

**NATIONAL REGULATORY FRAMEWORKS
REGARDING HUMAN CLONING FOR REPRODUCTIVE
AND THERAPEUTIC/RESEARCH PURPOSES**

A Report for the Genetics and Public Policy Center

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Human cloning, an umbrella phrase used traditionally by scientists to describe various processes for duplicating biological material, has sparked worldwide interest due to its scientific and ethical implications. In 2005, the United Nations adopted the *Declaration on Human Cloning* which “prohibit[s] all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life.” This nonbinding text won the vote of only 84 countries, demonstrating is a lack of global consensus regarding human cloning.

The following report provides a comparative overview of regulatory approaches to human cloning, whether reproductive or therapeutic, across 16 countries. Depending on the moral or legal status given to the human embryo by each country, reproductive and therapeutic cloning is defined and regulated differently among the countries. The major goal of this study is to provide an analytical understanding of the policy landscape around the globe, with an aim to contribute to worldwide policy debates.

POLICIES REGARDING HUMAN CLONING FOR REPRODUCTIVE AND RESEARCH/THERAPEUTIC PURPOSES

AUSTRALIA (Federal)

- Australian Academy of Science, *On Human Cloning*, (1999),
<http://www.science.org.au/reports/clone.pdf>
- Australian Academy of Science, *Human Stem Cell Research*, (2001),
<http://www.science.org.au/reports/stemcell.pdf>
- *Research Involving Human Embryos Act No. 145, An Act to regulate certain activities involving the use of human embryos, and for related purposes*, (2002),
<http://scaleplus.law.gov.au/html/comact/11/6603/pdf/1452002.pdf>
- *Prohibition of Human Cloning Act No. 144, An Act to prohibit human cloning and other unacceptable practices associated with reproductive technology, and for related purposes*, (2002), <http://www.nhmrc.gov.au/publications/files/prohibit.pdf>
- Council of Australian Governments, *Arrangements for Nationally-Consistent Bans on Human Cloning and Other Unacceptable Practices, and Use of Excess Assisted Reproductive Technology (ART) Embryos*, (April 2002),
http://www.pm.gov.au/news/media_releases/2002/media_release1588.htm
- National Health and Medical Research Council, *Ethical guidelines on the use of the assisted reproductive technology in clinical practice and research*, (September 2004),
<http://www.nhmrc.gov.au/publications/files/e56.pdf>
- Australian Government, *Legislation Review of Australia's Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002*, (August 2005),
<http://www.lockhartreview.com.au/files/Legislation%20Review%20Reports%20Full%20Doc-19Dec05.pdf>

Descriptive Synopsis

Legislative acts:

In 2002, the Australian Government adopted federal legislation to regulate cloning and embryonic stem cell research under the *Research Involving Human Embryos Act* and the

Prohibition of Human Cloning Act. These two acts limit research on human embryos under certain criteria.

The *Research Involving Human Embryos Act 2002* ensures that embryos are not created solely for the purpose of harvesting their stem cells. A “human embryo” in this Act is “a live embryo that has a human genome or an altered human genome and that has been developing for less than 8 weeks since the appearance of 2 pro-nuclei or the initiation of its development by other means.”

The *Prohibition of Human Cloning Act 2002*, on the other hand, comprehensively prohibits and sanctions any kind of human cloning (therapeutic or reproductive) along with a range of other practices relating to assisted reproductive technology (ART). This Act prohibits the creation of an embryo other than by the fertilization of a human egg by a human sperm and the creation of human embryos for research purposes. Therefore, creating a human embryo for purposes other than achieving pregnancy is considered an offense in Australia. According to the Act, a *human embryo* is defined as “a live embryo that has a human genome...that has been developing for less than 8 weeks...since the initiation of its development.”

The *Prohibition of Human Cloning Act 2002* criminalizes the creation of a human embryo clone, the placement of a human embryo clone in the body of a human or the body of an animal, and the export or import of a human embryo clone into Australia. For the purpose of this Act, a “human embryo clone” means “a human embryo that is a genetic copy of another living or dead human, but does not include a human embryo created by the fertilization of a human egg by human sperm.” Furthermore, the Act specifies that for the purpose of establishing that a human embryo clone is a genetic copy of a living or dead human, “it is sufficient to establish that the set of genes in the nuclei of the cells of the living or dead human has been copied; and it is not necessary to establish that the copy is an identical genetic copy.”

