



**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 II  
Countries acceding to the EU,  
Countries associated to FP6  
and Third Countries**

**Edited by Line MATTHIESSEN-GUYADER**

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**Directorate E  
Biotechnology, Agriculture and Food**



## EUROPEAN COMMISSION

Directorate General: RESEARCH

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](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](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](mailto: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.

Etienne MAGNIEN  
Acting Director

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<sup>1</sup> FP6: the 6<sup>th</sup> Framework Programme of the European Community for Research, Technological Development and Demonstration Activities (2002-2006); websites: <http://europa.eu.int/comm/research/fp6/index.html> ; <http://fp6.cordis.lu/fp6/home.cfm>

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## **COUNTRIES ACCEDING TO THE EU**

# 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. In March it will be a theme for the conference of the Bioethics Commission of the Czech Government.

## 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.

- 
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 exception, 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

### 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?

---

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](mailto: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.

## 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

Contact person: **Prof. Katalin Pálóczy**, Országos Haematológiai és Immunológiai Intézet, BUDAPEST, Daróczi út 24, H-1113

## 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 Embryo. There is not any regulations directly on human embryonic 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 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 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?**

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

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](http://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](mailto:lbek@sam.lt)

## 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:

- 
- 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?

- 
- 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 Cell Research and Use**

**POLAND**

## 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?**

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](mailto:joze.trontelj@kclj.si)

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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?

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 than 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.

## **COUNTRIES ASSOCIATED TO FP6**

## Survey on Human Embryonic Stem Cells research and use

### ICELAND

**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:

**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?

No organised public debate has taken place but the issue is being discussed, in particular by professional groups.

**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 only provisions relevant for embryonic stem cells research are provisions in the Act on Artificial Fertilisation Act no. 55/1996, where *Research on embryos* is dealt with in Art. 11 and 12:

Art. 11: All research, experiments and operations on embryos is prohibited.

Nevertheless, it is permitted to carry out research on embryos:

- a) if it is part of an *in vitro* fertilisation treatment, b) if the intention is to diagnose hereditary diseases in the embryos themselves, c) if the purpose is to advance the treatment of infertility, or d) if the purpose is to improve understanding of the causes of congenital diseases and miscarriages.

Art. 12: It is prohibited to:

- a) cultivate or produce embryos solely for research purposes, b) cultivate embryos for more than 14 days outside the body or once the primitive streak has appeared, c) transplant human embryos into animals, and d) perform cloning.

In Regulation no. 568/1997 on Artificial Fertilisation it is further stipulated in Art. 22 that it is prohibited to carry out research on embryos based on Act no. 55/1996, Art. 11, as defined in c) and d) (*c) if the purpose is to advance the treatment of infertility, and d) if the purpose is to improve understanding of the causes of congenital diseases and miscarriages*), unless the research fulfills the criteria of a scientific study as defined in Art. 1, paragr. 8 of the regulation (*A scientific study means research conducted with the aim of achieving further knowledge, making it possible, among other things, to improve health and cure diseases*), and has been granted approval by the National Bioethics Committee or an institutional ethics committee, according to the Act no. 74/1997 on Patients Rights.

*The Artificial Fertilisation Act no. 55/1996, the Regulation no. 568/1997 on Artificial Fertilisation and the Act no. 74/1997 on Patients Rights* are available in English on the homepage of the Ministry of Health and Social Security.

<http://brunnur.stjr.is/interpro/htr/htr.nsf/pages/lawsandregs>

Contact: Gudridur Thorsteinsdottir, Director Legal Department, Ministry of Health and Social Security, Laugavegur 116, 150 Reykjavik, Iceland.

E-mail: [gudridur.thorsteinsdottir@htr.stjr.is](mailto:gudridur.thorsteinsdottir@htr.stjr.is)

**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 change in legislation or regulations regarding "Human Embryonic Stem Cells Research" is being prepared, according to information from the Ministry of Health and Social Security.

## Survey on Human Embryonic Stem Cells research and use

### ISRAEL

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

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:

See attached Recommendations. Contact persons: Prof. Michel Revel and Dr. Joseph Segal, the Israel Academy of Sciences and Humanities, Jerusalem 91040, Israel, POB 4040, Tel.: 972.2.567.6220, fax: 972.2.567.6242, email: [yossis@academy.ac.il](mailto:yossis@academy.ac.il).

