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**REPORT OF
THE WORKING GROUP OF IBC
ON HUMAN CLONING AND INTERNATIONAL GOVERNANCE**

Division of Ethics of Science and Technology

I. BACKGROUND AND MANDATE

The issues of human cloning and its practical applications and regulations have been discussed by the international community for some time. The UNESCO Universal Declaration on the Human Genome and Human Rights (1997) – a legally non-binding document for Member States - prohibits reproductive cloning (Article 11).

Recent technological developments and new prospects for the use of stem cells in the therapy of human diseases have once again raised the issue of adequacy of international regulations governing this research. In August 2001 in the United Nations General Assembly, the Permanent Missions of France and Germany requested the Secretary-General to include a supplementary item in the agenda of the 56th session entitled *International Convention against the Reproductive Cloning of Human Beings*. An international convention would be legally binding to Member States.

After almost 4 years of discussion the United Nations Declaration on Human Cloning was adopted on 8 March 2005 (A/RES/59/280). The Declaration was voted and passed with 84 countries supporting it, 34 countries voting against and 37 abstaining. The wording of the document left room for very different interpretations of the text, which reflected, in part, the lines of division between different Member States on this issue. The main point of contention was the question of linking the issues of reproductive and non-reproductive cloning, which was not agreeable to many States, who abstained and voted against the Declaration.

In 2007, the United Nations University Institute of Advanced Studies (UNU-IAS) produced a Report entitled *Is Human Reproductive Cloning Inevitable: Future Options for UN Governance*, which summarized up-to-date technical information on cloning, ethical issues accompanying it and the state of the art of international governance of these issues, specifically analyzing the discussions during the 4 years of United Nations General Assembly debate leading to the voting on the United Nations Declaration of Human Cloning. The Report expressed the view that further development of international governance would be needed and envisaged several options along this line.

The Director-General of the UNESCO has expressed his wish that the examination of the UNU report be added as an agenda item for discussion by IBC at its session(s). At its meeting in January 2008, the Bureau of IBC therefore decided to include the discussion of the UNU report and the issue of human cloning and international governance to the work programme of IBC for 2008-2009.

The Bureau also decided to establish a working group on this topic initially consisting of four members: Prof. (Mr) Toivo Maimets (Estonia) as Chairperson, Dr (Mrs) Ephrat Levy-Lahad (Israel), Prof. (Mr) Ching-Li Hu (China) and Prof. (Mr) Gamal Ibrahim Abou Serour (Egypt). The focused task and mandate of the Working Group is to explore whether there is any scientific, social or political change that would justify a new initiative at the international level, rather than to initiate another ethical and scientific analysis of the issue of human cloning. The preliminary results of the Working Group will be presented and discussed at the fifteenth session of IBC in October 2008. The Committee will then decide whether it is ready to present its opinion to the Director-General, or whether it considers necessary to further pursue its work on this issue.

II. FIRST MEETING OF THE WORKING GROUP

The Working Group held its first meeting from 30 June to 2 July 2008 at UNESCO Headquarters in Paris. One day of the meeting was devoted to public hearings of specialists in the field. These hearings open to the participation of Member States, constituted a starting point for the deliberations of the Working Group and allowed transparency and clarity as per the mandate and the work of the Committee⁽¹⁾.

1. The report of the meeting is available online (www.unesco.org/bioethics) or upon request at the Division of Ethics of Science and Technology of UNESCO.

The specialists involved were: Dr (Mr) Darryl Macer (Adjunct Professor of the UNU-IAS and one of the authors of the UNU-IAS Report), Professor (Mr) Richard Gardner (University of Oxford), Professor (Mr) Hans Galjaard (Erasmus MC Rotterdam) and Dr (Ms) Marie-Charlotte Bouésseau (WHO). The speakers were given an outline including the following questions:

1. In August 2001 the Permanent Missions of France and Germany requested the Secretary-General of the United Nations to include an additional item on the agenda of the 56th Session of the General Assembly entitled “International Convention against the Reproductive Cloning of Human Beings”. After years of debates, instead of a convention, a legally non-binding United Nations Declaration on Human Cloning was adopted on 8 March 2005. Three years later, is there any scientific, social or political change that would justify a new initiative at the international level?
2. The UNU-IAS report states that “international regulation is a necessity in this area...” and offers three possible options:
 - a. the International Bioethics Committee of UNESCO (IBC) takes up the issue of reproductive and research cloning, in the context of resolution A/RES/59/280 and also in the context of the Universal Declaration on Bioethics and Human Rights, adopted by the General Conference of UNESCO on 19 October 2005;
 - b. the sixth committee of the General Assembly takes up the issue of customary international law on cloning;
 - c. dissemination, discussion and debate on cloning issues at the international level, so that all countries including the developing and least developed countries can participate and put forward their concerns regarding this new technology.

Would any of these actions be realistic in terms of different cultural, religious and social backgrounds of Member States and their interests in developing medical research towards treatment of numerous incurable diseases?

3. The same UNU-IAS document describes the following options available for regulation of cloning:
 - a) total ban on all cloning research,
 - b) ban on reproductive cloning,
 - c) ban on reproductive cloning and allow research cloning,
 - d) ban reproductive cloning, allow research cloning for 10 years,
 - e) place a moratorium on all cloning research.

For further actions within the United Nations system, what options could be feasible and serve the interests of Member States in the best possible way?

4. The terms and definitions we use can themselves start leading the discussion and build boundaries. Do the words “reproductive cloning” and “therapeutic cloning” introduced into bioethical debates several years ago still adequately describe the technical procedures scientists use (and are potentially able to use) today?

III. THE UNU-IAS REPORT

The Working Group is of the opinion that the UNU-IAS Report *Is Human Reproductive Cloning Inevitable: Future Options for UN Governance* is an important document comprehensively describing the present situation in international governance of human reproductive cloning. Whilst it is understood that the report was not intended to provide a complete review of the scientific issues, the Working Group found that it did not take note of several new scientific advances (induced pluripotent cells, role of epigenetics in individual development), which are not just mere technical details, but add new aspects to the bioethics and governance issues.

The Working Group found that the options for further activities offered in the UNU-IAS report are limited in the sense that they are based on the framework of discussions previously held on this topic. In this respect, the report mostly describes what cannot be achieved given current differences of opinion between Member States, especially regarding the moral status of the embryo. The Working Group therefore finds that it is important to search for different approaches to this issue, rather than remaining in the same arena where many of the arguments were based on technical distinctions which are becoming obsolete (e.g. use of embryonic stem cells as opposed to other stem cells). The Working Group believes that the issue of reproductive cloning, as it is targeted towards different purposes than all the other embryo and stem cell research, should be kept apart from all other research and handled separately from these.

IV. PRESENT SITUATION OF THE INTERNATIONAL GOVERNANCE OF HUMAN CLONING⁽²⁾

At the international level, two United Nations declarations and a World Health Organization resolution are the present instruments of governance of human cloning.

The Universal Declaration on the Human Genome and Human Rights, adopted on 11 November 1997 by the General Conference of UNESCO and endorsed by the General Assembly of the United Nations by its resolution 53/152 of 9 December 1998, is the first international instrument which prohibits human reproductive cloning. Indeed, Article 11 of the Declaration states that:

Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted. States and competent international organizations are invited to co-operate in identifying such practices and in taking, at national or international level, the measures necessary to ensure that the principles set out in this Declaration are respected.

The United Nations Declaration on Cloning of 8 March 2005 states in its paragraph b):

Member States are called upon to prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and protection of human life.

The World Health Organization found in its Resolution WHA51.10 of 16 May 1998 that “cloning for the replication of human individuals is ethically unacceptable and contrary to human dignity and integrity”. Therefore it “urges Member States to foster continued and informed debate on these issues and to take appropriate steps, including legal and juridical measures, to prohibit cloning for the purpose of replicating human individuals”. This resolution confirms another WHO resolution adopted at the 50th session in 1997 (WHA 50.37).

At the regional and national levels, the regulations governing human embryo research and cloning are diverse and reflect the different cultural, religious, social and political backgrounds of countries⁽³⁾.

V. WHY ARE NEW ACTIVITIES OF INTERNATIONAL GOVERNANCE NEEDED?

The Working Group identified several new scientific, social and political changes, which would justify new initiatives in the international governance of human cloning.

