cells research and use?

No

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

In the last 5 years there was no Medical Research Council Scientific and Ethical Committee statement dealing with human embryonic stem cell research and use. In decisions of different cases the committee accepted always the EC recommendation

2. Will (or has) a public debate take(n) place on human embryonic stem cells?

No

If yes, how was / will it be organised, what were the conclusions; who is the contact person?
Several articles were published about the human embryonic stem cells in newspapers and medical journals. Several scientific radio and TV program focused on stem cells, but these actions weren't central organised.

3. Could you please describe the current legal and/or regulatory framework for human embryonic stem cells research and use in your country and indicate a contact person?

The human embryonic stem cells research and use is regulated by law and three decrees.
The 1997. CLIV. law about the health regulated the general conditions of the use and research of the human embryonic stem cells (180- 182 §).
The 21/1998. (VI.3.) MH decree contains the minimum conditions of the use of human embryonic stem cells (15/B attachment).
The 22/1998. (VI.3.) MH decree contains the detailed regulation of the transplantation of different organs and tissues.
The 31/1998. (VI.24.) MH decree regulated the ethical approval system of biomedical research.

4. Could you please indicate if any new legal and/or regulatory framework for human embryonic stem cells research and use is under preparation?

A new decree dealing with biomedical research is under preparation
Contac person**: Prof. Katalin Pálóczy,** Országos Haematológiai és Immunológiai Intézet, BUDAPEST, Daróczi út 24, H-1113

Survey on Human Embryonic Stem Cell Research and Use

IRELAND

1. Has your National Ethics Committee or similar body provided an opinion on human embryonic stem cells research and use?

yes

The Commission on Assisted Human Reproduction is considering this issue within its remit and is expected to report in 2003.

The Irish Council for Bioethics has recently been set up and is working on this area at present : http://www.bioethics.ie/

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2. Will (or has) a public debate take(n) place on human embryonic stem cells?

☐ yes X no

If yes, how was / will it be organised, what were the conclusions; who is the contact person?

The Commission on Assisted Human Reproduction was established by the Department of Health in March 2000 to prepare a report on the possible approaches to the regulation of all aspects of human reproduction and the social, ethical and legal factors to be taken into account in determining public policy in this area. The Commission will address the issue of embryonic stem cell research in its deliberations. The publication of its report in 2002 will provide the basis for informed public debate before the finalisation of any policy proposals.

The work of the Irish Council on Bioethics should also provide an opportunity for public debate on this issue in due course.

3. Could you please describe the current legal and/or regulatory framework for human embryonic stem cells research and use in your country and indicate a contact person?

There is no legislation dealing with embryo research in Ireland but the relevant provision of the Irish Constitution 1937 (as amended in 1983) provides as follows: « The State acknowledges the right to life of the unborn and, with due regard to the equal right to life of the mother, guarantees in its laws to respect, and, as far as practicable, by its laws to defend and vindicate that right. »

It is unclear whether this provision obliges the State to defend the right to life of the pre-implantation embryo as the term « unborn » has not been judically interpreted to

date. If the Constitutional provision applies from the moment of conception then embryo and stem cell research (as well as embryo freezing and certain forms of contraception) would be unconstitutional as the State would not be vindicating the right to life of the unborn. If, however, the provision applies from implantation of the embryo into the womb, then it may be that such procedures may be carried on in the State within the terms of the Constitution. Clarification of the constitutional provision is therefore necessary before the legal position on embryonic stem cells can be described.

4. Could you please indicate if any new legal and/or regulatory framework for human embryonic stem cells research and use is under preparation

No legislation is currently under preparation in Ireland dealing with stem cell research. However, the Commission on Assisted Human Reproduction is examining this issue in its remit and will report in 2003 on the possible approaches to regulation within the Irish Constitutional framework.

Survey on Human Embryonic Stem Cells research and use

ITALY

1. Has your National Ethics Committee or similar body provided an opinion on human embryonic stem cells research and use?

X yes

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

Yes, the recommendations are the following:

The Italian National Bioethics Committee (http://www.palazzochigi.it/bioetica/):
deems that the possibility of cultivating in the laboratory stem cells having the capacity to reproduce indefinitely and to specialize in the formation of any tissue of the human body represents a line of research of particular interest as regards therapeutic applications, The use of these cells to repair damaged tissues and, in future, also damaged organs, by means of cells replacement opens up new prospects of treatment for a wide range of frequently occurring diseases that are today difficult to treat and often incurable;
expresses the hope that such a line of research will pursue the optimal objective of succeeding in "reprogramming" mature cells, that is, of deriving stem cells capable of differentiating into the desired tissues directly from the already differentiated cells of the patient whose tissue is intended to regenerate. This would represent a cellular auto-transplant that had the major advantage of tissue compatibility and would thus presumably be used for important therapeutic applications;
is fully aware that the pluripotent stem cells with the greatest potential for differentiating into the widest range of tissues (in animal models as well as in observed human cases) are the stem cells derived from the embryo at the blastocyst stage even when they are derived through the somatic nuclear replacement technique. The alternative attempts at deriving stem cells from umbilical cord blood or from other tissues capable of expanding and differentiating into cells of tissues other than the original ones are still at the early experimental stage;
deems it to be ethically legitimate to derive stem cells from the cells of spontaneously aborted foetuses or those produced by voluntary interruption of pregnancy, provided suitable steps are taken to exclude both causal relations between abortion and stem cell derivation and any collaboration among corresponding operators, and marketability. Some members of the Committee have nevertheless expressed reservations on the possibility of distinguishing de facto the collaboration among the team involved in performing the voluntary interruption of pregnancy and the team using the derived foetuses, even when suitable formal procedures are adopted to distinguish their possible relationship of causality;
points out that several of its members acknowledge and agree with the ban on creating human embryos for the sole purpose of using them for scientific research, as provided for in art.18, paragraph 2 of the *Convention on Human Rights and Biomedicine*.

According to other members of the Committee, a thorough evaluation of the experimental results of somatic nuclear replacement may suggest that this new line of research could produce therapeutic results of great impact for the being without any alternative such as to suggest evaluating the ethical aspects of future applications on a case by case basis;
reiterates the illegitimacy of using the somatic nuclear replacement technique for reproductive purposes ("reproductive cloning");
points out that part of the Committee consider it ethically allowed to derive stem cells for therapeutic purposes from embryos that are no longer possible to implant, again on condition that they are wittingly donated by the women or the couples concerned. They nevertheless recommend performing rigorous tests and checks on a case basis on the suitability for implantation, the consent to donate and the therapeutic purpose of the experimentation. These should be carried out only ad hoc indicators of a reasonable impracticability of implantation, as well as by following adequate guidelines and ensuring a preventive evaluation is made by an ethical committee. Other members of the Committee are in any case against using supernumerary or spare embryos even when cryopreserved and not required for transfer to the uterus, because they consider such practices to entail the direct and deliberate suppression of the embryos and thus an instrumental use of human beings and on offence to their dignity;
expresses the hope that a topic of such importance for biological and medical research and so significant as regards the possible treatment of diseases of great social impact and today difficult to treat will be the object of accurate information and wide debate. This should be the case not only within the scientific community but also within laymen, so the latter can be made aware of and responsibly address the problems of a chapter of medicine that, while certainly new, it is hoped will also be effective, and to which the name of "regenerative medicine" has been given.
Please note: See also the opinion of the ad hoc commission of the Ministry of Health. The text is available in website www.sanita.it

On this matter the Italian National Committee for Bioethics has analysed on October 2000 the various positions without taking a formal decision. On 11 April 2003, however, said Committee reached a majority decision against the utilisation of human supernumerary embryos for the derivation of human cells[1].

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2. Will (or has) a public debate take(n) place on human embryonic stem cells?

☐ yes ☐ no

If yes, how was / will it be organised, what were the conclusions; who is the contact person?

The public has been informed by the media. Nevertheless this issue has been discussed in many conferences, and also in some meetings with students.

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[1] Information provided by the Ministry of Research.

3. Could you please describe the current legal and/or regulatory framework for human embryonic stem cells research and use in your country and indicate a contact person?

On 28 March 2001 the Italian Parliament has approved the law n. 145/2001, named **Reception and execution of the Convention of European Council for the protection of human rights and of the dignity of human beings in regard to the application of Biology and Medicine (Oviedo 4 April 1997),** including an additional protocol of 12 January 1998, n. 168 forbidding human clonation[1].

The Italian Senate approved in December 2003 the law on In Vitro Fertilisation -IVF (Ddl Senato 1514 - Norme in materia di procreazione medicalmente assistita).

The law states that only homologous IVF is allowed to de facto couples and only 3 embryos can be produced and all have to be implanted.

Art. 13 of the law regulates embryo research. According to article 13 research on human embryo is not permitted, except for research carried out on embryos for therapeutic or diagnostic purposes which will be beneficial for the embryo concerned.

Both reproductive and therapeutic cloning are prohibited and the creation of human-animal hybrid-chimeras.

Sanctions against those who do not follow the article above include sanctions from 50.000 to 150.000€ and the suspension from 1 to 3 years of the habilitation to practice the medical profession.

The Higher Institute of Public Health (Istituto Superiore di Sanità -ISS) is the authority that has to validate the protocols involving the use of embryos under the conditions described in Art 13, as well as to produce an annual report on the implementation of the law.

There exists no specific legislation concerning research on already isolated hES cells or lines. The opinion of a local ethics committee is required prior to the import of hES cell lines.[2]

4. Could you please indicate if any new legal and/or regulatory framework for human embryonic stem cells research and use is under preparation

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[1] Information provided by the Ministry of Research.