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

not yet

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?**

The currently existing Public Health (Extra-Corporeal Fertilization) Regulations, 1997 address neither the question of the fate of frozen embryos at the end of the freezing period nor the issue of supernumerary embryos (i.e. embryos initially formed in the course and for the sake of infertility treatment and not replaced or donated for implantation for some *bona fide* reason). Likewise, the currently proposed law for the regulation of the donation of eggs for purposes of *in vitro* fertilization does not address the possibilities of embryo stem cell research. In 1999, the Israel Parliament enacted the Prohibition of genetic intervention Act 1999-5759 (human cloning and genetic modification of reproductive cells). The law prohibits specifically human reproductive cloning but does not relate to cloning for non-reproductive purposes, such as ES cell derivation

The Bioethics Advisory Committee of the Israel National Academy of Sciences and Humanities, adopted a recommendation on 8 August 2001 stating that it should be permissible to donate human supernumerary embryos no longer destined to implantation for research under certain conditions, such as:

- free and informed consent,

- no selling or buying of human embryos,
- no *in vitro* culturing of human embryos beyond 2 weeks.
- separation of the medical teams involved in the IVF treatment and in the stem cell research.

The Advisory Committee also considers it ethically permissible to experiment with new technologies to produce ES cells such as nuclear transfer (so-called therapeutic cloning without reproductive purpose).

The Advisory committee also recommends that the “National Helsinki committee for genetic research in humans” of the Israel Ministry of Health examine the research protocols. In November 2002, the National Helsinki Committee has accepted in principle to authorise applications in the two above categories.

For further details : <http://www.academy.ac.il/bioethics/reports-e.html>

**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 yet

## Survey on Human Embryonic Stem Cells research and use

### NORWAY

#### 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:

Several bodies have provided an opinion on this issue. The Norwegian Ministry of Health can provide the most recent update.

##### I. The Norwegian Ministry of Health

- Contact: Ingrid Renolen, tel. +47 22 24 87 63
- The Government presented (05.07.02) a bill to Parliament proposing a prohibition against the use of therapeutic cloning as a method to produce embryonic stem cells for medical research. The bill also proposes to maintain today's prohibition on research on human embryos. The Government wants to support research using stem cells derived from adult individuals (adult stem cells).
- The bill was passed 13.12.03 by the Parliament and became effective on 01.01.03.

##### II. The Norwegian Biotechnology Advisory Board

- Contact person: Sissel Rogne, the Norwegian Biotechnology Advisory Board (tel.: +47 22248791/96, Fax: + 47 22 24 27 45, e-mail:: [ole.borge@bion.no](mailto:ole.borge@bion.no)).
- The boards opinion can be found at [www.bion.no](http://www.bion.no) (in Norwegian).
- A majority of the board members suggested April 5<sup>th</sup> 2002 to lift the ban on research on fertilised eggs and allow research on pluripotent stem cell lines generated from supernumerary fertilised eggs. A majority of the board members suggested banning therapeutic cloning.

##### III. The National Committee on Medical Research Ethics

- Contact person: Knut Reuter
- [www.etikkom.no](http://www.etikkom.no)

#### 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?

I. Open meeting on stem cells organized by the Norwegian Biotechnology Advisory Board, June 15<sup>th</sup> 2000 ([www.bion.no](http://www.bion.no))

II. Open meeting on stem cells and therapeutic cloning organized by the Norwegian Biotechnology Advisory Board, December 14<sup>th</sup> 2000 ([www.bion.no](http://www.bion.no))

III. Consensus conference with a citizen panel organized by the Norwegian Biotechnology Advisory Board and The Norwegian Board of Technology on November 22-26, 2001 ([www.bion.no](http://www.bion.no)).

- The citizen panel concluded that therapeutic cloning should be prohibited whereas research on, included the generation of, embryonic stem cell lines should be allowed.

Contact person: Ole Johan Borge, tel.: +47 22248791/96, Fax: + 47 22 24 27 45, e-mail: [ole.borge@bion.no](mailto:ole.borge@bion.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?**

- Adult stem cell: allowed
- Cells from aborted foetuses: allowed given certain conditions
- Research on fertilised eggs: not allowed
- Fertilisation solely for research: not allowed
- Research on embryonic stem cells derived from fertilised eggs: not allowed
- Therapeutic cloning: not allowed

Contact person: Ole Johan Borge, tel.: +47 22248791/96, Fax: + 47 22 24 27 45, e-mail: [ole.borge@bion.no](mailto:ole.borge@bion.no).