1. There are new scientific developments, which make the need for international governance more urgent. On one hand, the construction of induced pluripotent stem (iPS) cells and their possible uses has created more technical possibilities for reproductive manipulation of human embryos and hence brings new problems into the debate. Since it

2. The Working Group highly appreciates the contributions of two members of IBC, Prof. (Mrs) Sheila A.M. McLean and Prof. (Mr) Fawaz Saleh in preparing this section.

3. The materials describing these regulations are provided in the Annex to this Report.

has been demonstrated that functional germ cells may be created from embryonic stem cells, this raises the possibility of creating germ cells from somatic cells (via iPS cells) which further blurs the borders between different stages of human development and reproduction. On the other hand, it is clear to scientists that “cloning” in the sense of producing identical human beings is impossible because of differences in developmental and environmental conditions, epigenetic modifications of the DNA involved, etc. In addition, it is scientifically clear that in the current state of technology, reproductive cloning is associated with serious health risks for both women and fetuses.

2. During the last three years since the adoption of the United Nations Declaration on Human Cloning the public sensitivity and awareness of the issues has increased, whereas the information and dissemination of the issues could be improved.

3. Several Member States have recently updated their national regulations of governance of human cloning and embryo research in general and therefore there is more awareness and information among politicians in these countries.

4. The financing of human embryo research has considerably increased over recent years, whereas more and more multinational commercial private interest is being involved. This is accompanied by international traffic (both legal and illegal) of embryos, eggs and stem cells.

5. If the argument remains at the level of the moral status of the embryo, there is no room for achieving consensus. Also, as detailed in item #1 of this section, reproductive cloning may become possible without using embryos. So there is a clear need to move to ethics of international governance of cloning, where different countries can find agreement, e.g. a ban on reproductive cloning.

Based on these findings, the Working Group is of the position that the issues surrounding human reproductive cloning can not be ignored and therefore a focused international dialogue considering a binding instrument against reproductive cloning is needed.

VI. SUGGESTIONS OF THE WORKING GROUP

1. The Working Group is of the position that some of the terminology used in these discussions is misleading and should be re-defined according to the new developments in human embryo research. The term “reproductive cloning” contains misleading reference to producing the “identical copy”. However, since it is so well entrenched, the term could still be preserved and should be defined as using technical manipulations of the human embryo (outside the context of well regulated *in vitro* fertilization procedures), which include the implantation of the manipulated embryo in the womb. Implantation reflects the PURPOSE of instrumental use of the human organism. In this way, the term “reproductive cloning” would also describe, in addition to somatic cell nuclear transfer, embryo splitting and possible developments of induced pluripotent stem (iPS) cells, with implantation for giving birth to new organisms.

The purpose of any other embryo and stem cell research is distinct from reproductive cloning as defined above. This should be subject to the ethical guidelines set forth in the UNESCO Universal Declaration of Bioethics and Human Rights (2005).

2. Human reproductive cloning, as defined in the previous paragraph, should be banned at the international level. Although this position is fixed already in the UNESCO Universal Declaration on the Human Genome and Human Rights (1997), the Working Group believes that a declaration, which is legally non-binding to the Member States, is not sufficient and the final aim of the developments in international governance of human reproductive cloning should be a total ban of this at the level of a legally binding convention.

To attain the adoption of a convention will be clearly time-consuming, but the Working Group believes that the new developments, including scientific, social and political, which are identified in the previous paragraph, give new arguments for a ban on reproductive cloning.

3. In parallel to the development of a convention, the Working Group also suggests other methods for international governance of human cloning and its applications. It believes that guidelines for regulating human embryo and stem cell research in the countries where it is legal, should be developed at international level. This could be developed from several already existing guidelines formulated by different professional societies.

Also, an Observatory Group could be established, which would permanently follow the new ethical, legal, social, political and scientific developments in this area and regularly report to the Director-General of UNESCO about possible new problems emerging from these developments.

4. One of the international governance options indicated in the UNU-IAS Report (p. 26) is the “dissemination, discussion and debate on cloning issues at the international level”, so that all countries including the developing and least developed countries can participate and put forward their concerns regarding this new technology. The Working Group believes that these activities are very important and should be actively worked upon in parallel with the other possible normative developments. More specifically, the Working Group suggests that national research organizations/academies and national bioethics committees should be more actively encouraged and supported in these activities. To this end, the Working Group recommends that UNESCO develop specific strategies and materials to promote international discourse on this topic.

Study on National Legislation concerning Human Cloning

This document presents an overview of existing legal framework concerning human cloning. It does not pretend to be exhaustive and will be periodically revised⁴.

Table 1 is limited to national legislation on human cloning and does not include:

- 1) national *guidelines*, even if these guidelines are, in state practice, applied in the same manner as laws.;
- 2) patents laws that prohibit granting of a patent for processes intended to lead to human cloning;
- 3) public national laws that guarantee the fundamental human rights such as human dignity or the human rights in biomedical research. It should be noted that in view of official positions from governments and/or national bioethics bodies in these countries, human cloning directly violates these fundamental rights and is therefore banned;
- 4) provisions which could be interpreted as banning human cloning if such interpretation has not been legally implemented by a convention or a court decision.

Not being listed in this table does not mean that a country has no human cloning policy, or that it does not apply it. Indeed, many countries have opted for *guidelines* in order to regulate human cloning activities or have officially expressed their position through governmental declarations or by official recommendation of national bioethics bodies.

Furthermore, some countries, having ratified conventions related to the ban of human reproductive cloning, have applied its provisions without adopting specific domestic legislation on it. These countries can be found in Table 2 related to international treaties and conventions.

A note on main sources

Because many national sources are unavailable on the web or not translated, this table is using many reliable secondary sources like Digest of Legislation of WHO or Official reports. When the legal text is available and translatable, the provision is cited directly; when only a reliable secondary source is mentioned, a summary replaces the original wording.

⁴. Any information on relevant law and regulations that could assist in updating this document should be addressed to the division of Ethics of Science and Technology (fax +33 (0) 45 68 55 15; e-mail: s.colombo@unesco.org).

Table I – National legislation

| STATES | DOMESTIC LAWS | | | |
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| | REPRODUCTIVE CLONING | | RESEARCH/THERAPEUTIC CLONING | |
| | Reference | Main Provisions | Reference | Main Provisions |
| Algeria* | Research Law n°08-05 of 23 February 2008 related to the orientation and research program for 5 years (2008-2012) | This law prohibits any form of cloning. | <i>IDEM</i> | This law prohibits any form of cloning. |
| Argentina* | Regional laws: Buenos Aires Law n°712/2001 Province of Cordoba Law n° 9072 (13/01/2003). | <u>Section 14:</u> The City adopts as program for the regulation and the interpretation of the conduct for investigations on human genome and its applications the Universal Declaration on Human Genome and the Human rights of UNESCO of 11 November 1997 (Annex I) (Ref. Article 11) <u>Section 1:</u> Insert as a s) to law n°6222 section 7 titled “they are prohibited to” the following text: “s) Create human reproduction by the technique of cloning, in the understanding that such a process leads to the creation of a human being derived from a unique individual without the characteristics of sexual reproduction”. | Presidential Decree n°200/97 on the Prohibition on Human Cloning Research of 7 March 1997 Province of Mendoza Law n° 6581 of 24 March 1998 | <u>Section 1:</u> Research cloning related to human beings is prohibited. <u>Section 1:</u> Prohibition in the whole territory of Mendoza of experiments on cloning with human beings. |
| Australia** | <i>Prohibition on human cloning for reproduction Act</i> of 19 December 2002 amended by the Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act of 12 December 2006 <i>Notice of variation</i> signed between the Commonwealth, the States and the Australian Capital Territory of 13 April 2007. | <u>Section 9:</u> Placing intentionally a human embryo clone in the body of a human or of an animal is as offence punished by 15 years of imprisonment. <u>Section 20:</u> Placing a prohibited embryo in the body of a human or of an animal is punished by a 15 years imprisonment penalty. Prohibited embryos are embryos “created by a process other than the fertilization of a human egg by human sperm”. The States, ACT and the Commonwealth signed an Intergovernmental Agreement for the implementation of the legislation adopted in 2006 consisting in the ban of reproductive cloning. | <i>IDEM</i> <i>IDEM</i> | <u>Section 22:</u> The creation of human embryo clones is submitted to the deliverance of a license. Furthermore, the development of a human embryo outside the body of a woman for more than 14 days is punished by a 10 years imprisonment penalty. This agreement consists in implementing a national consistent legislative scheme on human embryo research as well. |

* Countries that have a legislative ban on reproductive cloning and the corresponding penal provisions.