[2] Information from DG Research

Survey on Human Embryonic Stem Cells research and use

LATVIA

1. **Has your National Ethics Committee or similar body provided an opinion on human embryonic stem cells research and use?**

YES

Central Medical Ethics Committee of Latvia was involved in preparation of Act on Human Reproductive and Sexual Health which regulate the human medical assisted reproduction and protection of Embrio.There is not any regulations directly on human embrionic stem cells research and use.

- Creation of human embryos for research prohibited;
- Cloning of human being prohibited;
- Research on embryos in vitro is allowed under Regulation of Ministry of Welfare

2. **Will (or has) a public debate take(n) place on human embryonic stem cells research and use?**

YES

Few public debate has been induced by draft Act on Human Reproductive and Sexual Health. There were a big difference in opinion between public and religion.

3. **Could you please describe the current legal and/or regulatory framework for human human embryonic stem cells research and use in your country and indicate a contact person**

Convention on Human rights and Biomedicine
Act on Human Reproductive and Sexual Health
Regulation of Ministry of Welfare of Latvia on human medical assisted reproduction nr.173, June 10,1999.

- Creation of human embryos for research prohibited;
- Cloning of human being prohibited;
- Research on embryos in vitro is allowed under Regulation of Ministry of Welfare

There is not any regulations directly on human embrionic stem cells research and use.

4. **Could you please indicate if any new legal and/or regulatory framework for human embryonic stem cells research and use in your country is under preparation and indicate a contact person**

None

Survey on Human Embryonic Stem Cells research and use

LITHUANIA

1. **Has your National Ethics Committee or similar body provided an opinion on human embryonic stem cells research and use?**

   X no

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

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2. **Will (or has) a public debate take(n) place on human embryonic stem cells?**

   X yes

If yes, how was / will it be organised, what were the conclusions; who is the contact person?

Public debate follows the most important international developments, e.g., USA response to the issue.

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3. **Could you please describe the current legal and/or regulatory framework for human embryonic stem cells research and use in your country and indicate a contact person?**

It has not been specifically addressed in the law. However, Lithuanian Law on Biomedical Research allows only observational studies of human embryo. All other research with human embryo are forbidden (see www.lrs.lt, legal acts).

Lithuanian Bioethics Committee (http://www.sam.lt/bioetika/)

4. **Could you please indicate if any new legal and/or regulatory framework for human embryonic stem cells research and use is under preparation**

Contact address: Dr. Eugenius Gefenas, Chairman
Lithuanian Bioethics Committee
Vilnius 33, Lithuania
Tel./fax: 3702 224565
Email: lbek@sam.lt

Survey on Human Embryonic Stem Cells research and use

LUXEMBOURG

1. Has your National Ethics Committee or similar body provided an opinion on human embryonic stem cells research and use?

Yes

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

The problem was raised when our opinion on the "Convention pour la protection des droits de l'homme et de la dignité de l'être humain à l'égard des applications de la biologie et de la médecine" was elaborated.

Contact:
Jean-Paul Harpes
Co-ordinator of CNE
20, montée de la Pétrusse Tel.: 352.478.66.28
L – 29 12 Luxembourg Fax: 352.2921.86

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2. Will (or has) a public debate take(n) place on human embryonic stem cells?

☐ yes ☐ no

If yes, how was / will it be organised, what were the conclusions; who is the contact person?

The problem was raised when the above-mentioned opinion was presented to the public.

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3. Could you please describe the current legal and/or regulatory framework for human embryonic stem cells research and use in your country and indicate a contact person?

This framework does not exist yet.

4. Could you please indicate if any new legal and/or regulatory framework for human embryonic stem cells research and use is under preparation

Maybe in the middle-term.

Survey on Human Embryonic Stem Cell Research and Use

MALTA

1. Has your National Ethics Committee or similar body provided an opinion on human embryonic stem cells research and use?

NO

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

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2. Will (or has) a public debate take(n) place on human embryonic stem cells?

Yes (**partly**)

Articles have been written in local papers about the subject, but no formal public debate has been organised.

If yes, how was / will it be organised, what were the conclusions; who is the contact person?

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3. Could you please describe the current legal and/or regulatory framework for human embryonic stem cells research and use in your country and indicate a contact person?

None

4. Could you please indicate if any new legal and/or regulatory framework for human embryonic stem cells research and use is under preparation

No such legislation is currently envisaged.

Survey on Human Embryonic Stem Cells research and use

THE NETHERLANDS

1. Has your National Ethics Committee or similar body provided an opinion on human embryonic stem cells research and use?

X yes ☐ no

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

Yes, The Health Council (http://www.gr.nl) has provided two advisory reports on this issue.
1) The report on "Research and Use of Human ES Cells" (November 1997; only in Dutch) focussed on the need to take account of ES cell research in planned legislation of Embryo research.

2) In June 2002, the Health Council has issued the report 'Stem cells for tissue repair. Research on therapy using somatic and embryonic stem cells » (http://www.gr.nl/pdf.php?ID=429)

Contact: dr WJ Dondorp e-mail wj.dondorp@gr.nl Tel +31 70 6575 and dr PA Bolhuis e-mail pa.bolhuis@gr.nl Tel +31 70 3407717.

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2. Will (or has) a public debate take(n) place on human embryonic stem cells?

☐ yes X no

If yes, how was / will it be organised, what were the conclusions; who is the contact person?

No public debate has taken place on this particular subject; however, there has been public debate on the related topic of human cloning, which includes non-reproductive embryocloning in the context of stem cell research or therapy (feb 97- oct 99). The conclusions of the debate call for a moratorium on human reproductive cloning but would not rule out non-reproductive embryocloning. The debate was organised by the Rathenau Institute. It has led to a publication ("kloneren in de polder") issued by the Rathenau Institute, with a summary in English.
Contact: dr K van der Bruggen e-mail: K.vanderBruggen@Rathenau.nl tel +31 703421542. website: www.rathenau.nl

3. Could you please describe the current legal and/or regulatory framework for human embryonic stem cells research and use in your country and indicate a contact person?

The Act containing rules relating to the use of human gametes and embryos (Embryos Act) came into force on September 1th 2002. A translation can be found at: http://www.minvws.nl/documents/IBE/Wetstekst/eng-embryowettekst.pdf

The Act allows the use of spare embryos for scientific research (including obtaining stem cells from such embryos for the purposes of research), subject to review of the research protocol by the Central Committee on Research Involving Human Sunjects and Embryo Research (CCMO). The Act prohibits the creation of embryos for purposes other than reproduction (section 24a). This also applies to 'therapeutic cloning' using human stem cells. However, this ban can be lifted and is thus in effect a moratorium (section 33 sub 2). The decision to lift the ban has to be taken within 5 years. The Act already contains provisions for the handling of embryos created for purposes other than reproduction which would come into force after the lifting of the ban (section 11). This complex construction was chosen in order to allow for making a reservation to Article 18 of the European Convention on Human Rights and Biomedicine (forbidding the creation of embryos for research purposes) when ratifying that Convention (as the Dutch intend to do). The Health Council, in its report on' IVF-related research' (1998), had insisted on not closing the door for research using especially created embryos. However, the summer of 2002 has brought a new coalition to power, with the Christian Democrats as numerically strongest party. This political party is firmly against lifting the moratorium.

The head of the bureau of the national review committee (CCMO) is Dr. Marcel Kenter; e-mail ccmo@ccmo.nl Website: www.ccmo.nl Tel +31 70 3406700.

4. Could you please indicate if any new legal and/or regulatory framework for human embryonic stem cells research and use is under preparation

No such preparations

Annex

Developments identified which could affect new legislation

Research using embryonic stem cells

On 26 November 1997, the Health Council submitted a report on research using embryonic stem cells to the Minister of Health, Welfare and Sport. In the report the Council highlights certain important developments taking place in the field and urges the government to take account of these developments when drafting the planned bill on procedures involving human reproductive cells and embryos

Embryonic stem cells are the undifferentiated precursors of the many different types of cell from which the tissues and organs of the growing embryo are made. Scientists have succeeded in isolating and cultivating ES cells; in the laboratory , ES cells can be used to grow more stem cells, or, through controlled differentiation, to form cells of various types. Such procedures create enormous scope for research into embryonic development processes and into the emergence of certain diseases. Far-reaching practical applications also look likely in fields such as pharmacology and transplantation.

To date, only animal ES cells have been studied. However, in anticipation of research into possible human applications, the question arises: is it ethically acceptable to use human embryos to establish the necessary cell lines? Human ES cells could be obtained from embryos which, having been created by in vitro fertilization (IVF), can no longer be used for their original purpose, i.e. to initiate pregnancy. The government' s planned act on procedures involving human reproductive cells and embryos will clarify whether and, if so, under what conditions it is permissible to use these "surplus" IVF embryos for research or therapeutic ends. The Minister of Health, Welfare and Sport has already outlined the content of the bill in a memorandum to the Lower House. According to this document, the government intends to outlaw research involving the use of human embryos, except where the object is to benefit scientific understanding of (in)fertility, artificial reproduction or hereditary or congenital medical conditions.

The Health Council endorses the view that research involving the use of human embryos is only acceptable if it serves an important medical purpose. However, the Council believes that the restrictive definition of conditionally acceptable research fields could prevent other, equally important research.

Survey on Human Embryonic Stem Cell Research and Use

POLAND

Under the Physician profession's Act of 1996, human embryos may not be use for non-therapeutic research.[3]

[3] Information provided by DG Research

Survey on Human Embryonic Stem Cells research and use

PORTUGAL

1. **Has your National Ethics Committee or similar body provided an opinion on human embryonic stem cells research and use?**

X☐ yes

A "White Book" on the use of human embryo in scientific research has been edited by Prof. Daniel Serrão on February 2003, under request of the Portuguese Minister of Science.

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

Ana Sofia Carvalho
Instituto de Bioética
Universidade Católica Portuguesa
Rua Diogo Botelho, 1327
4669-005 Porto
Fax: +351 226196291
Email: anasofia@netc.pt

This report does not contemplate any recommendations but only the different positions regarding embryo research (including stem cell research). It intends to prepare a public discussion on the subject and be a base for the preparation of legislation on the subject.