**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 new legal and/or regulatory framework is planned.

# Survey on Human Embryonic Stem Cells research and use

## SWITZERLAND

### 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 Swiss National Advisory Commission on Biomedical Ethics (NEK-CNE) has been elected in July 2001. The NEK-CNE has the order by law to consult the government, both houses of parliament and the public concerning bioethical questions and to elaborate recommendations for medical practice. The Commission has published its opinion on human embryonic stem cell research and their use in June 2002. In summary, the conclusions are as follows:

The majority of the NEK-CNE favours the use of surplus human embryos for harvesting embryonic stem cells under certain restrictive circumstances. The most important restrictions are:

- The embryos must be created in in-vitro fertilisation clinics and were created only for procreation reasons, within the limits of the law limiting the number of embryos to the number that can be implanted within one cycle (i.e. 3 embryos), not for research purposes (no “de novo” production).
- The embryos cannot be used anymore to bring about pregnancy.
- The parents must give their free, informed and written consent.
- The subject of research must be of significant importance for basic research or for the development of therapeutic treatment.
- Patents on embryos, organs, cells and cell lines shall not be permitted.
- No commerce shall be permitted with embryos and cells that were directly extracted from embryos.
- The research on embryos and the extraction of stem cells shall only be allowed until the blastocyst stage.
- Imported embryonic stem cells must obtain the same restrictions like “Swiss” embryonic stem cells.

A NEK-CNE-minority is against any use of human embryos for therapeutical or research purposes. They see it as a fundamental infliction of the basic principle of human dignity, because stem cell harvesting instrumentalizes an embryo for the sake of the well-being of others.

The full length version of the NEK-CNE-statement is available on the home page of the NEK-CNE (in French, German or Italian): [www.nek-cne.ch](http://www.nek-cne.ch)



Under certain conditions, the proposal of the Federal Council would allow research on "surplus" embryos from in-vitro fertilisation for purposes of an important scientific interest in the context of reproductive medicine or developmental biology [and not "any possible purpose"] until the 14<sup>th</sup> day after fertilisation, and the derivation of embryonic stem cells from spare embryos for research purposes. The EFG draft defines an embryo as "the developing organism from the point of nuclear fusion until the completion of organ development". Interpreting the constitutional paragraph that bans "all kinds of cloning" it forbids therapeutical cloning explicitly. The law on reproductive medicine (Fortpflanzungsmedizingesetz, FMedG) forbids the extraction of a blastomer from an embryo for study purposes, a formula directed against preimplantation diagnosis.

Therewith, several ethical questions are currently under discussion. One of them concerns new technological developments that show that embryo-like entities can also be created without nuclear fusion having taken place. It remains unclear how to treat embryonic entities that don't fall under the draft's narrow definition of an embryo.

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#### **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 act on "Research on Human Subjects" is in preparation. All aspects of research and use of human subjects should be regulated in this act. A first draft is expected in winter 2004 to be sent into pre-legislative consultation procedure. But it will take several years before it will become effective. The "Federal Act on Research on Embryonic Stem Cells" will then be integrated in the new act on "Research on Human Subjects".

Contact person: Dr. Verena Schwander, Head of the project management EFG, Swiss Federal Office of Public Health, Berne. Phone number: +41 +31 323 95 76, [verena.schwander@bag.admin.ch](mailto:verena.schwander@bag.admin.ch)

## **THIRD COUNTRIES**

## Survey on Human Embryonic Stem Cell Research and Use

### AUSTRALIA\*

- 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:

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

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 **Research Involving Human Embryos Act 2002** and **Prohibition of Human Cloning Act 2002** were passed by Parliament in December 2002. These Acts establish a strong regulatory framework to prohibit certain unacceptable practices including human cloning, and to regulate uses of excess human embryos created through assisted reproductive technology (ART).

<http://www.nhmrc.gov.au/embryo/index.htm>

Research involving the destruction of existing excess assisted reproductive technology embryos is permitted under a strict regulatory regime.

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

\*information collected by DG Research

## Survey on Human Embryonic Stem Cell Research and Use

### AZERBAIJAN

- 2. 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?