** Countries with a ban on reproductive human cloning, but without penal provisions.

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| Austria** | Federal Law on Reproductive medicine of 1992 as modified in 2001 and 2004 (N°98/2001, N° 163/2004) | Article 9 of this law prohibits implicitly human reproductive cloning as it prohibits the use of human embryos (fertilized eggs) for another purpose than the medically assisted procreation which is, itself, submitted to strict restrictions. A violation is subject to administrative or criminal prosecution. | <i>IDEM</i> | Research on embryonic cells is prohibited for the same reason. |
| Belgium** | In Vitro Embryos Research Act dated of 11 May 2003 | <u>Article 6:</u> Human reproductive cloning is forbidden. <u>Article 13:</u> Any person who commits a forbidden intervention prohibited by articles 3 (5), 4, 5 or 6 of this law is liable to a 1 to 5 years imprisonment penalty and/or a 1000 to 10000 Euros fine. <u>Article 14:</u> Without prejudice to article 13, any condemnation for the facts forbidden by article 6 is liable to a 5 years ban of exerting any medical or research activity. | <i>IDEM</i> | <u>Article 3:</u> Research on in vitro embryos is allowed if all requirements of this law are respected [...] <u>Article 4. 1):</u> The creation of embryos for research purposes is forbidden excepted if the aim of the research cannot be reached by research on excess embryos and only if all requirements of this law are respected. |
| Brazil** | Law n°11105 on Biosecurity of 24 March 2005 | <u>Section 6:</u> Is forbidden: [...] IV- Human cloning. <u>Section 26:</u> Performing human cloning is punished by a 2 to 5 years imprisonment penalty and a fine. | | <u>Section 5:</u> Embryonic stem cells obtained from human embryos produced by in vitro fertilization and not used in the respective procedure may be used for research and therapeutic purposes, provided that the embryos are non-viable or have been frozen for three years or more prior to the publication of this Law. <u>Section 6:</u> The following activities, inter alia, are prohibited: genetic engineering involving human germline cells, human zygotes, or human embryos; and human cloning. Comment: Brazilian Supreme Court upheld this legislation allowing stemcell research by a decision of 29 May 2008. |
| Bulgaria | | | People's Health Law n°88 dated on 6 November 1973 as amended several times from 1973 to 1995 | <u>Article 34:</u> (4) Under the procedure of the preceding paragraphs organs and tissues may be used also for other therapeutic purposes, as well as for research and training purposes of public health. |
| Canada** | <i>Assisted human reproduction Act of 11 February 2004</i> | <u>Article 5 a):</u> This provision prohibits the creation of a human clone by using any technique. Human clone is defined by the Act as "an embryo that, as a result of the manipulation of human reproductive material or an in vitro embryo, contains a diploid set of chromosomes obtained from a single-living or deceased-human being, foetus or embryo"(article 3) | <i>IDEM</i> | <u>Article 5 b):</u> This provision prohibits the creation of an "in vitro embryo for any purpose other than creating a human being or improving or providing instruction in assisted reproduction procedures" <u>Article 40:</u> This provision states that the authorization for research |

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| | | <p><u>Article 60:</u> A person who would contravene to this provision would be liable of a 500000\$ fee and 10 years imprisonment penalty.</p> | | <p>on stem-cells can only be delivered with the written consent of the original gamete providers. It also appears that even if research on human embryos is permitted under restrictions, research cloning keeps prohibited as embryos have to come from supernumerary embryos from ART.</p> <p><u>Article 60:</u> A person who would contravene to this provision would be liable of a 500000\$ fee and 10 years of imprisonment.</p> |
| Chile** | Law N°20120 of 7 September 2006 on scientific research on human beings, the human genome and the prohibition of cloning. | <p><u>Article 5:</u> This provision prohibits the cloning of human beings whatever the purpose or the method used.</p> <p><u>Penal:</u> According to article 17 of this law, a person guilty of cloning a human being would be liable to imprisonment and to an interdiction of exercising his profession</p> | <i>IDEM</i> | <p><u>Section 5:</u> This provision authorizes the culture of tissues and organs but only for diagnostic purposes or scientific research and prohibits the destruction of human embryos to obtain stem cells to give rise to such tissues and organs. Hence, research cloning and therapeutic cloning are prohibited.</p> <p><u>Penal:</u> The same penalties as for research cloning have been prescribed.</p> |
| China (Hong Kong)* | Human Reproductive Technology Ordinance of 17 November 2000 as amended by law n°106 of 2002 and law n° 130 of 2007. | <p><u>Section 15:</u> (1) No person shall: [...] (e) replace the nucleus of a cell of an embryo with a nucleus taken from any other cell; or (f) clone any embryo.</p> <p>Comment: Penal provisions are to be issued by the Ministry of Health and the Council on Human Reproductive Technology</p> | <p><i>IDEM</i> +</p> <p>Human Reproductive Technology (licenses) regulation of 1 August 2007</p> | <p>The ordinance sets the procedure to carry out research on embryos by setting up a system of licenses.</p> <p><u>Section 10:</u> (1) Subject to subsections (2), (3), (4), (5) and (6), the Council may only grant a licence that belongs to one of the following classes: [...] (c) a research licence, which authorizes (i) the conduct of one project of embryo research; and (ii) the storage of gametes or embryos used or intended to be used in such research;</p> <p>Comment: Research cloning is allowed in respect of the principles set by the law such as the prohibition of creating an embryo for research purposes or the prohibition of developing an In vitro embryo over 14 days. These regulations are completed with guidelines</p> |
| Colombia** | Law n°599 of 24 July 2000 promulgating a new criminal code | <p><u>Section 133:</u> <i>Human being duplication</i> -Those who would be creating identical human beings by cloning or by any other process would be liable to a 2 to 6 years imprisonment penalty.</p> | <i>IDEM</i> | <p><u>Section 134:</u> <i>Fertilization and human embryos traffic</i> - Those who would be fertilizing human eggs for another purpose than human procreation, without prejudice of scientific research, treatments or diagnostics having a therapeutic purpose for human beings in respect of human beings as subject of research, will be liable to a 1 to 3 years imprisonment penalty.</p> |

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| Costa Rica | Case law N°2000-02306 by the Supreme Court invalidating Decree n°24029-S on “In Vitro Fertilization and Human embryos transfer” of 3 February 1995 | Human reproductive cloning is not prohibited by law but is commonly condemned like any manipulation of embryos. The Supreme Court decision can be clearly interpreted in this sense as it is strongly pointed out that any intervention endangering embryos which is not in its own interests shall be prohibited. | Case law N°2000-02306 by the Supreme Court invalidating Decree n°24029-S on “In Vitro Fertilization and Human embryos transfer” of 3 February 1995 | By this decision Costa Rica’s Supreme Court declared unconstitutional the in vitro fertilization as contrary to human right to life considering embryos as human beings from the day of their conception. This decree was censured for both legal and technical reasons as this is not a matter that can be ruled by the executive body and because of the technical aspects endangering embryos life. It appears that any embryo manipulation shall be prohibited. |
| Czech Republic ** | Act on Human Embryonic Stem Cell Research Law n° 227/2006 of 26 April 2006 | <p><u>Section 3:</u> (3) Such manipulations (stem cells research) with human embryonic stem cells must be prevented within the research which could lead to creation of a new human individual (reproductive cloning).</p> <p><u>Section 20: Penal code amendments</u> (1) Who: [...] f) Manipulates the human embryonic stem cells during their research in a way leading to creation of a new human individual (reproductive cloning), shall be punished by imprisonment up to three years or ban on activity.</p> <p>Comment: The penalty can be extended to 8 years in certain conditions (ex: international organized operation, etc.)</p> | <i>IDEM</i> | <p><u>Section 3:</u> (1) Research on human embryonic stem cells may be conducted only on the basis of a permission issued by the Ministry of Education, Youth and Sport (hereinafter referred to as the “Ministry”). This research may be conducted only on workplaces listed in the permission for research on human embryonic stem cells.</p> <p><u>Section 20: Penal code amendments</u> (1) Who a) performs interventions leading to creation of a human embryo for purposes other than implantation into a woman’s body, b) uses a human embryo or larger number of human embryonic stem cells or their lines for research inconsistent with a separate regulation, c) imports or exports a human embryo or larger number of human embryonic stem cells or their lines inconsistent with a separate regulation, d) implants the created human embryo into the uterus of another animal species, e) implants a human genome into the cells of another animal species or vice versa, or [...] shall be punished by imprisonment up to three years or ban on activity.</p> |
| Cyprus* | Ratification Law n°31 (III)/2001 article 38 on Convention on Human Rights and Biomedicine | <p>Comment: No specific legislation deals neither with human reproductive cloning nor embryo status and IVF. Nonetheless, by ratifying Oviedo’s convention including Protocol n°1 banning reproductive cloning, this prohibition entered in force in Cyprus.</p> | <i>IDEM</i> | <p><u>Article 7:</u> 1. Where the law allows research on embryos in vitro, it shall ensure adequate protection of the embryo. 2. The creation of human embryos for research purposes is prohibited.</p> <p>Comment: No legal frame has been set to regulate research on embryos and stem cells lines even if it appears that Cyprus consider unethical and illegal such practices in consideration of its interpretation of article 7 above mentioned.</p> |