2. **Will (or has) a public debate take(n) place on human embryonic stem cells?**

X☐ yes X☐ no

If yes, how was / will it be organised, what were the conclusions; who is the contact person?

See answer to question nº 1. A few workshops have been organised.

3. **Could you please describe the current legal and/or regulatory framework for human embryonic stem cells research and use in your country and indicate a contact person?**

Portugal has signed and ratified the Convention of the Council of Europe on Human Rights and Biomedicine
There is no legal and/or regulatory framework for human embryonic stem cells research and use.

4. Could you please indicate if any new legal and/or regulatory framework for human embryonic stem cells research and use is under preparation

A Commission on Embryo Research is expected to be formed and prepare a draft for a law to be presented to the Parliament

Survey on Human Embryonic Stem Cells research and use

SLOVAK REPUBLIC

1. Has your National Ethics Committee or similar body provided an opinion on human embryonic stem cells research and use?

no

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

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2. Will (or has) a public debate take(n) place on human embryonic stem cells?

no*

If yes, how was / will it be organised, what were the conclusions; who is the contact person?

*Only a few articles appeared in the daily or popular press expressing different views.

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3. Could you please describe the current legal and/or regulatory framework for human embryonic stem cells research and use in your country and indicate a contact person?

There is no specific legislation on the issue so far.
However, the Slovakia's signing and ratifying the *Convention on Human Rights and Biomedicine* and of the *Additional Protocol on the Prohibition of Cloning of the Human Beings*, already implemented in the national legislature, together with the older provisions contained in the law No. 277/1994 on health care, especially the prohibition of the "non-therapeutic research" to be performed on human embryos and fetuses, were interpreted recently as effectively banning all human cloning (the so-called "reproductive" as well as "therapeutical").
There is a governmental proposal to ammend the Slovakia's Penal Code accordingly - i.e. making human cloning a penal offence in Slovakia (relevant wording being taken basically from the *Protocol,* and the legislature implementing it in Slovakia).

4. Could you please indicate if any new legal and/or regulatory framework for human embryonic stem cells research and use is under preparation

See 3.

Survey on Human Embryonic Stem Cells research and use

SLOVENIA

1. **Has your National Ethics Committee or similar body provided an opinion on human embryonic stem cells research and use?**

   X yes

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

The creation of human embryos for research or for therapeutic purposes for the benefit of other human beings is not considered ethically acceptable. Stem cells may be acquired in other ways (from umbilical cord blood, from aborted fetuses, from embryos created in the process of medically assisted reproduction which ceased to be part of a parental project)

Contact person: Prof. Jože Trontelj, Chair, National Medical Ethics Committee, Zaloška 7, SI-1525 Ljubljana, Slovenia. E-mail: joze.trontelj@kclj.si

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2. **Will (or has) a public debate take(n) place on human embryonic stem cells?**

   X yes

If yes, how was / will it be organised, what were the conclusions; who is the contact person?

Considerable public debate has taken place during the last 2 years in the media and various round tables have been held open to public, in particular in connection with human cloning. Contact person: see above.

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3. **Could you please describe the current legal and/or regulatory framework for human embryonic stem cells research and use in your country and indicate a contact person?**

Slovenia is party to the Oviedo Convention and the protocol on prohibition of human cloning. It has a law on medically assisted reproduction (MAR) which forbids the creation of human embryos for research, the production of cloned embryos and the use of in vitro fertilisation for any purpose other that birth of a child. Also prohibited is the use of parts of embryo for any purpose other than is explicitly allowed by law.
Contact person: see above.

4. **Could you please indicate if any new legal and/or regulatory framework for human embryonic stem cells research and use is under preparation**

Not at present.

Survey on Human Embryonic Stem Cells research and use

SPAIN

1. Has your National Ethics Committee or similar body provided an opinion on human embryonic stem cells research and use?

This particular point is sufficiently developped in the survey you have previously prepared and has not been substantially modified in the last months. As stated in the survey, following body's opinions have to be take into account:

- National Commission on Human Assisted Reproduction.
- National Commission for Hematopoietic progenitor transplants.
- Advisory Committee on Ethics of Scientific and Technical Research (Spanish Foundation for Science and Technology, Ministry of Science and Technology).

The Spanish National Commission on Human Assisted Reproduction had underlined the need of considering the possibility of using these surplus embryos to undergo research, due to the fact that the Spanish legal framework establishes that the human embryos once 5 years since their obtention have passed, can no more be used in the field of the assisted reproduction techniques. In February 2003, another Report on "Research with Stem Cells" published by the Advisory Committee on Ethics dependent on the Foundation for Science and Technology (Comité Asesor de Ética dependiente de la Fundación Española para la Ciencia y la Tecnología), set some conclusions in this field, pointing out the possible use of surplus embryos from Assisted Reproduction Techniques in order to undergo research**.**

2. Will (or has) a public debate take(n) place on human embryonic stem cells?

On top of the argumentation developped on the survey it has to be said that research and experimentation with embryonic stem cells constitues one of the scientific points which has generated a more opened public debate in Spain. In fact, the legislation in force has given raise to different social positions on this subject, beeing the problem widely analysed by the mass media.

This positions can be summarised as follows: on one side, a social sector considers that human embryo posesses dignity and cannot be submitted to research and experimentation. Contrary to that, another social sector has put pressure on the government in order to change the law and to allow research with surplus embryos from assisted reproduction techniques.

Previously to the change of the national government as a result of the recent (14th March 2004) elections, a modification of Law 35/1988 (Law 45/2003, of 21 November, which modifies Law 35/1988, of 22th November, of Assisted Reproduction Techniques, see Annex) was approved in the Spanish Parliament (November 2003), adopting several measures in this field (see answer to question 3 where legislative innovations are explained).

3. Could you please describe the current legal and/or regulatory framework for human embryonic stem cells research and use in your country?

First of all, we have to establish the legal framework existing in Spain, which includes the following laws:

- Law 35/1988, of 22th November, of Assisted Reproduction Techniques recently modified by Law 45/2003, of 21 November.
- Law 42/1988, of 28th December, of donation and use of embryos and human foetuses and of its cells, tissues and organs.
- Law 45/2003, of 21 November, which modifies Law 35/1988, of 22th November, of Assisted Reproduction Techniques

Developing this two laws there are other norms of inferior category (basically, Royal Decree 412/1996, of 1st March, which establishes the obligatory protocols of study of donors and users related with assisted reproduction techniques and which regulates the creation and organization of the National Register of Donors of Gametes and Preembryos with human reproduction purposes and Royal Decree 413/1996, of 1st March, which establishes the technical and functional conditions needed for the authorization and homologation of centres and sanitary services related with human assisted reproduction techniques and).

- Criminal Code of 1995 (art. 161.1 Criminal Code).
- Decision of the Spanish Constitutional Court 212/1996, of 19th December.
- Decision of the Spanish Constitutional Court 116/1999, of 17th June.

The legislation in force in Spain under Law 35/1988 and 42/1988 (arts. 14-17 of Law 35/1988, of 22th November, of Assisted Reproduction Techniques and arts. 7 and 8 of Law 42/1988, of 28th December, of donation and use of embryos and human foetuses and of its cells, tissues and organs), in order to manipulate pre-embryos (pre-implantatory embryos) it is necessary to fulfil the following conditions:

a) Written consent of the persons from which they proceed, including in its case the donors, having being previously detailed the purposes which are to be reached with the research.
b) The embryos should not be developed in vitro more than 14 days after the fertilisation of the ovule, not taking into account the period which they have been cryocenserved.
c) The research has to be done in sanitary centers and by multidisciplinary scientific teams, according to the law, dully qualified and authorised under control of the competent public authorities.

Specifically, and in order to authorise research in pre-embryos it is necessary to demonstrate:

d) That the preembryos are not viable.
e) It has to be proved that the research cannot be made in the animal model.
f) The research has to be integrated in a project authorized by the competent scientific and sanitary authorities (or by a National Commission).
g) It has to be done respecting the fixed legal terms.

Of the aforementioned requirements the basic one is the need of non viability of the embryos employed for research in Spain. But the Spanish law does not define the concept of viability, so we have to develop an interpretation of the legal terms in order to determine which embryos are viable under the Spanish legal framework and which are not.

In principle, we understand the term "viable" in a biological sense (opinion confirmed by two decisions of the Spanish Constitutional Court, decisions 212/1996 and 116/1999), which implies that in principle, in Spain, the only embryos which can be employed for research are those which are unable to develop in order to become a person (such as died embryos, embryos with defects which make impossible their use for reproduction, etc.). Specifically, the aborted pre-embryos are considered non viable ones (as stated by art. 17 of Law 35/1988, of 22th November, on Assisted Reproduction Techniques).

In conclusion, the traditional Spanish legal framework in this field has been very restrictive in relation with the possibility of undergo research with human embryos (and with stem cells obtained thereof).

The aforementioned limitation was particularly constraining, due to the fact that the application of the Assisted Reproduction Techniques in Spain has generated an important number of surplus human embryos.

The Spanish National Commission of Human Assisted Reproduction had underlined in two reports (years 1998 and 2000) the need of considering the possibility of using this surplus embryos to undergo research, due to the fact that the Spanish legal framework establishes that the human embryos once 5 years since their obtention have passed, can no more be used in the field of the assisted reproduction techniques. In February 2003, another Report on "Research with Stem Cells" published by the Adviser Committee on Ethics dependent on the Foundation for Science and Technology (*Comité Asesor de Ética dependiente de la Fundación Española para la Ciencia y la Tecnología*), set some conclusions in this field, pointing out the possible use of surplus embryos from Assisted Reproduction Techniques in order to undergo research. Obviously if the human embryos surpasses this legal term only two options are possible: or to destroy them or to employ them for research, but the Law in force up to November 2003 did not state which option had to be adopted in this case.