- 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?**

N/A

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

N/A



## Survey on Human Embryonic Stem Cells research and use

### CROATIA

- 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 no framework 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**

No

## Survey on Human Embryonic Stem Cell Research and Use

### GEORGIA

**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:

National Ethics Committee of Georgia – National Council on Bioethics had extensive debates on the use of human foetal (material obtained after termination of pregnancy) stem cells research. I was asked to prepare the draft project of the opinion of the Council. However, the document has not been approved yet. The Ministry asked different international bodies to send relevant information about international developments in this sphere. We have translated the draft opinion of the National Council on Bioethics which is attached to this questionnaire. However, there were no debates yet about human embryonic stem cells.

**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?

---

**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 problem of human embryonic stem cells research is addressed by the Law of Georgia on "Health Care "and the "Convention on Human Rights and Biomedicine" (together with the additional protocol on Prohibition of Cloning Human Beings), which are now part of Georgian legislation as they have been ratified by Georgia (the Convention as well as additional protocol entered into force on the 1<sup>st</sup> March 2001.

National Council of Bioethics (NCB) produced an official statement of human cloning including cloning for research purposes. The above statement says that reproductive cloning is illegal in Georgia, because firstly it is prohibited by additional protocol to the Convention, on Prohibition of Cloning Human Beings and secondly human cloning has been prohibited by the Law on Health Care since 1997.

As to therapeutic cloning, on the one hand NCB recognises that at the moment only cloning for research purposes may exist, because there are no proven therapeutic cloning methods available yet. On the other hand cloning for research purposes may be considered to be prohibited in Georgia. The basis for such interpretation serves the

Article 18.2 of the Convention on Human Rights and Biomedicine, which says that creation of embryo for research purposes, is prohibited. Such interpretation may be controversial, because when Article 18.2 was in the process of drafting, the working group and later everyone participating in the process of ratification didn't have the purpose to ban therapeutic cloning (because, simply this method was not known that times).

**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

Contact person:

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## Survey on Human Embryonic Stem Cells research and use

### TAIWAN

- 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:

Yes, Medical Ethics Panel of Department of Health. An opinion regarding human embryo research was given on 21.02.2002.

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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?

---

- 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?**

1. Pursuant to the Guideline for Artificially Assisted Reproduction, human reproductive cloning is forbidden.
2. Subject to the Ethical Code for Stem Cell Research,
  - (1) Using spare embryos left over from artificial insemination is under conditions permitted.
  - (2) Production of embryos for the sole purpose of research is forbidden.
  - (3) Due to lacking consensus, and because the issue is of great importance, it needs further discussion, weather therapeutic cloning should be permitted.

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

Pursuant to the draft bill of Artificially Assisted Reproduction Act submitted by the Department of Health, spare embryos left over from artificial insemination would be permitted.

Two more liberal drafts concerning research on the human embryonic stem cells are submitted by legislators. Subject to these bills, stem cells may be derived not only from the spare embryos, but also from embryos created by SCNT. Whereas the one bill permits creating embryos for the sole purpose of research, the other prohibits such method.

## Survey on Human Embryonic Stem Cells research and use

### UNITED STATES<sup>1</sup>

Only publicly funded research is regulated. On 9 August 2001, President Bush announced that federal funds might be awarded for research using human embryonic stem cell lines that meet certain criteria<sup>2</sup>. Such research is now eligible for federal funding as long as the derivation process (which begins with the destruction of the embryo) was initiated prior to 9 August 2001. These stem cells must have been derived from embryos created for reproductive purposes and no longer needed for those purposes. In addition, informed consent must have been obtained for the donation of the embryo and the donation must not have involved financial inducements. The NIH Human Embryonic Stem Cell Registry has been created and is updated to reflect stem cell lines that meet the eligibility criteria (see also chapter 2.6). There is no federal law regulating research on human embryos and the derivation of human ES cells when such research is funded by the private sector.

However, California has passed a law, in September 2002, allowing the procurement of human embryonic stem cells from supernumerary embryos. New legislation authorising the procurement of human ES cells from supernumerary embryos is under discussion in the States of New Jersey and Massachusetts.

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<sup>1</sup> The information has been prepared by DG Research

<sup>2</sup> <http://stemcells.nih.gov/index.asp>

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