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| <p>Denmark*</p> | <p>Act N°460 on medically assisted procreation in connection with medical treatment, diagnosis and research of 10 June 1997, amended by Act N°427 of 10 June 2003 and Act n°923 of 4 September 2006</p> <p>Act N°503 on a scientific, ethics committee system and the handling of biomedical research projects</p> | <p><u>Section 15:</u> "The following experiments shall be prohibited: 1. Experiments whose purpose is to enable the production of genetically identical human beings [...]"</p> | <p><i>IDEM</i> (Considering amendment Act n°427 of 10 June 2003 and Act n°923 of 4 September 2006)</p> | <p><u>Act n°427:</u> List the purposes of biomedical research on embryos created for fertilization purposes: - improving the techniques to bring about pregnancy - improving techniques for genetic diagnosis on embryos - obtain new knowledge that could improve the possibilities of treating diseases in human beings.</p> <p>Comment: Embryos creation for research purposes is not allowed.</p> |
| <p>Ecuador*</p> | <p>New Politic Constitution of the Republic of Ecuador of 5 June 1998</p> | <p><u>Article 49:</u> Children and adolescents will benefit from the common rights of human beings, in addition with their specific rights. The State will ensure and guarantee the Right to life, from the conception; to physic and psychic integrity; to identity, name and citizenship; to integral health and nutrition [...]</p> | <p><i>IDEM</i></p> <p>Penal Code of Ecuador</p> | <p><u>Comment:</u> As stated by the Constitution, the right to life is guaranteed from the conception. It prohibits therefore any endangering of embryos life and prohibits therefore human cloning.</p> <p>The penal code sanctions abortion by a 6 month to 16 years imprisonment penalty depending on the circumstances (articles 441 to 447).</p> |
| <p>Egypt**</p> | <p>Resolution (Ministerial decree) of the Minister of Health and Population No. 238/2003 of 5 September 2003</p> | <p><u>Article 60:</u> They are also prohibited from carrying out or participating in medical research which aim at cloning the human being.</p> <p>Sanction: Chapter 5, page 19, of the Laws of Medical Syndicates, 3rd edition, 2005 states that the Disciplinary Council, which is a professional board ruling in medicine's field, may transfer the case to Criminal Investigation Authority as well as taking disciplinary sanctions against lawbreakers like the retirement of the professional license.</p> | <p><i>IDEM</i></p> | <p>The text doesn't specify what kind of cloning is prohibited. Research cloning having for purpose the creation of a human being is prohibited; hence, reproductive cloning is prohibited. As for therapeutic cloning and research cloning, no provision states whether it is or not possible. Nonetheless, research on cloning a human being is forbidden and, as the technique is the same whatever the final purpose, this issue remains unclear.</p> |
| <p>El Salvador**</p> | <p>Politic Constitution of El Salvador of 15 December 1983 as amended in 2003</p> | <p><u>Article1:</u> El Salvador recognizes human persons as the origin and the end of States activities [...]. It recognizes as Human persons all Human beings from the day of their conception [...]</p> <p>Comment: The recognition of human beings as human person from their conception results from a constitutional amendment operated by law n° 541 of 3 February1999.</p> | <p><i>IDEM</i></p> | |

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| | Penal Code of El Salvador entered in force on 20 April 1998 | <u>Article 140:</u> [...] The same penalty (3 to 6 years of prison) will be applied to a person who experiment or manipulate cloning with human cells in view of reproducing human beings. | <i>IDEM</i> | <u>Article 137:</u> Those who guiltily will provoke an abortion will be liable to 6 months to 2 years imprisonment penalty. <u>Comment:</u> Human beings are considered constitutionally as human persons from their conception. Research cloning and therapeutic cloning, as provoking the death of the embryo, could be also considered as a voluntary abortion. |
| Estonia** | Penal code §130 (adopted on 6 June 2001) | <u>§ 130 - Prohibited acts with embryo:</u> Human cloning or creating a human hybrid or human chimera is punishable by a pecuniary punishment or up to 3 years' imprisonment. | Penal code §131 (adopted on 6 June 2001) | <u>§ 131 - Abuse of human embryo or foetus</u> A person who creates a human embryo or foetus <i>in vitro</i> without the intention to transfer the embryo of foetus to a woman, or outside an institution duly authorised by law [...] shall be punished by a pecuniary punishment." <u>Comment:</u> Embryo creation for research cloning purpose is explicitly prohibited but there is no provision on the use of existing <i>in vitro</i> embryo for research. |
| Finland** | Act on Medical Research, N°488/1999 of 1 November 1999 as amended by law n°295 of 29 April 2004 and entered in force on 1 May 2004 | <u>Section 13:</u> "Restrictions on research on embryos Embryos that have been used for research may not be implanted in a human body. <u>Section 25:</u> "Unlawful research on embryos and gametes Any person who conducts research on embryos without the licence referred to in section 11 or in contravention of the restrictions laid down in sections 11 and 13 [...] shall be fined or imprisoned for a period not exceeding a year for <i>unlawful research on embryos and gametes.</i> " | <i>IDEM</i> | <u>Section 13:</u> Research on embryos outside a woman's body may be carried out only by agencies that have been granted the appropriate licence by the National Authority for Medicolegal Affairs [...] Medical research shall be permitted on embryos only if no more than 14 days have passed from their formation. <u>Penal provisions:</u> The same penal provisions as for human reproductive cloning. |
| France** | "Bioethics" law of 8 July 2004 amending law of 29 July 1994, included in Civil, Penal and public health codes | <u>Civil code article 16-4:</u> Any attempt to give birth to a person genetically identical to another person, dead or alive, shall be forbidden. <u>Penal code article 214-2:</u> Human reproductive cloning is qualified as a "crime against the human species". It is punished by a 7.500.000 Euros fine and a 30 years imprisonment penalty. | <i>IDEM</i> | <u>Article L-21515 of public health code:</u> By principle, research on human embryos is forbidden. Nonetheless, during a period of five years (2004-2009), which constitutes a moratorium, research cloning is allowed under strict conditions. It is also controlled by the Biomedicine agency which delivers authorizations for intending such research and importing Stemcells lines. The law allows for creation and working on embryonic stem cell lines from human embryos conceived in the context of medically assisted insemination, and on imported cell lines created under the same conditions. The decree allows research on: - embryos that are no longer subject to a parental project, with the consent of parents - embryos whose condition does not permit the relocation - embryos carrying the discrepancy sought in connection with pre-implantation diagnosis. |