In order to establish a general perspective of the Spanish current legal framework in this field we have to mention the importance of Law 45/2003, of 21th November which has modified Law 35/1998, of 22th November, on Assisted Reproduction Techniques. On top of other legal modifications that will be explained in the following lines, this Law has created the National Center of Trasplants and Regenerative Medicine, being developped by Royal Decree 176/2004, of 30th January, which has aproved the legal status of the National Center of Trasplants and Regenerative Medicine.

So it has to be said that as a result of the public debate generated in Spain, the former national government decided to change the legal framework in field of research and experimentation with human embryos. In November 2003, a modification of Law 35/1988 (Law 45/2003, of 21 November, which modifies Law 35/1988, of 22th

November, of Assisted Reproduction Techniques) was approved in the Spanish Parliament, adopting several measures in this field:

- First of all, and in order to avoid the creation of surplus embryos, the new regulation in force in Spain limits to 3 the number of embryos which could be transferred to the woman in each cycle (having been fecundated 3 ovules per cycle). Due to this fact, the idea is to avoid the existence of surplus embryos in Spain in a long term.

The only exception to this limit will be the case of couples with serious reproductive problems which will be allowed to have a major number of embryos transferred per cycle, being the wole process controlled by the sanitary authorities.

- Related to the surplus embryos already existing in Spain the couples have to decide their destiny between the following options:
  - To maintain them cryoconserved until the end of the 5 years legal term in order to have them transferred during this period.
  - To donate them to other couples with reproductive purposes.
  - To allow their use for research and experimentation (under the responsibility of the National Centre of Transplants and Regenerative Medicine).
  - To defrost them with no ulterior purpose.

Under the legislation in force in Spain research can not only be developped in non viable human embryos, but in surplus embryos fulfilling the aforementioned conditions too.

4. Could you please indicate if any new legal and/or regulatory framework for human embryonic stem cells research and use is under preparation?

Change in the national government as a consequence of the last elections will probably give raise to important modifications in the legislation in force in the field of research and experimentation with embryonic stem cells. One of the points in the programme of the Spanish Socialist Party was the modification of the Laws affecting research and experimentation with human embryos, in order to increase the possibilities for such research. So it can be said that a new regulatory framework for human embryonic stem cells research and use is or will be under preparation in Spain. Previously, one Autonomous Community gobernated by Socialist Party (Andalusia) had regulated research with human embryos non viable for in vitro fertilisation (see Annex).

Annex:

1) Law 45/2003, of 21th November which has modified Law 35/1998, of 22th November, on Assisted Reproduction Techniques

LEY 45/2003, de 21 de noviembre, por la que se modifica la Ley 35/1988, de 22 de noviembre, sobre Técnicas de Reproducción Asistida.

http://www.boe.es/g/es/boe/dias/2003-11-22/seccion1.php

2) **Law 7/2003, of 20th October, which regulates the research in Andalusia with Human Preembryos non viable for in vitro fertilization**

Ley 7/2003, de 20 de octubre, por la que se regula la investigación en Andalucía con preembriones humanos no viables para la fecundación in vitro.

http://www.boe.es/boe/dias/2003-11-21/pdfs/A41238-41241.pdf

Annex

FUNDACIÓN ESPAÑOLA PARA LA CIENCIA Y LA TECNOLOGÍA
SPANISH FOUNDATION ON SCIENCE AND TECHNOLOGY

Comité Asesor de Ética en la Investigación Científica y Tecnológica
Ethics Advisory Committee on Scientific and Technological Research

Informe sobre la investigación sobre células troncales
Report on Research on Stem Cell

RECOMMENDATIONS

1) The research with animal stem cells will have to be treated as a priority when the results of the investigations can be extrapolated to those that can be obtained with human cells.

2) The research with adult human stem cells does not raise a specific ethical problem as they are derived from adult tissues. The case of the obtaining of those cells from umbilical cord or from miscarried foetus leads to a similar situation. This Committee recommends intensifying the investigation with this kind of cells, considering their great plastic potentiality.

3) The investigation that uses established lines of stem cells does not raise a specific ethical problem.

4) The research with embryonic human stem cells does generate ethical problems, as they must be derived from early embryos. This Committee knows this problem, and estimates that the early embryo has a value and it deserves special respect, but this value can be pondered with regard to other values.

5) In our country there are thousands of surplus human embryos remaining after *in vitro* fertilisations. Considering the presumed negative effect of the long freezing, as well as their possible destruction once the term settled by law is overcome, this Committee recommends their use to obtain embryonic stem cells, against the alternative of their destruction. Since the investigations with these cells can produce results that can be applicable to the prevention and treatment of serious diseases.

6) The use of these surplus embryos will be acceptable under the following conditions:

i) The parents´ informed consent or, if this is not possible, the permission of the Centre of Assisted Reproduction in charge of keeping the embryos according to the regulation in force.
ii) The investigation must have the aim of alleviating the human suffering and not just economic ends.
iii) It must be exclusively done by working groups with a proved experience in this field.
iv) The protocol of investigation must be previously evaluated by Ethics Committees and it must be under their exhaustive control. Therefore, the control and supervision of these investigations by a national committee is recommended.

7) Avoiding the accumulation of surplus embryos in the Centres of Assisted Reproduction is recommended. It must be reduced to the minimum, and the cataloguing and control of them should be intensified. Promoting the donation of those embryos to couples, who need them with reproductive ends, is desirable.

8) The applicable legislation will have to be modified in order to establish an appropriate legal framework with regard to the research with stem cells derived from surplus embryos.

9) The specific creation of human embryos in order to derive stem cells for investigation is not recommended.

10) The experimentation with stem cells on human beings must be preceded by exhaustive samples on animals. These experiments must be done according to the applicable legislation on clinical trials and clinical research. Notwithstanding the Spanish law ought to be modified in the future to regulate these new techniques.

11) Given that the adult stem cells and embryonic ones have specific features, this Committee estimates that there is no competition between both researches. So, the Committee recommends the investigation with both types of cells.

Survey on Human Embryonic Stem Cells research and use

SWEDEN

1. Has your National Ethics Committee or similar body provided an opinion on human embryonic stem cells research and use?

X yes

The Swedish Research Council published ethical guidelines for stem cell research in December 2001 (http://www.vetenskapsradet.se.

In brief, the guidelines mean that researchers may take stem cells from embryos that can no longer be used for further IVF treatment. Moreover, the creation of embryos by somatic cell nuclear transfer (therapeutic cloning) to get access to stem cells is deemed to be ethically defensible. The reason for this is the prospect for major long-term advances in treating diseases. However, therapeutic cloning cannot be allowed in the present legal situation, and the Board of the Swedish Research Council proposes a review of legislation.

The Swedish National Council on Medical Ethics (Statens Medicinsk-Etiska Raad) has also produced an opinion (http://www.smer.gov.se/)

The Council holds that embryonic stem cell research:

- is ethically defensible on the condition that it is conducted in controlled forms and under public scrutiny, including legally regulated ethical examination of each individual project by a committee of research ethics;
- is permissible only if there are no scientifically well-founded and ethically acceptable alternatives for attaining the same goals of knowledge;
- may, after careful information to, and free informed consent from, both the woman and the man, use fertilised eggs which are left after test-tube fertilisation and which have been donated explicitly for this purpose;
- does not justify the creation of embryos, through test-tube fertilisation, solely for research purposes;
- must be subject to continued evaluation and ethical discussion, in pace with the growth of knowledge and the development of new techniques;
- must be protected from unethical commercialisation.

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2. Will (or has) a public debate take(n) place on human embryonic stem cells?

X yes ☐ no

If yes, how was / will it be organised, what were the conclusions; who is the contact person?

The debate was rather intense, in the media and various political bodies and meetings, during the fall of 2001. In the end, there was a general consensus that embryonic stems cell research is acceptable, under certain conditions. However, cell nuclear transfer (therapeutic cloning) remains a dividing issue, with a minority being opposed to such procedures. The debate is likely to be rekindled, when the present Parliamentary Committee on Genetic Integrity presents its report on January 29, 2003.

(The description of the Swedish debate could perhaps be a bit more nuanced. There may be a more or less general consensus concerning the acceptability of stem cell research being performed on left-over fertilised eggs, but there are still groups and individuals in the Swedish society who take a different stand on this issue. Whether or not a majority of the population is actually in favor of therapeutic cloning would also seem unclear).

3. Could you please describe the current legal and/or regulatory framework for human embryonic stem cells research and use in your country and indicate a contact person?

The Act (1991:115) on Measures for Purposes of Research and Treatment Involving Ferlilized Human Ova is considered applicable to *in vitro* research aimed at procuring stem cells from fertilised human eggs. According to this Act, research is legally permissible until 14 days after conception (not counting frozen time of a maximum of five years), after which the fertilised egg must be destroyed. The Act does not, however, regulate the creation of embryos for research, nor any measures with embryos that have not been produced by fertilization.

The Act (2002:297) on Biobanks in Health Care, which entered into force January 1, 2003, regulates the collection, storage and use of identifiable human biological material, for certain purposes. If a biobank is set up within the professional activities of a health care provider, or by the receipt of samples from such a bank, the biobank will thus come under the new Act. It is unclear what degree of manipulation or processing will be required in order for the biological material to cease being a sample under the Act on Biobanks.

Section 15 of the Transplant Act (1995:831) prohibits certain commercialisation of human biological material, but it has been questioned if the provision is really formulated in a way that covers human embryos.

4. Could you please indicate if any new legal and/or regulatory framework for human embryonic stem cells research and use is under preparation

In January 2003, the Parliamentary Committee on Genetic Integrity presented a report on the regulation of stem cell research (Rättslig reglering av stamcellsforskning, SOU 2002:119, available in Swedish with an English summary at http://social.regeringen.se/propositionermm/sou/pdf/sou2002/sou2002_119.pdf

In short, the Committee proposes that
- No general prohibition of producing fertilised eggs for research purposes should be introduced

- Donation of human ova for research purposes should not be forbidden
- transfer of somatic cell nuclei should not be prohibited, but subject to limitations corresponding to those that apply to research on fertilised eggs
- Reproductive cloning should be unequivocally forbidden
-The Transplant Act (1995:831) should be clarified to prohibit also commercialisation of human embryos, as well as cells and cell lines from embryos.

The rather non-regulative character of the proposals concerning stem cell research is motivated by the recent introduction of the comprehensive new Act (2003:460) on Ethics Review of Research Involving Humans, which has been passed by the Swedish Parliament and will enter into force January 1, 2004. Research involving identifiable human biological material will then be subject to mandatory ethics review, and certain fundamental requirements must be met in order for the project to be approved. In the light of this new legislation, the Committee on Genetic Integrity does not find additional legislation on stem cell research to be quite so necessary.

The Swedish government adopted in June 2004 a new bill which has been sent to the parliament for discussion in autumn.

In short, the bill proposes
- No general prohibition of producing fertilised eggs for research purposes
- That donation of human ova for research purposes should be allowed
- That transfer of somatic cell nuclei should not be prohibited, but subject to limitations corresponding to those that apply to research on fertilized eggs
- That reproductive cloning should be unequivocally forbidden

Contact Person:
Mr Hans Gunnar-Axberger, Associate Professor of Law
Head Secretary to the Parliamentary Committee on Genetic Integrity;
e-mail: hans-gunnar.axberger@telia.com

Survey on Human Embryonic Stem Cells research and use

UNITED KINGDOM

1. Has your National Ethics Committee or similar body provided an opinion on human embryonic stem cells research and use?

X yes ☐ no

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

Yes, The House of Lords Select Committee published a report in 2002, see :

http://www.parliament.the-stationery-office.co.uk/pa/ld200102/ldselect/ldstem/83/8301.htm

The Government response to the House of Lords Select Committee report on "Stem Cell Research" was published in July 2002 (www.doh.gov.uk/stemcellresearch/)

The Nuffield Council published a short discussion paper called 'Stem cell therapy; the ethical issues' in 2000. This can be obtained in full from the Council's website; http://www.nuffieldfoundation.org/bioethics/publication/index.html.

The paper was prepared by Professor Martin Bobrow CBE, Professor Tom Baldwin, Lady Hornby, Professor Alexander McCall Smith and Dr Anne McLaren DBE FRS. The members can be contacted via the Council.

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2. Will (or has) a public debate take(n) place on human embryonic stem cells?

X yes ☐ no

If yes, how was / will it be organised, what were the conclusions; who is the contact person?
Much public debate in this country was generated by patient groups, including:

The Association of Medical Research Charities.

Chief Executive: Mrs Diana Garnham. www.amrc.org.uk

The Parkinson's Disease Society; www.parkinsons.org.uk

The Alzheimer's Disease Society; Mr Harry Cayton, www.alzheimers.org.uk

An on-line Consultation for the House of Lords Committee on Stem Cell Research (www.publicevidence.net) took place in 2001.

3. Could you please describe the current legal and/or regulatory framework for human embryonic stem cells research and use in your country and indicate a contact person?

The Human Fertilisation and Embryology Authority (HFEA) (www.hfea.gov.uk/) is responsible for licensing and regulating, *inter alia*, any research involving the creation or use of human embryos.

Embryo research is permitted under the HFEA Act for any of five specified purposes, briefly:

- To promote advances in the treatment of infertility
- To increase knowledge about the causes of congenital disease
- To increase knowledge about the causes of miscarriage
- To develop more effective contraceptive techniques
- To develop methods for detecting gene or chromosome abnormalities in pre-implantation embryos.

In January 2001, Regulations were made extending the purposes for which embryo research could be licensed. The further purposes are:

- To increase knowledge about the development of embryos
- Increasing knowledge about serious disease
- To enable such knowledge to be applied in developing treatments for serious disease.

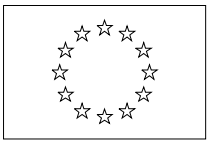
Isolated embryonic cell lines are not covered by the 1990 Act nor the 2001 Regulations. The Medical Research Council has established an oversight committee for the UK's new national stem cell bank. This committee has been asked to prepare a code of practice for use of isolated embryonic stem cell lines."

Details of the current legal and future changes can be obtained from the Department of Health –http://www.doh.gov.uk/stemcellresearch/index.htm

4. Could you please indicate if any new legal and/or regulatory framework for human embryonic stem cells research and use is under preparation

No

OPINION OF THE EUROPEAN GROUP ON ETHICS REGARDING ETHICAL ASPECTS OF HUMAN STEM CELL RESEARCH AND USE



OPINION OF THE EUROPEAN GROUP ON ETHICS
IN SCIENCE AND NEW TECHNOLOGIES
TO THE EUROPEAN COMMISSION

No 15 14 November 2000

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ETHICAL ASPECTS OF HUMAN STEM CELL RESEARCH AND USE

Reference: Initiative of the Group
Rapporteurs: Anne McLaren and Göran Hermerén

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The European Group on Ethics in Science and New Technologies (EGE),

Having regard to the Treaty on European Union as amended by the Treaty of Amsterdam, and in particular Article 6 (formerly Article F) of the common provisions, concerning the respect for fundamental rights, Article 152 (formerly Article 129) of the EC Treaty on public health, (namely paragraph 4(a) referring to substances of human origin) and Articles 163-173 (formerly Articles 130F-130P) on research and technological development;

Having regard to the European Parliament and Council Directive 65/65/CEE of 26 January 1965 and the modified Directive 75/319/CEE of 20 May 1975 concerning medicinal products;

Having regard to the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and the European Parliament and Council Directive 98/79/EC of 27 October 1998 concerning *in vitro* diagnostic medical devices, in particular Article 1-4 which refers to ethics and requires the respect of the principles of the Convention of the Council of Europe on Human Rights and Biomedicine, with regard to the removal, collection and use of tissues, cells and substances of human origin;

Having regard to the Council Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions and in particular Article 6, concerning certain inventions excluded from patentability, and Article 7 giving mandate to the European Group on Ethics (EGE) to evaluate "all ethical aspects of biotechnology";

Having regard to the Parliament and Council Decision of 22 December 1998 concerning the 5th Framework Programme of the European Community for research, technological development and demonstration activities (1998-2002) and in particular Article 7 requesting compliance with fundamental ethical principles;

Having regard to the Council Decision of 25 January 1999 adopting the specific programme for research, technological development and demonstration activities on quality of life and management of living resources and in particular the ethical requirements mentioned in its Annex II;

Having regard to the Charter of 28 September 2000 on Fundamental Rights of the European Union, approved by the European Council in Biarritz on October 14th 2000, in particular Article 1 on “Human dignity”, Article 3 on the “Right to the integrity of the person”, which refers to the principle of "free and informed consent" and prohibits "the reproductive cloning of human beings" and Article 22 on “Cultural, religious and linguistic diversity”;

Having regard to the Council of Europe’s Convention on Human Rights and Biomedicine, signed on 4 April 1997 in Oviedo, in particular Article 18 on embryo research, and to the additional protocol to the Convention on the prohibition of cloning human beings signed on 12 January 1998 in Paris;

Having regard to the Universal Declaration on the Human Genome and Human Rights adopted by the United Nations on 11 December 1998, in particular Article 11 which recommends to prohibit reproductive cloning of human beings, and Article 13 which refers to the responsibilities of researchers as well as of science policy makers;

Having regard to national regulations on stem cell and on embryo research and to national ethics bodies opinions, at the European Union level, concerning these subjects;

Having regard to the reports of the US National Bioethics Advisory Committee dated September 13, 1999 on the "Ethical Issues on Human Stem Cell Research", the hearings on the same subject by the US Congress, on April 2000 and the guidelines published by the Clinton administration on August 26, 2000 to be forwarded to a NIH (National Institutes of Health) scientific review in 2001;

Having regard to the Round Table organised by the Group on 26 June 2000 in Brussels with members of the European Parliament, jurists, philosophers, scientists, representatives of industries, of religions, of patients' associations, and of international organisations (Council of Europe, UNESCO, WHO);

Having regard to the Hearings of scientific experts on 6 June 2000 and on 2 October 2000, and to the Hearings of representatives of religions on 8 September 2000;

Having heard the rapporteurs Anne McLaren and Goran Hermerén;

1 - WHEREAS

SCIENTIFIC BACKGROUND

1.1. How to define stem cells?

Stem cells are cells that can divide to produce either cells like themselves (self-renewal), or cells of one or several specific differentiated types. Stem cells are not yet fully differentiated and therefore can reconstitute one or several types of tissues.

1.2. What are the different kinds of stem cells?

Different kinds of stem cells can be distinguished according to their potential to differentiate. They are progenitor, multipotent or pluripotent stem cells.

- Progenitor stem cells are those whose terminally differentiated progeny consist of a single cell type only. For instance, epidermal stem cells or spermatogonial stem cells can differentiate respectively into only keratinocytes and spermatozoa.

- Multipotent stem cells are those which can give rise to several terminally differentiated cell types constituting a specific tissue or organ. Examples are skin stem cells which give rise to epidermal cells, sebaceous glands and hair follicles or haematopoietic stem cells, which give rise to all the diverse blood cells (erythrocytes, lymphocytes, antibody-producing cells and so on), and neural stem cells, which give rise to all the cell types in the nervous system, including glia (sheath cells), and the many different types of neurons.