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| Iceland** | Artificial Fertilization Act, n°55, of 29 May 1996 | <p><u>Article 12:</u> It is prohibited to: [...] d) perform cloning.</p> <p><u>Article 14:</u> Violation of the provisions of this Act or of rules based on it entails fines or imprisonment of up to three months under the terms of this Act.</p> | IDEM | <p><u>Article 11:</u> 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 <i>in vitro</i> fertilization 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.</p> <p><u>Article 12:</u> 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 [...]</p> |
| Ireland* | Constitution of Ireland enacted on 1 July 1937 (Article 40 3° has been incorporated in the constitution in 1983) | <p><u>Article 40 3):</u> 3° 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.</p> <p>Comment: There is no specific regulation on reproductive cloning in Ireland. Nonetheless, the illegality of this practice is not contradicted.</p> | IDEM | <p>Comments: 1° There is an actual controversy on the legality of stemcells research in Ireland. Some lawyers interpret the Constitution as prohibiting it while others interpret the word "unborn" as not including supernumerary embryos (out of a womb). A judgment of the High Court, <i>M.R. v T.R. & Ors</i>, 15 November 2006, stated that the term "unborn" is not applicable to frozen embryos. This judgment is currently on Appeal process to the Supreme Court. 2° Stemcells research is currently processed in Ireland. 3° There is a chronic debate on the embryo statute as abortion is prohibited considering that a human embryo shall be considered as a person according to the constitution.</p> |
| Israel** | The Prohibition of Genetic Intervention Law, 5759-1999, of 29 December 1998 | <p><u>Section 1:</u> The purpose of this Law is to determine a prescribed period of five years [<i>until 2009 according to a five years extension decided by the Knesset assembly in March 2004</i>] during which no kind of genetic intervention shall be performed on human beings [...]</p> <p><u>Section 3:</u> [...] throughout the period during which the Law is in force, no person is to perform any act of intervention in the cells of any person for the purpose of human cloning.</p> <p><u>Section 6:</u> Any offence against this regulation is subject to imprisonment.</p> | | <p>Comment: No provision forbids research on therapeutic cloning. Furthermore, Israel is involved in stemcells research and these researches are partially financed by the government.</p> |

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| <p>Italy**</p> | <p>Law n°40/2004 on medically assisted reproduction entered in force on 24 February 2004</p> | <p><u>Article 13. 3):</u> Are forbidden: [...] c) Cloning interventions [...] for reproduction or research purpose.</p> <p><u>Article 13. 4):</u> A violation of the 1° is liable to a 2 to 6 years imprisonment penalty and a 50.000 to 150.000 Euros fine. A violation of 3° shall be more severe.</p> | <p><i>IDEM</i></p> | <p><u>Article 13.1):</u> Any experiment on human embryo is prohibited.</p> <p><u>Article 13. 2):</u> Clinical experimentation on human embryo is only possible for a therapeutic or a diagnostic purpose concerning the embryo's health itself.</p> <p>Comment: However, the law allows importing and working on embryonic stem cell lines produced before July 2001.</p> <p>A referendum occurred on 12 June 2005 asking whether limitations to research on embryos and provisions on human embryo status had to be abrogated. The referendum failed because of an insufficient vote number.</p> |
| <p>Japan**</p> | <p>Law regulating the technique of human cloning and other similar techniques of 30 November 2000</p> | <p><u>Article 3:</u> No person shall transfer a human somatic clone embryo, a human-animal amphimictic embryo, a human-animal hybrid embryo or a human-animal chimeric embryo into a uterus of a human or an animal.</p> <p><u>Article 16:</u> A person who has violated the provisions under Article 3 shall be punished with imprisonment for not more than ten years or a fine of not more than ten million yen, or with both of these penalties cumulatively.</p> <p>Comment: Article 1 defines the purpose of the law as well as some technical expressions employed. In this article, amphimictic is an individual which cannot be clearly assimilated to a human being or an animal.</p> | <p><i>IDEM</i></p> | <p><u>Article 1:</u> Based upon these understandings, the purpose of this law is [...] to regulate artificial creation of individuals similar to such individuals set forth herein [...] by means of taking other necessary measures to secure appropriate handling of such embryos.</p> <p>Comment: The law states about "specified embryos" which are embryos complying with the guidelines set by the minister of sciences and technologies in order to ensure the respect of ethics principles upon research on embryos. Example: Any Specified Embryo shall be handled in accordance with the Guidelines (article 5). Research cloning is therefore permitted.</p> |
| <p>Kosovo*</p> | <p>Law N°2004 / 4 Kosovo Health Act of 20 August 2004</p> | <p><u>Section 111:</u> Individual cloning is forbidden.</p> <p>Comment: No specific penalty on human reproductive cloning has been set whereas it should be considered as a violation of ethical principles punishable by a 500 to 1000 Euros fine (section 119.3 d).</p> | <p><i>IDEM</i></p> | <p>Comment: No legal frame on research cloning and therapeutic cloning is set up by this law. Nonetheless, <u>section 106</u> states that: "Issues related to research on humans shall be defined with a special law".</p> |
| <p>Latvia*</p> | <p>Law on Sexual and Reproductive Health of January 2002</p> | <p>Section 16 of this law prohibits human reproductive cloning.</p> | <p><i>IDEM</i></p> | <p>Section 16 of this law also prohibits the creation of embryo for both research and therapeutic purposes.</p> <p>Comment: If the creation of embryos for research or therapeutic purposes is forbidden, no provision sets any prohibition upon the use of supernumerary embryos for such purposes.</p> |

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| Lithuania* | Law n°VIII-1679 on ethics of biomedical research dated on 11 May 2000 | <p><u>Section 3.3:</u> Cloning of human being shall be prohibited.</p> <p><u>Section 18:</u> Persons in breach of the requirements of this law shall be held liable in the manner provided by the law.</p> | <i>IDEM</i> | <p><u>Article 3.2:</u> Human embryos may be subjected only to clinical observations (non-invasive investigations). Other clinical investigations involving human embryos and their creation for purposes of biomedical research shall be prohibited. Human embryos may be subjected to such biomedical risks if they are not disproportionate to the potential benefit.</p> <p>Comment: Stemcells research is therefore prohibited.</p> |
| Mexico** | Mexico's Federal District Penal Code (local legislation). | <p><u>Section 154:</u> Is liable to a 2 to 6 years imprisonment sentence and a ban on public employment any person who: [...] iii) Creates human beings by cloning or performs genetic engineering with illicit purposes</p> <p>Comment: This is a local regulation only concerning Mexico's district. Nonetheless, some federal regulations are interpreted by Mexican lawyers as banning human reproductive cloning such as the General Health Law (1984) and its regulation on the sanitary control of organs, tissues and human cadavers (1986) as well as its regulation on scientific research (1987).</p> | National Institutes of Health Amendment Act dated of 20 July 2004 | This Act created the National Institute of Genomic Medicine (INMEGEN) which has been authorized by lawmakers to undertake research on stemcells. This is an implicit recognition of research cloning. |
| Netherlands** | The Embryos Act entered in force on 1 September 2002. | <p><u>Section 24:</u> The following procedures are prohibited: [...] f. performing procedures with gametes or embryos with a view to the birth of a genetically identical human individuals;</p> <p><u>Section 28:</u> 1. Any person who acts in contravention of a prohibition contained in Section [...24...] whether intentionally or unintentionally, shall be liable to a prison sentence not exceeding one year or a fourth-category fine.</p> | <i>IDEM</i> | <p><u>Section 10:</u> The Central Committee shall deliver a favourable recommendation on a research protocol concerning research with embryos which does not induce pregnancy only if:</p> <ul style="list-style-type: none"> - it can reasonably be assumed that the research will lead to a new insights in the field of medical science; - it can reasonably be assumed that the insights referred to under a. cannot be achieved through any forms or methods of research other than research with the embryos in question or through a less invasive form of research; - the research in question meets the standards of proper research methodology; - the research is carried out by or under the direction of persons who are experts in the relevant research area; - the research also satisfies requirements which might reasonably be imposed on it in other respects. |

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| <p>New Zealand**</p> | <p>The Human Assisted Reproductive Technology Act (N°92/2004) of 10 November 2004 as amended by the Human Assisted Reproductive Technology Amendment Act (n°63/2007) of 19 September 2007</p> | <p><u>Schedule 1: FIRST Prohibited actions</u> 1) Artificially form, for reproductive purposes, a cloned embryo [...]. 3) Implant into a human being a cloned embryo. [...] 9) Implant into a human being gametes derived from a foetus, or an embryo that has been formed from a gamete or gametes derived from a foetus.</p> <p><u>Section 8:</u> (1) Every person commits an offence who takes an action described in Schedule 1. [...] (4) A person who commits an offence against this section is liable on conviction on indictment to imprisonment for a term not exceeding 5 years or a fine not exceeding \$200,000, or both.</p> | <p><i>IDEM</i></p> | <p>Research on stemcells is not prohibited by the law which gives the authority to advisory boards in cooperation with the Ministry of Health to edit guidelines on this issue. These guidelines have been adopted in September 2006 by the Ministry of Health authorizing the use of established stemcells for research even if the use of IVF (in vitro fertilized) embryos is prohibited.</p> <p>Comment: The law sets some restrictions as the prohibition to develop an in vitro embryo after 14 days or the storage of such embryos for more than 10 years. It also sets conditions on the acquisition of embryos from donors or import. Any violation shall be liable to imprisonment penalties and/or fines.</p> |
| <p>Norway**</p> | <p>Act of 5 December 2003 N° 100 on the application of biotechnology in human medicine as amended by law n°31 of 15 June 2007</p> | <p><u>Paragraph 3-5: Ban on the creation of human embryos through the use of cloning techniques</u> It is forbidden: a) to create human embryos the use of cloning</p> <p><u>Paragraph 7-5. Penal provisions</u> Whoever wilfully contravenes to this Act or provisions laid down pursuant thereto is liable to fines or to a term of imprisonment not exceeding three months. An accomplice is liable to the same penalties.</p> | <p><i>IDEM</i></p> | <p><u>Paragraph 3-1: Use of supernumerary fertilized eggs for research</u> Supernumerary eggs and cells originating from supernumerary fertilized eggs can only be used in research when the purpose is: [...] 3. to develop new knowledge for the purpose of future treatment of serious diseases in humans.</p> |
| <p>Panama**</p> | <p>Law n°4 prohibiting all forms of cloning and stating other provisions of 15 January 2004</p> | <p><u>Article 1:</u> All kind of promotion, financing or donation as well as the use of public or private funds to experiments, investigate and perform any form of cloning a human beings, meaning the creation of an embryo being the biological duplication of a human beings based on his DNA structure, is forbidden.</p> <p><u>Article 3:</u> Whoever violate the provisions of this law will be sanctioned to a 1.000.000 Balboas fine (1000\$).</p> | <p><i>IDEM</i></p> <p>Familial code article 489 issued by law n°3 of 17 May 1994</p> | <p><u>Article 2:</u> Without prejudice to the previous article, it is allowed to reproduce tissues to repair organs in a therapeutic view, for prevention and to cure diseases, by using umbilical cord of birth babies or by any mean or method that could be developed, only in his favour, in his family's favour or in a third party's benefit.[...] Tissues reproduction is allowed as long as it doesn't imply to create a human beings and it is out of lucrative interests for the person who grant his consent.</p> <p><u>Article 489:</u> Every minor has the right to: 1. His prenatal protection.</p> <p>Comment: An embryo is interpreted as a human beings.</p> |
| <p>Peru**</p> | <p>Children and Adolescents Rights Code</p> | <p><u>Article 1:</u> Is considered as a child any human beings from its conception to 12 years old [...]. The State protects those conceived (children) for everything that is benefitting to</p> | <p><i>IDEM</i></p> | <p>Considering the Constitution and the definition of the children as human beings until their conception and the general prohibition on human cloning, research and therapeutic cloning should also be considered illegal.</p> |

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| | | them [...]. | | |
| | <p>General Health Law n°26842 of 9 July 1997</p> <p>Criminal Code of Peru as amended by law n°27636 published on 16 January 2002</p> | <p><u>Article 7:</u> [...] The fertilization of human oocytes for purposes other than procreation shall be prohibited, as shall the cloning of human beings.</p> <p><u>Article 324:</u> Any person using any genetic manipulation technique to clone human beings shall be liable to a 6 to 8 years imprisonment penalty and an incapacitation [...] (Incorporated by 16 January 2002 Amendment law).</p> | | |
| Poland** | | | <p>Act n°17 of 7 January 1993 on family planning, protection of human foetus and admissible conditions for an abortion + Medical professions Act of 5 December 1996</p> | <p>According to article 1 of the Family Planning Act, the right to life is accorded to every human being including at the prenatal stage. Furthermore, in accordance with the Medical Professions Act, unborn child cannot be part of a scientific experiment. Article 21 of this law, specifies that research on stemcells cannot either be qualified as therapeutic research as it has no direct benefit for the subject of the experiment. Hence, research on embryos is prohibited even if no specific legislation has been set in force on this issue.</p> <p>Comment: There is no definition on embryonic stages in the Polish legislation even if penalties are heavier when the foetus has become capable of living outside the pregnant mother's body. Therefore any attempt to produce stemcells lines will be considered as an illegal abortion, as the embryo is destructed, which is liable to 3 years of prison.</p> |
| Portugal** | <p>Law N° 32/2006 on medically assisted reproduction of 26 July 2006</p> | <p><u>Article 7:</u> 1. Reproductive cloning is prohibited as it tends to create human beings genetically identical to another one.</p> <p><u>Article 36:</u> 1. The transfer in a womb of an embryo created by nuclear transfer, unless if this technique is used for MAP applications, is punished by 1 to 5 years of prison. 2. The same penalty is required for those who proceed to embryo transfer obtained by embryo splitting.</p> | <i>IDEM</i> | <p><u>Article 9:</u> 1. It is prohibited to create embryos by MAP in the deliberate view of its use in research. 2. Scientific research on embryos is nonetheless legal if performed with the purpose of prevention, diagnostic or embryo therapy, of improving MAP's techniques, constituting Stemcells banks for transplants or for any other therapeutic purpose.[...]</p> <p>Comment: Research cloning is only allowed on supernumerary or abnormal embryos from MAPs and genetic diagnostics. Any research attempt violating the legal provisions set by this law is punished by 1 to 5 years in prison (art. 40).</p> |
| Republic of Korea** | <p>The Bioethics and Safety Law n°7150 entered in force on 1 January 2005 as revised on 16 March 2008</p> | <p><u>Article 1:</u> 1. No one shall implant a somatic cell embryo clone into a uterus, maintain a cloned embryo within a uterus, or give birth when the pregnancy results from the act of implanting a somatic cell embryo clone into a uterus. 2. No one shall induce or assist in the activities defined in</p> | <i>IDEM</i> | <p><u>Article 17:</u> Remaining Embryos that have passed the storage period outlined in Article 16 may be utilized for the following purposes, but only until the embryological primitive streaks appear in their developmental process:</p> |

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| | | <p>Article 11-1.</p> <p><u>Article 49:</u> 1. Anyone who, in violation of Article 11-1 implants a somatic cell embryo clone into a uterus, maintains a cloned embryo within a uterus, or gives birth when the pregnancy results from the act of implanting a somatic cell embryo clone into a uterus shall be sentenced to up to 10 years of imprisonment.</p> | | <p>1. To conduct research aimed at developing contraception and infertility treatments;</p> <p>2. To conduct research aimed at curing rare or incurable diseases, as decreed by the President.</p> <p>3. To conduct other research approved by the President after being reviewed by the Committee. However, in order to utilize a remaining embryo that has been stored for less than 5 years, a new consent, for this new purpose, is required from the Consenters.</p> <p>Comment: Research on stemcells was banned on 2005 because of fraudulent claims from Korean scientists. The National Bioethics Committee removed this ban on March 2007.</p> |
| Russian Federation (outdated moratorium) | Federal Law on Temporal Ban on Human Cloning of April 2002 | The law was prohibiting reproductive cloning as well as import/export of clone through a 5 years moratorium that expired in 2007. So far, this legislation has not been extended or renewed. | | |
| Singapore** | Human cloning and Other Prohibited Practices Act n°34 of 1 October 2004 | <p><u>Section 5:</u> No person shall place any human embryo clone in the body of a human or the body of an animal.</p> <p><u>Section 18:</u> Any person who contravenes section 5, 7, 8, 9, 10, 11, 12 or 13 shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$100,000 or to imprisonment for a term not exceeding 10 years or to both.</p> | <i>IDEM</i> | <p><u>Section 7:</u> No person shall develop any human embryo that is created by a process other than the fertilisation of a human egg by human sperm, for a period of more than 14 days excluding any period when the development of the embryo is suspended.</p> <p>Comment: Research cloning is allowed with embryos that are not "prohibited embryos" in accordance with this law and under the conditions set up by the Ethical Guidelines on Gene Technology.</p> |
| Slovakia** | <p>Law n°277/1994 on Healthcare + Act No. 576/2004 of 22 September 2004 on healthcare, healthcare-related services and on the amendment and supplementing of certain laws</p> <p>Penal code (Law N°140/1961 , as later amended)</p> | <p><u>Paragraph 46a:</u> Any intervention seeking to create a human being genetically identical to another human being, whether living or dead is prohibited.</p> <p>Comment: The wording of the additional Protocol on the Prohibition of Cloning Human Beings of the European Convention on Biomedicine and Human Rights has been reproduced. This wording has been also reused in Act n°576/2004 of 22 September 2004.</p> <p><u>Penal code paragraph 246 a):</u> Any intervention aiming to create a human being in any stage of its formation, which is genetically identical to another human being whether living or dead is punished by imprisonment for 3 to 8 years, a financial penalty and the injunction of professional activities.</p> | <i>IDEM</i> | <p><u>Paragraph 26:</u> (10) It is not allowed to perform the research without medical indication on (a) a living foetus or an embryo,</p> <p>Comment: No specific regulation exist on therapeutic cloning even if the above mentioned provision forbids research cloning as it is not a research performed on medical indication for the embryo.</p> |