- Pluripotent stem cells are able to give rise to all different cell types *in vitro.* Nevertheless, they cannot on their own form an embryo. Pluripotent stem cells, which are isolated from primordial germ cells in the foetus, are called: embryonic germ cells ("EG cells"). Those stem cells which are isolated from the inner cell mass of a blastocyst-stage embryo are called: embryonic stem cells ("ES cells").

It should be noted that scientists do not yet all agree on the terminology concerning these types of stem cells.

1.3. What are the characteristics of the different stem cells?

Progenitor and multipotent stem cells may persist throughout life. In the foetus, these stem cells are essential to the formation of tissues and organs. In the adult, they replenish tissues whose cells have a limited life span, for instance skin stem cells, intestinal stem cells and haematopoietic stem cells. In the absence of stem cells, our various tissues would wear out and we would die. They are more abundant in the foetus than in the adult. For instance haematopoietic stem cells can be derived from adult bone marrow but they are particularly abundant in umbilical cord blood.

Pluripotent stem cells do not occur naturally in the body, which distinguishes them from progenitor and multipotent stem cells.

1.4. Where can stem cells be found?

The possible sources of stem cells include adult, foetus and embryos. Accordingly, there are:

- Adult stem cells: progenitor and multipotent stem cells are present in adults. Mammals appear to contain some 20 major types of somatic stem cells that can generate liver, pancreas, bone and cartilage but they are rather difficult to find and isolate. For instance, access to neural stem cells is limited since they are located in the brain. Haematopoietic stem cells are present in the blood, but their harvesting requires stimulatory treatment of the donor's bone marrow. By and large, adult stem cells are rare and do not have the same developmental potential as embryonic or foetal stem cells.

- Stem cells of foetal origin:

  - Haematopoietic stem cells can be retrieved from the umbilical cord blood.

  - Foetal tissue obtained after pregnancy termination can be used to derive multipotent stem cells like neural stem cells which can be isolated from foetal neural tissue and multiplied in culture, though they have a limited life span. Foetal tissue can also give rise to pluripotent EG cells isolated from the primordial germ cells of the foetus.

- Stem cells of embryonic origin: Pluripotent ES cells are those which are derived from an embryo at the blastocyst stage. Embryos could be produced either by *in vitro* fertilisation (IVF) or by transfer of an adult nucleus to an enucleated egg cell or oocyte (somatic cell nuclear transfer – SCNT).

1.5. Human embryonic development

- At two to three days after fertilisation, an embryo consists of identical cells which are totipotent. That is to say that each could give rise to an embryo on its own producing for example identical twins or quadruplets. They are totally unspecialised and have the capacity to differentiate into any of the cells which will constitute the foetus as well as the placenta and membranes around the foetus.

- At four to five days after fertilisation (morula stage), the embryo is still made up of unspecialised embryonic cells, but these cells can no longer give rise to an embryo on their own.

- At five to seven days after fertilisation (blastocyst stage), a hollow appears in the centre of the morula, and the cells constituting the embryo start to be differentiated into inner and outer cells:

  - The outer cells will constitute the tissues around the foetus, including the placenta.

  - The inner cells (20 to 30 cells) will give rise to the foetus itself as well as to some of the surrounding tissues. If these inner cells are isolated and grown in the presence of certain chemical substances (growth factors), pluripotent ES cells can be derived. ES cells are pluripotent, not totipotent since they cannot develop into an embryo on their own. If they are transferred to a uterus, they would neither implant nor develop into an embryo.

HISTORICAL BACKGROUND

1.6. Research on animals

- Embryonic stem cells

  Scientists have been working with mouse embryonic stem cells *in vitro* for more than 20 years, noting very early their remarkable capacity to divide. Some mouse ES cell lines have been cultured for more than 10 years, while retaining their ability to differentiate.

  There is today some evidence from animal models that multipotent stem cells can be used for somatic therapy. Convincing evidence however has been provided up until now from ES cell-derived, and not adult derived multipotent somatic cells. For instance neural differentiated mouse ES cells when transplanted into a rat spinal cord several days after a traumatic injury can reconstitute neuronal tissue resulting in the (partial) recovery of hindlimb co-ordinated motility. Similarly, selected cardiomyocytes obtained from differentiating ES cells can be grafted into the heart of dystrophic mice to effect myocardial repair. Whether the same cellular derivatives when obtained from adult stem cells would be able to correct for the deficiencies induced in those animal models remains to be determined.

  Much research on mouse ES cells has also been focused on using these cells to create transgenic animals, in particular as disease models to study human genetic disorders.

- Adult stem cells

  Research is also carried out on mouse adult stem cells. While many scientists had assumed that these cells were programmed to produce specific tissues and were thus no longer able to produce other sorts of tissue, recent studies suggest that adult stem cells may be able to show more malleability

than previously believed. For instance, it has been shown that mouse neural stem cells could give rise, in specific conditions of culture, to cells of other organs such as blood, muscle, intestine, liver and heart. Moreover marrow stromal cells can generate astrocytes, a non-neuronal type of cell of the central nervous system and haematopoietic stem cells can give rise to myocytes.

1.7. First grafts of human foetal cells

Stem cells in tissues such as skin or blood are able to repair the tissues throughout life. By contrast, the nervous system has a very limited capacity for self-repair because the neural stem cells in the adult brain are few in number and have a poor capacity to generate new neurons for instance to repair injury.

Based on the positive results of experimentation on rodents and primates, clinical trials in patients with Parkinson's disease have been performed on around 200 patients over the last 10 years especially in Sweden and the USA. They have shown that the transplantation of neural cells derived from the human foetus can have a therapeutic effect, with an important reduction of the symptoms of the disease in the treated patients. The clinical improvement among these patients has been observed for 6-24 months after transplantation and in some cases for 5-10 years. It has recently been shown that 10 years after the transplantation surgery, the transplanted neural cells were still alive and producing dopamine, the compound which is deficient in the brain of patients with Parkinson's disease.

However, this therapeutic approach still remains experimental. In addition, the availability of neural foetal tissue is very limited. Five to six aborted foetuses are needed to provide enough neural tissue to treat one Parkinson's patient. That is why new sources of neural cells have been explored in some countries such as the US and Sweden. The aim is to derive neural stem cells from foetuses: these stem cells could be induced to proliferate in culture, providing much greater amounts of neural tissue for transplantation.

1.8. Transplantation of human haematopoietic stem cells

The transplantation of human haematopoietic stem cells is routinely used to restore the production of blood cells in patients affected by leukaemia or aplastic anaemia after chemotherapy. There are two sources of haematopoietic stem cells:

- Adult stem cells: they can be retrieved under anaesthesia, from the bone marrow of donors, or from the patients themselves (before chemotherapy). Haematopoietic stem cells can also be retrieved directly from the blood, which requires a treatment to induce the passage of stem cells from the bone marrow into the blood circulation.
- Stem cells of foetal origin: haematopoietic stem cells can be retrieved from the umbilical cord blood at birth, though care must be taken to ensure that the baby receives enough cord blood. There are at present cord blood banks designated to facilitate haematopoietic stem cell transplantation. The systematic retrieval and cryopreservation of cord blood, at birth, has even been considered in order to have autologous stem cells available in case of later need. Stem cells of foetal origin give rise to less rejection reaction than adult stem cells.

1.9. Discoveries on human stem cells

In the late 70's, the progress of infertility treatment led to the birth of the first child by *in vitro* fertilisation. The formation of human embryos *in vitro* during the course of infertility treatment has made possible the study of human embryogenesis following fertilisation, and thus has increased our knowledge of the behaviour and characteristics of embryonic cells at a very early stage.

Since 1998, derivation and culture of embryonic and foetal human pluripotent stem cells has been performed, a process which had never been achieved before with human cells. A team at the University of Wisconsin in Madison (USA) announced in November 1998 that it had successfully isolated and cultured for several months cells from 14 human blastocysts obtained from donated surplus embryos produced by *in vitro* fertilisation. This team established five embryonic ES cell lines with the ability to be grown continuously without losing their capacity to differentiate into the many kinds of cells that constitute the body. At the same time, a team at the Johns Hopkins University in Baltimore (USA) reported that foetal primordial germ cells had been isolated from the gonads of foetuses obtained after pregnancy termination and cultured to make EG cells. Cell lines derived from these cells were grown for many months while maintaining the same capacity to differentiate as the ES cell lines.

In 1999, research on adult stem cells revealed that their plasticity was much higher than previously thought. Adult neural stem cells have been reported to give rise occasionally to other cell types including blood cells. A team at the University of Minnesota in Minneapolis, (USA) has shown that cells isolated from the bone marrow of adults or children were able to become neural or muscle cells. Nevertheless, bone marrow cells with such extraordinary malleability are extremely rare. In any case, these recent findings still require to be substantiated.

The future challenge is to control the differentiation of human stem cells. It has been shown in animals that by culturing stem cells in the presence of certain chemical substances referred to as "growth factors", it is possible to induce differentiation of specific cell types. Experiments on human stem cells are less advanced but finding ways to direct differentiation is presently an active focus of research.

1.10. What is the main interest of stem cell research and what are the hopes?

The main interests at present include:

- Basic developmental biology. Culturing of human stem cells offers insights that cannot be studied directly in the human embryo or understood through the use of animal models. For instance, basic research on stem cells could help to understand the causes of birth defects, infertility and pregnancy loss. It could also be useful to give a better understanding of normal and abnormal human development.

- Studies of human diseases on animal models. For example, mouse ES cells can be engineered to incorporate human mutated genes known to be associated with particular diseases and then used to make transgenic mouse strains. If such mice express the pathology of the human disease, this confirms the hypothesis that the gene is involved with the etiology of the disease. This strategy also yields an animal model of the human disease which has in most cases a much better predictability for the human situation than more conventional animal models. One of the most illustrative examples of that method is its use in order to address the potential causes of Alzheimer's disease.