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| <p>Slovenia**</p> | <p>Law on Biomedically assisted reproduction n°70/2000 of 8 August 2000</p> | <p>Section 33 of this law prohibits human reproductive cloning within the terms of the European Convention on Biomedicine and Human Rights which has been ratified by this country.</p> | <p><i>IDEM</i></p> | <p><u>Article 38:</u> Scientific research on [...] early embryos, created for the purposes of biomedically assisted fertilisation is allowed exclusively for the purposes of protecting and improving human health and only when the research cannot be performed, with comparable effectiveness, on animal embryos or by other methods, [...]</p> <p>Comment: No regulation prohibits research cloning but therapeutic cloning which implies the creation of an embryo genetically identical to another is prohibited because of article 33 of this law.</p> |
| <p>South Africa**</p> | <p>National Health Act n°61 of 23 July 2004.</p> | <p><u>Paragraph 57:</u> (1) A person may not: (a) manipulate any genetic material, including genetic material of human gametes, zygotes or embryos: or (b) engage in any activity, including nuclear transfer or embryo splitting, [...] (5) Any person who contravenes a provision of this section or who fails to comply therewith is guilty of an offence and is liable on conviction to a fine or to imprisonment for a period not exceeding five years or to both a fine and such imprisonment.</p> | <p><i>IDEM</i></p> | <p><u>Paragraph 57:</u> (2)The Minister may under such conditions as maybe prescribed, permit therapeutic cloning utilising adult or umbilical cord stem cells. (3) No person may import or export human zygotes or embryos without the prior written approval of the Minister. (4) The Minister may permit research on stem cells and zygotes which are not more than 14 day olds on a written application and if- (a) the applicant undertakes to document the research for record purposes: and (b) prior consent is obtained from the donor of such stem cells or zygotes.</p> |
| <p>Spain**</p> | <p>Law n° 14 on assisted reproductive techniques of 23 May 2006</p> <p>Penal code, provision introduced by organic law n°15/2003 of 23 November 2003</p> | <p><u>Article 26: Infractions</u> c. Very serious infractions [...] 9. The practice of nuclear transfer within a reproductive purpose.</p> <p><u>Article 160:</u> 2. Whoever fertilizes a human egg for another purpose than human procreation will be punished by a penalty of 1 to 5 years imprisonment and a special incapacity for public or office employment for 6 to 10 years. 3. The same penalties are applied for the creation of identical human beings by cloning or other procedures directed at racial selection</p> <p>Comment: Originally, law n°35/1988 on assisted Human Reproduction prohibited human reproductive cloning in its article 20 paragraph 2B k) until organic law n°10/1 995 suppressed this provision. Then, organic law n°15/2 003 replaced this prohibition on Spanish penal code as above mentioned. These changes are the result of a Constitutional Court decision n°116/1999 of 16 June 1999. Finally, law n°35/1988 has been abrogated and</p> | <p><i>IDEM</i></p> <p>Law N° 14/2007 on biomedical research of 3 July 2007</p> | <p>Research cloning on supernumerary embryos is allowed under the terms of articles 15 and 16 on the use of pre-embryos for investigations and conservation and use of pre-embryos for investigations respectively.</p> <p><u>Article 33: Procurement of embryonic cells</u> (1) The creation of human pre-embryos and embryos solely for experimental purposes shall be prohibited. (2) The use of any technique for obtaining human stem cells for therapeutic or research purposes, including the activation of oocytes through nuclear transfer, shall be permitted under the terms laid down in this Law, provided that it does not entail the creation of a pre-embryo or embryo solely for this purpose.</p> <p>Comment: Research cloning is allowed.</p> |

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| | | replaced by law n°14/2006. | | |
| Sweden** | Law n° 115 on measures for the purposes of research or treatment in connection with fertilized human oocytes of 14 March 1991 as revised on 1 April 2005 (text not found in English) | Human reproductive cloning is explicitly prohibited in the 2005 version of the law. | <i>IDEM</i> | The law on 1 April 2005 authorized research on fertilised eggs for purposes other than IVF treatment and research on therapeutic cloning. |
| Switzerland ** | Federal Law on Embryonic Stemcells Research of 19 December 2003 entered into force on 1 March 2005 | <p><u>Article 3:</u> It is forbidden: [...] c. To create a clone, a chimera or a hybrid (Article 36, al.1, law of 18 December 1998 on medically assisted procreation), to produce embryonic stemcells from a clone, a chimera or a hybrid, or to use their cells. [...] Is also forbidden; [...] d. To implant into a woman a supernumerary embryo used to produce stemcells. [...]</p> <p><u>Article 24:</u> Is liable to an imprisonment penalty whoever intentionally ; [...] b. Uses supernumerary embryos for a purpose other than the producing of stemcells.</p> | <i>IDEM</i> | <p><u>Article 12: Scientific and ethical requirements for research projects</u> A research project within embryonic stemcells are to be used can only be managed if: a. The project aims to acquire essential knowledge: 1. Aiming to diagnostic, to treat or to prevent serious human diseases, or [...] b. Equal value knowledge cannot be obtained by other means c. The project complies with scientific quality requirements; d. The project is acceptable in view with the ethical grounds</p> <p>Comment: Research cloning is also allowed with restrictions. This law deals as well with patent law, stemcells international exchanges, etc.</p> |
| Tunisia** | Law n°2001-93 relative to the medicine of reproduction of 7 August 2001 | <p><u>Section 8:</u> Reproductive medicine by the mean of cloning techniques shall be strictly prohibited.</p> <p>Sanction: 5 years imprisonment and 10.000 dinars fine.</p> | <i>IDEM</i> | <p><u>Section 9:</u> The in vitro conception or by other means of human embryos, for studies, research or experiment purposes is forbidden.</p> <p><u>Section 11:</u> The freezing of gametes or embryos is allowed only for therapeutic purposes in view of assisting two members of a couple to procreate [...] gametes can be conserved for a maximum period of 5 years [...]. At this delay expiry [...] these gametes shall be destroyed and the embryos freezing shall be interrupted.</p> <p><u>Section 13:</u> A human embryo shall only be conceived in vitro or by other techniques in the frame reproductive medicine.</p> <p>Comment: These 3 provisions implicitly prohibit therapeutic cloning as mentioned by recommendation n°5 of the National Medical Ethics Committee.</p> |
| Turkey | Regulation on In Vitro Fertilization and Embryo | Prohibits human reproductive cloning. | | |

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| | Transfer Centers, 1996 | | | |
| Ukraine | Ban on Human Reproductive Cloning Bill 16 December 2004 (text not found) | Prohibits human reproductive cloning. | | |
| United Kingdom** | Human reproductive cloning Act of 4 December 2001 Human Embryology & Fertilization Act of 1 November 1990 | <p><u>Section 1: The Offence</u> (1) A person who places in a woman a human embryo which has been created otherwise than by fertilization is guilty of an offence. (2) A person who is guilty of the offence is liable on conviction on indictment to imprisonment for a term not exceeding 10 years or a fine or both.</p> <p><u>Section 3: Prohibitions in connection with embryos</u> (3) A licence cannot authorise— [...] (d) replacing a nucleus of a cell of an embryo with a nucleus taken from a cell of any person, embryo or subsequent development of an embryo</p> <p>Comment: This provision is not respected as therapeutic cloning researches are processed in accordance with regulations n°188 of 31 January 2001. When the law was passed in 1990, this provision consisted in preventing human reproductive cloning. Nonetheless, this inconsistency has been criticized by Ministry of Health review on HFE Act in 2006 and it has been proposed to remove it.</p> <p>The British Parliament adopted at the end of May 2008 a new law on human fertilization and embryology. It allows the creation of human-animal hybrid embryos from integration of human DNA into animal eggs. These hybrids are designed for research purposes, and they must be destroyed after 14 days of development.</p> | Human Embryology & Fertilization Act of 1 November 1990 as amended by regulations n°188 and entered in force on 31 January 2001 | <p><u>Section 2: Further purposes for which research licences may be authorised</u> (1) The Authority may issue a licence for research under paragraph 3 of Schedule 2 to the Act for any of the purposes specified in the following paragraph. (2) A licence may be issued for the purposes of (a) increasing knowledge about the development of embryos (b) increasing knowledge about serious disease, or (c) enabling any such knowledge to be applied in developing treatments for serious disease</p> <p>Comment: Regulations n°188 add research purposes for license granting in order to allow stem cells research.</p> |
| United Arab Emirates | Draft law on accreditation of fertilization centers (prepared in July 2007) | The draft law implicitly prohibits all forms of human cloning, because it prohibits the marketing of human oocytes, zygotes and sperm for research purposes. It also prohibits research on embryos even if they are no longer subject to a parental project. | | The draft law implicitly prohibits all forms of human cloning, because it prohibits the marketing of human oocytes, zygotes and sperm for research purposes. It also prohibits research on embryos even if they are no longer subject to a parental project. |
| United States of America | <p><u>California</u>: (Business And Professions §16004-5 Health & Safety §24185, §24187, §24189, §12115-7). <u>Arkansas</u>: §20-16-1001 to 1004. <u>Connecticut</u>: 2005 SB 934 <u>Indiana</u>: 2005 Senate Enrolled Act No. 268 <u>Iowa</u>: 707B.1 to 4</p> | Regulations on reproductive cloning have only been issued by state governments. So far, 15 States have a pertaining legislation on it and the following 13 States banned reproductive cloning explicitly: California, Arkansas, Connecticut, Indiana, Iowa, Maryland, Massachusetts, Michigan, Rhode Island, New Jersey, North Dakota, South Dakota, and Virginia. | Public Law n° 104-99 ("Dickey Amendment") of 1996 | Dickey amendment, passed under Clinton's presidency and renewed under Bush's presidency prohibits the allowance of federal funding for: (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero [...]. |

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| | <p><u>Maryland</u>: 2006 SB 144 <u>Massachusetts</u>: 2005 SB 2039</p> | | | |
| | <p><u>Michigan</u>: §333.2687-2688, §333.16274-16275, 333.20197, 333.26401-26403, 750.430a <u>Rhode Island</u>: §23-16.4-1 to 4-4 <u>New Jersey</u>: §2C:11A-1, §26:2Z-2 <u>North Dakota</u>: §12.1-39 <u>South Dakota</u>: §34-14-27 <u>Virginia</u>: §32.1-162.32-2</p> | | <p>US Statement of 9 August 2001</p> <p>States regulations:</p> | <p>US Statement allowed federal financing for stemcells research on 22 lines existing before 9 august 2001. Nonetheless, stemcells financing by private funds is not limited. Regulations on cloning are issued by States.</p> <p><u>States banning therapeutic cloning and research destroying embryos:</u> Louisiana, Michigan, Minnesota, Arkansas, Indiana, Iowa, Michigan, North Dakota, South Dakota, and Virginia (because 'human being' was left undefined in the legislation).</p> <p><u>States without cloning legislation:</u> Alabama, Alaska, Colorado, Delaware, Florida, Georgia, Hawaii, Idaho, Kansas, Kentucky, Maine, Minnesota, Mississippi, Montana, Nevada, New Mexico, New York, North Carolina, Oregon, South Carolina, Tennessee, Texas, Utah, Vermont, Washington, West Virginia, Wisconsin, and Wyoming</p> <p><u>States funding Stemcells research:</u> California (California Institute for Regenerative Medicine), Connecticut (Connecticut Stem Cell Research Grants Program), Illinois (Illinois Regenerative Medicine Institute), Maryland (Maryland Stem Cell Research Fund),and New Jersey (The Stem Cell Institute of New Jersey and the New Jersey Stem Cell Research Grants Program).</p> |
| Vietnam** | <p>Government Decree banning human cloning and surrogacy of 12 February 2003</p> | <p>This ordinance prohibits human reproductive cloning.</p> | | |

Table 2: International Conventions

| | OVIEDO'S CONVENTION PROTOCOL N°1⁵ | PACT OF SAN JOSE, COSTA RICA⁶ |
|----------------------------|--|--|
| Source | Council of Europe done at Oviedo, Spain, on 4 April 1997 and Additional Protocol done at Paris on 12 January 1998. | Inter-American Specialized Conference on Human Rights of 22 November 1969, entered in force on 18 July 1978 |
| Short title | Convention on Human Rights and Biomedicine and Protocol N°1 of Paris | American Convention on Human Rights |
| Long Title | 1) Convention for the protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine 2) Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings. | <i>IDEM</i> |
| Relevant provisions | <u>Article 1:</u> 1. Any intervention seeking to create a human being genetically identical to another human being, whether living or dead is prohibited. 2. For the purpose of this article, the term human being "genetically identical" to another human being means a human being sharing with another the same nuclear gene set. | <u>Article 1:</u> 2. For the purposes of this Convention, "person" means every human being <u>Article 2:</u> Where the exercise of any of the rights or freedoms referred to in Article 1 is not already ensured by legislative or other provisions, the States Parties undertake to adopt, in accordance with their constitutional processes and the provisions of this Convention, such legislative or other measures as may be necessary to give effect to those rights or freedoms. <u>Article 4.1:</u> 1. Every person has the right to have his life respected. This right shall be protected by law and, in general, from the moment of conception. No one shall be arbitrarily deprived of his life. |
| Comment | Bulgaria, Croatia, Moldova and Romania don't appear in the table even though these States signed and ratified protocol N°1 of Oviedo's convention on Human reproductive cloning prohibition. They should be therefore considered as countries having a legislation banning it | This Convention sets as a principle (using the term "in general") the right to life from the conception. Therefore, countries which ratified it should be considered as banning research destructing embryos as well as therapeutic cloning. Nonetheless, the term "in general" can be interpreted otherwise as Mexico did to allow therapeutic cloning research. |

⁵. Countries having ratified the Protocol: Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Georgia, Greece, Hungary, Iceland, Lithuania, Moldova, Portugal, Romania, Slovakia, Slovenia, Spain, Switzerland

⁶. Countries having ratified the Pact: Argentina, Barbados, Bolivia, Brazil, Chile, Colombia, Costa Rica, Dominica, Ecuador, El Salvador, Grenada, Guatemala, Haiti, Honduras, Jamaica, Mexico, Nicaragua, Panama, Paraguay, Peru, Dominican Republic, Suriname, Trinidad and Tobago, Uruguay, Venezuela

Main sources

- WHO - International Digest Of Health Legislation: - <http://www.who.int/idhl-rils/frame.cfm?language=english>
- Center for Genetics and Society - <http://www.geneticsandsociety.org/index.php>
- Global Lawyers and Physician - <http://www.glyphr.org/>
- Oxford Journals - <http://humrep.oxfordjournals.org/>
- World Law Bulletin - <http://www.fas.org/sgp/othergov/wlb/index.html>
- European Commission – National Ethics Committees - http://ec.europa.eu/research/biosociety/bioethics/bioethics_ethics_en.htm
- Stem Cell policy - <http://www.mbbnet.umn.edu/scmap.html>
- Bionetonline - http://www.bionetonline.org/english/Content/sc_leg2.htm
- Connexions - <http://cnx.org/content/m14836/latest/>
- The Hinxton Group - http://www.hinxtongroup.org/wp_am_exc.html
- DNApolicy - <http://www.dnapolicy.org/>
- WHO –Ethics and Health (Bioethics committees) - <http://www.dnapolicy.org/>
- Lexadin - <http://www.lexadin.nl/>
- Regulacion Juridicas de las Bioetnologias - <http://www.biotech.bioetica.org/>
- Eureth.net - <http://eurethnet.kib.ki.se/Inline/links.htm>
- Americans to ban cloning - <http://www.cloninginformation.org/>
- UK Department of Health - <http://www.advisorybodies.doh.gov.uk/>
- The Human Future - <http://www.thehumanfuture.org/>
- Pew Forum Stem Cells - <http://pewforum.org/docs/?DocID=318>
- Baltic countries Stem Cells - <http://www.scanbalt.org/>
- National legislation sites, National parliament sites, National Health Departments sites, Ethics committees sites, Council of Europe, Organisation of American States, etc.