- Culturing specific differentiated cell lines to be used for pharmacology studies and toxicology testing. This is the most likely immediate biomedical application, making possible the rapid screening of large numbers of chemicals. By measuring how pure populations of specific differentiated cells respond to potential drugs, it will be possible to sort out medicinal products that may be either useful or on the contrary problematic in human medicine.

- Use of stem cells in gene therapy. Stem cells could be used as vectors for the delivery of gene therapy. One current application in clinical trials is the use of haematopoietic stem cells genetically modified to make them resistant to the HIV (virus responsible for AIDS).

- Production of specific cell lines for therapeutic transplantation. If feasible, this would be the most promising therapeutic application of ES cells. Research is being actively pursued, mostly in the mouse, with the aim of directing the differentiation of pluripotent stem cells to produce pure populations of particular cell types to be used for the repair of diseased or damaged tissues. For instance, the aim would be to produce cardiac muscle cells to be used to alleviate ischaemic heart disease, pancreatic islet cells for treatment of diabetes (juvenile onset diabetes mellitus), liver cells for hepatitis, neural cells for degenerative brain diseases such as Parkinson's disease, and perhaps even cells for treating some forms of cancer. The transplantation of stem cells could also help, for example, to repair spinal cord damage which occurs frequently, mainly following trauma (for instance car accidents) and is responsible for paraplegia. Results of that kind of cell therapy on animals are promising, but are still years away from clinical application. Even more remote (possibly decades away) is the prospect of being able to grow whole organs *in vitro*, but if tissues for the repair of organs become available, it would greatly relieve the existing unsatisfied demand for donated organs for transplantation. In providing a potentially unlimited source of specific clinically important cells such as bone, muscle, liver or blood cells, the use of human stem cells could open the way to a new "regenerative medicine".

1.11. Why is somatic cell nuclear transfer (SCNT) considered?

Apart from its interest for basic research, SCNT is considered as a possible strategy, in "regenerative medicine", for the avoidance of immunological problems after transplantation. Neural tissues can sometimes be transplanted from one individual to another without suffering immunological rejection, but for all other tissues, stem cell therapy would need to be accompanied by long-term treatments with immunosuppressive drugs, leading to increased susceptibility to infections and even to cancer.

- One approach to avoid this immune rejection problem would involve genetic engineering of stem cells to render them non-antigenic, or immunological manipulation of the patients to render them tolerant.

- An alternative approach is based on somatic cell nuclear transfer. It consists of transferring nuclei from the patient's own body cells into donated human or even animal unfertilised eggs from which the nuclei have been removed. If these reconstructed eggs were stimulated for example with electricity to develop to the blastocyst stage, pluripotent stem cells could be derived from them to form cells genetically identical to the patient. No rejection of any transplanted cells would then occur.

- Related technology could lead to the cloning of human individuals if the reconstructed embryos were transferred to a woman's uterus. However, this is contrary to European Community law and prohibited in most European countries.

1.12. Possible origins of the embryos in countries which allow embryo research

These embryos are:

  - either «spare embryos» (i.e. supernumerary embryos) created for infertility treatment to enhance the success rate of IVF, but no longer needed for this purpose. They are intended to be discarded but, instead, may be donated for research by the couples concerned,

  - or research embryos, created for the sole purpose of research.

- These may either be produced with donated gametes, i.e. they are derived from the fertilisation *in vitro* of a human oocyte by a human sperm,

- or they may be produced by embryo splitting or nuclear transfer. In the latter case they would be derived by introducing the nucleus of an adult somatic cell into an enucleated human oocyte (sometimes misleadingly termed "embryo cloning" or "therapeutic cloning").

LEGAL BACKGROUND

1.13. Legal situation in the Member States

At national level, stem cell research is not regulated as such.

With regard to embryonic stem cell research, it is thus necessary to refer to the general legislation on embryo research. In this respect, the situation in the Member States is diverse:

- Ireland is the only country of the EU whose Constitution affirms the right to life of the "unborn" and that this right is equal to that of the mother.

- In some Member States no legislation on embryo research exists. This is the case of Belgium and of the Netherlands, where embryo research is nevertheless carried out. In Portugal however, in the absence of legislation, no embryo research seems to be performed. This also seems to be the case in Italy although artificial reproductive techniques are widely practised.

- Where embryo research is legislated, legislation either prohibits any kind of embryo research (Austria, Germany), or authorises this research under specified conditions (Finland, Spain, Sweden, and UK). In France, where embryo research is still prohibited, the law authorises "the study of embryos without prejudicing their integrity" as well as preimplantation diagnosis.

- In some countries the Constitutional Courts have dealt with the use of human embryos (judgement of the French Constitutional Court of July 27, 1994 on Bioethics, and judgement of the Spanish Constitutional Court of July 10, 1999 on the legislation concerning assisted human reproduction techniques).

The legal situation of many countries in Europe is under development. New legislation is being drafted mainly in response to the challenge of stem cell research.

- In some countries, draft legislation is being prepared to allow research on stem cells derived from supernumerary embryos after *in vitro* fertilisation (The Netherlands).

- In other countries, draft legislation provides for the possibility of creating embryos by nuclear transfer, for the sole purpose of stem cell research. This is the case in Belgium, and in the UK. (In the latter case, legislation allowed creation of embryos for the purpose of research, but only

in relation to the treatment of infertility, to contraception or to the avoidance of genetic disease). In France legislation is under preparation.

1.14. European legislation in the field

At the Council of Europe's level, the Convention on Human Rights and Biomedicine signed in Oviedo in 1997 in its Article 18 establishes that it is up to each country to decide whether to authorise or not embryo research. Each country is only obliged to respect two conditions: "to ensure adequate protection of the embryo", that is to say to adopt a legislation fixing the conditions and limits of such research; and to prohibit "the creation of human embryos for research purposes". The Convention is binding only for the States which have ratified it. In the European Union so far only three countries have completed the procedure and some are in the process of doing so.

At EU level, although there is no legislative competence to regulate research, some Directives allude to the issue of embryo research and use. For instance, the Directive 98/44/EC on the legal protection of biotechnological inventions (patenting on life) stipulates that "processes for cloning human beings" and "uses of human embryos for industrial or commercial purposes"… "shall be considered unpatentable". The Directive 98/79/EC on *in vitro* diagnostic medical devices (including the use of human tissues) provides that " the removal, collection and use of tissues, cells and substances of human origin shall be governed, in relation to ethics, by the principles laid down in the Convention of the Council of Europe for the protection of human rights and dignity of the human being with regard to the application of biology and medicine and by any Member States regulations on this matter".

At this same level, the Charter on Fundamental rights of the European Union approved by the European Council in Biarritz (France) on October 14, 2000 prohibits different kinds of practices possibly related to embryo research, namely "eugenic practices, in particular those aiming at the selection of persons " and "the reproductive cloning of human beings".

1.15. US approach related to embryo research and stem cell research

The situation in the US contrasts with that in Europe. A substantial difference is a sharp distinction between the public and the private sector. Since 1995 the US Congress has been adopting each year a provision in the Appropriation Bill to prohibit public funding for embryo research. Thus, the National Institutes of Health (NIH) cannot carry out embryo research, which, in the absence of legislation, remains free and beyond control in the private sector.

New discoveries concerning the culturing of human stem cells in 1998 have led to the reopening of the debate. The National Bioethics Advisory Committee (NBAC) issued a report on September 1999; hearings took place in 1999 and 2000 before the competent Committees of the US Congress and finally the Clinton administration proposed that, under certain conditions, the funding of research to derive and study human ES cells be permitted. New guidelines of the NIH were published in August 2000 according to which research on human ES cells can be publicly funded if two conditions are respected. First, the cells must be taken from frozen spare embryos from fertility clinics and already destined to be discarded; second, Federal funds could not be used to destroy the embryos to obtain the cells; privately funded researchers will have to pass them on to Federally supported scientists.

ETHICAL BACKGROUND

1.16. Main ethical issues with regard to stem cell research

Human stem cell research is an example of bioethical value conflicts. On the one hand, the prospect of new therapies, even in the far future, is attractive in offering an alternative to organ and tissue donation. On the other hand, when this research involves the use of human embryos, it raises the question of its ethical acceptability and of the limits and conditions for such research. Embryo research has been extensively debated in the context of research carried out to improve IVF as a treatment for infertility. Embryonic stem cell research raises the following specific additional ethical questions:

New types of research to be performed on human embryos. Up until now, research that involved destroying embryos, if allowed, was limited to research on reproduction, contraception or congenital diseases. With human stem cell research, a much wider scope of research is being considered.

The use of ES cells and stem cell lines for therapeutic purposes. Human embryos used for research were destroyed after the research was completed and therefore were never used for fertility treatment. What remained was additional knowledge. Human embryonic stem cell research is aimed at creating cell lines with appropriate characteristics, in terms of purity and specificity. There is thus continuity from the embryonic cells to the therapeutic material obtained by culture.

The creation of embryos for research purposes. This delicate issue is now raised again since there is a scientific justification of this practice, namely the possibility of producing stem cells identical to the patient's cells and thus avoiding problems of rejection in the context of the future “regenerative medicine”. At the same time, creating human embryos raises new ethical concerns. The ethical acceptability of stem cell research depends not only on the objectives but also on the source of the stem cells; each source raising partly different ethical questions. Those who condemn embryo research in general will not accept this difference, but for those who accept it, this issue is of major importance.

1.17. Ethical issues in transplantation of stem cells

Clinical research and potential future applications in this field raise the same ethical issues as those dealt with in the EGE's Opinion on Human Tissue Banking (21/07/1998), concerning the respect of the donor, who should give informed consent to this use of the donated cells, the respect of the autonomy of the patients, their right to safety and to the protection of their private life and the right to a fair and equal access to new therapies.

2 - OPINION

The Group submits the following Opinion:

SCOPE OF THE OPINION

2.1 Ethical issues of stem cell research and use for clinical purposes.

This Opinion reviews ethical issues raised by human stem cell research and use, in the context of the European Union research policy and European Community public health competence to improve human health and to set high standards for the safety of substances of human origin.

With regard to the specific ethical questions related to the patenting of inventions involving human stem cells, on which President Prodi requested an Opinion from the Group on 18 October 2000, this will be made public in Brussels at a later date. The following Opinion therefore excludes the patenting issue.

GENERAL APPROACH

2.2. Fundamental ethical principles at stake

The fundamental ethical principles applicable are those already recognised in former opinions of the EGE, and more specifically:

- The principle of respect for human dignity
- The principle of individual autonomy (entailing the giving of informed consent, and respect for privacy and confidentiality of personal data)
- The principle of justice and of beneficence (namely with regard to the improvement and protection of health)
- The principle of freedom of research (which is to be balanced against other fundamental principles)
- The principle of proportionality (including that research methods are necessary to the aims pursued and that no alternative more acceptable methods are available).

In addition, the Group considers it important to take into account, based on a precautionary approach, the potential long-term consequences of stem cell research and use for individuals and the society.

2.3. Pluralism and European ethics

Pluralism is characteristic of the European Union, mirroring the richness of its tradition and adding a need for mutual respect and tolerance. Respect for different philosophical, moral or legal approaches and for diverse cultures is implicit in the ethical dimension of building a democratic European society.

From a legal point of view, respect for pluralism is in line with Article 22 of the Charter on Fundamental Rights on “Cultural, religious and linguistic diversity” and with Article 6 of the Amsterdam Treaty which ensures the protection of fundamental rights at EU level, notably based on international instruments as well as common constitutional traditions, while also stressing the respect for the national identity of all Member States.

2.4. Principal requirements according to the diverse sources of stem cells.

- The retrieval of **adult stem cells** requires the same conditions as those required in the case of tissue donation, based on respect for the integrity of the human body and the free and informed consent of the donor.

- The retrieval of stem cells **from the umbilical cord blood** after delivery requires that the donor (the woman or the couple concerned) is informed of possible uses of the cells for this specific purpose of research and that the consent of the donor is obtained.

- The retrieval of **foetal tissues** to derive stem cells requires, besides informed consent, that no abortion is induced for the purpose of obtaining the tissues and that the termination timing and the way it is carried out are not influenced by this retrieval.

- The derivation of **stem cells from embryonic blastocysts** raises the issue of the moral status of the human embryo. In the context of European pluralism, it is up to each Member State to forbid or authorise embryo research. In the latter case, respect for human dignity requires regulation of embryo research and the provision of guarantees against risks of arbitrary experimentation and instrumentalisation of human embryos.

2.5. Ethical acceptability of the field of the research concerned.

The Group notes that in some countries embryo research is forbidden. But when this research is allowed, with the purpose of improving treatment for infertility, it is hard to see any specific argument which would prohibit extending the scope of such research in order to develop new treatments to cure severe diseases or injuries. As in the case of research on infertility, stem cell research aims to alleviate severe human suffering. In any case, the embryos that have been used for research are required to be destroyed. Consequently, there is no argument for excluding funding of this kind of research from the Framework Programme of research of the European Union if it complies with ethical and legal requirements as defined in this programme.

2.6. Public control of ES cell research.

The Group deems it essential to underline the sensitivity attached to the use of embryonic stem cells, since this use may change our vision of the respect due to the human embryo.

According to the Group, it is crucial to place ES cell research, in the countries where it is permitted, under **strict public control by a centralised authority** - following, for instance, the pattern of the UK licensing body (the Human Fertilisation and Embryology Authority) - and to provide that authorisations given to such research are highly selective and based on a case by case approach, while ensuring maximum transparency. This must apply whether the research in question is carried out by either the public or the private sector.

2.7. Alternative methods to the creation of embryos for the purpose of stem cell research.

The Group considers that the creation of embryos for the sole purpose of research raises serious concerns since it represents a further step in the instrumentalisation of human life.

- The Group deems the creation of embryos with gametes donated for the purpose of stem cell procurement ethically unacceptable, when spare embryos represent a ready alternative source.

- The Group takes into account interest in performing somatic cell nuclear transfer (SCNT) with the objective of studying the conditions necessary for "reprogramming" adult human cells. It is also aware that, in view of future cell therapy, the creation of embryos by this technique may be the most effective way to derive pluripotent stem cells genetically identical to the patient and consequently to obtain perfectly histocompatible tissues, with the aim of avoiding rejection after transplantation. But, these remote therapeutic perspectives must be balanced against considerations related to the risks of trivialising the use of embryos and exerting pressure on women, as sources of oocytes, and increasing the possibility of their instrumentalisation. Given current high levels of inefficiency in SCNT, the provision of cell lines would require large numbers of oocytes.

- In the opinion of the Group, in such a highly sensitive matter, the proportionality principle and a precautionary approach must be applied: it is not sufficient to consider the legitimacy of the pursued aim of alleviating human sufferings, it is also essential to consider the means employed. In particular, the hopes of regenerative medicine are still very speculative and debated among scientists. Calling for prudence, the Group considers that, at present, the creation of embryos by somatic cell nuclear transfer for research on stem cell therapy would be premature, since there is a wide field of research to be carried out with alternative sources of human stem cells (from spare embryos, foetal tissues and adult stem cells).

2.8. Stem cell research in the European Framework Programme of research

Stem cell research based on alternative sources (spare embryos, foetal tissues and adult stem cells) requires a specific Community research budget. In particular, EU funding should be devoted to testing the validity of recent discoveries about the potential of differentiation of adult stem cells. The EU should insist that the results of such research be widely disseminated and not hidden for reasons of commercial interest.

At European Union level, within the Framework Programme of research, there is a specific responsibility to provide funding for stem cell research. This implies the establishment of appropriate procedures and provision of sufficient means to permit ethical assessment not only before the launching of a project but also in monitoring its implementation.

2.9. Stem cell research and rights of women

Women who undergo infertility treatment are subject to high psychological and physical strain. The Group stresses the necessity to ensure that the demand for spare embryos and oocyte donation does not increase the burden on women.

CLINICAL RESEARCH ON HUMAN STEM CELLS

The speed with which researchers, throughout the world, are moving to test stem cells in patients is remarkable, even if ES cell transplantation is unlikely to be attempted in the near future. Clinical trials with stem cells other than ES carried out on patients suffering from severe conditions such as Parkinson's disease, heart disease or diabetes raise the following issues:

2.10. Free and informed consent

Free and informed consent is required not only from the donor but also from the recipient as stated in the Group's opinion on Human Tissue Banking (21/07/1998). In each case, it is necessary to inform the donor (the woman or the couple) of the possible use of the embryonal cells for the specific purpose in question before requesting consent.

2.11. Risk-benefit assessment

Risk-benefit assessment is crucial in stem cell research, as in any research, but is more difficult as the uncertainties are considerable given the gaps in our knowledge. Attempts to minimise the risks and increase the benefits should include optimising the strategies for safety. It is not enough to test the cultured stem cells or tissues derived from them for bacteria, viruses or toxicity. Safety and security aspects are of utmost importance in the transplantation of genetically modified cells and when stem cells are derived from somatic cells. For example, the risks that transplanted stem cells cause abnormalities or induce creation of tumours or cancer have to be assessed. It is important that the potential benefits for the patients should be taken into account but not exaggerated. The grounds of a precautionary approach need to be taken into account.

2.12. Protection of the health of persons involved in clinical trials

The possibility that irreversible and potentially harmful changes are introduced in clinical applications of stem cell research should be minimised. Techniques enhancing the possibilities of reversibility should be used whenever possible. If, for example, genetically modified cells were encapsulated when they are transplanted in order to stimulate neural cell growth, it should be possible for the procedure to be reversed if something goes wrong.

2.13. Scientific evaluation of stem cell use for therapeutic purposes

It is urgent to outline strategies and specific requirements for the best evaluation of ethically sound and safe use of stem cells as means of therapy (gene therapy, transplantation, etc.). Such an evaluation should be done in collaboration with the European Agency for the Evaluation of Medicinal Products.

2.14. Anonymity of the donation

Steps must be taken to protect and preserve the identity of both the donor and the recipient in stem cell research and use. As stated in the EGE's Opinion on Human Tissue Banking (21/07/1998): "in the interests of anonymity, it is prohibited to disclose information that could identify the donor, and the recipient. In general, the donor should not know the identity of the recipient, nor should the recipient know the identity of the donor".

2.15. Stem cell banks and safety

Procurement and storage of stem cells in stem cell banks leads to the collection and storage of a growing number of personal and familial data. Cell banks should be regulated at European level in order to facilitate the implementation of a precautionary approach. If unsatisfactory side effects occur, it should be possible to trace donor and recipient and to reach their medical files. Traceability must be one of the conditions required for the authorisation of cell banks at national or European level.

2.16. Stem cell banks and confidentiality

In order to reconcile the traceability requirement and the need to protect the donor's rights - medical confidentiality and privacy - cell banks must take the necessary steps to protect confidentiality of the data.

2.17. Prohibition of commerce in embryos and cadaveric foetal tissue

The potential for coercive pressure should not be underestimated when there are financial incentives. Embryos as well as cadaveric foetal tissue must not be bought or sold, and not even offered for sale. Measures should be taken to prevent such commercialisation.

2.18. Export and import of stem cell products

Stem cell imports or exports should be licensed by public authorities either at national or European level. Authorisation should be subject to ethical as well as safety rules.

2.19. Education and dialogue

There is a need for continuing dialogue and education to promote the participation of citizens, including patients, in scientific governance, namely in the social choices created by new scientific developments.

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