In 2005, the Legislation Review Committee (also referred to as the “Lockhart Review Committee”) conducted an independent review of both the *Research Involving Human Embryos Act* and the *Prohibition of Human Cloning Act* in order to assess the existing regulatory framework in light of scientific progress and changes in community understanding and standards since 2002. One key recommendation made by the committee consists of changing the legal definition of the human embryo. A “human embryo” would then be considered a “discrete living entity” and defined as such when it is 14 days old and no sooner. Lifting the ban on therapeutic cloning, or somatic cell nuclear transfer (SCNT), under strict ethical and scientific regulation, was supported by the committee in this review. However, reproductive cloning should remain banned, the committee stated. The Lockhart Review also recommends certain administrative improvements that will help increase regulatory flexibility in the licensing process and the provision of further support to the regulatory scheme by enhancing the National Health and Medical Research Council guidelines. The committee's reports were tabled in both Houses of Parliament and presented to the Council of Australian Governments on December 19, 2005.

There is heated debate currently at the Australian Parliament regarding whether to translate into national law the recommendations made by the Lockhart Committee. The federal government strongly opposes liberalizing the current legal framework in order to allow therapeutic cloning.

Other normative measures:

In 2002, the Council of Australian Governments (COAG) agreed that there is a need for consistent legislation between the Commonwealth, states and territories in Australia concerning the ban on human cloning and other unacceptable practices. The council has agreed to enforce nationally consistent legislation to allow research only on existing excess ART embryos that would otherwise have been destroyed under a strict regulatory regime. The arrangements agreed by the council aim to prohibit human cloning, regulate certain unacceptable practices involving human embryos, ensure the respect for ethical issues in research involving human embryos (as consistent with NHMRC ethical guidelines), and allow research on existing stem cell lines.

In both its position statements on human cloning (“*On Human Cloning*”) and on stem cell research (“*Human Stem Cell Research*”), the Academy of Science clearly supports the ban on reproductive cloning to produce human fetuses based on ethics and safety. With respect to research using human embryonic stem cell lines for the cloning of human tissues, the academy is of the opinion that “human cells, whether derived from cloning techniques, from ES [embryonic stem] cells...should not be precluded from use in approved research activities in cellular development biology.” The academy first defines an embryo as “the developing human organism from the time of fertilization until the main organs have developed, eight weeks after fertilization. After this time the organism becomes a fetus.” The process of cloning in general is defined by the academy as the “production of a cell or organism with the same nuclear genome as another cell or organism.” In particular, “human reproductive cloning” is defined as “the production of a human fetus from a single cell by asexual reproduction,” while “therapeutic cloning” is defined as “medical and scientific applications of cloning technology which do not result in the production of genetically identical fetuses or babies.”

CANADA

- Medical Research Council of Canada, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement — Ethical Conduct for Research Involving Humans*, (August 1998, amended 2000, 2002 and 2005), <http://www.pre.ethics.gc.ca/english/pdf/TCPS October 2005 E.pdf>

- Standing Committee on Health- House of Commons, *Assisted Human Reproduction: Building Families*, (2001).
- *An Act Respecting Assisted Human Reproduction and Related Research*, (March 2004), <http://laws.justice.gc.ca/en/A-13.4/text.html>
- Canadian Institutes of Health Research, *Updated Guidelines for Human Pluripotent Stem Cell Research*, (June 2006) (this version supersedes the June 2005 version), <http://www.cihr-irsc.gc.ca/e/31488.html>

Descriptive Synopsis

Legislative acts:

The *Act Respecting Assisted Human Reproduction and Related Research* defines an embryo as “a human organism during the first 56 days of its development following fertilization or creation and includes any cell derived from such an organism that is used for the purpose of creating a human being.” The Act prohibits the creation of embryos for research.

Concerning the issue of cloning, the Act prohibits anyone from offering or advertising the following activities:

- (a) creation of a human clone using any technique, or transplantation of a human clone into a human being or into any non-human life form or artificial device;
- (b) creation of an *in vitro* embryo for any purpose other than creating a human being or improving or providing instruction in assisted reproduction procedures;
- (c) for the purpose of creating a human being, creation of an embryo from a cell or part of a cell taken from an embryo or fetus or transplantation of an embryo so created into a human being.

The Act defines a human clone 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, fetus or embryo.”

Other normative measures:

The Canadian Institutes of Health Research (CIHR) was established in 2000 as a federal funding agency with the duty to ensure that all health research carried out under its authority involving human or human biological material conforms with the highest ethical standards. The *Updated Guidelines for Human Pluripotent Stem Cell Research* (2006) supersede earlier guidelines and is based on principles established in the *Tri-Council Policy Statement*. According to the guidelines, it is prohibited to conduct:

- research involving the creation of human embryos specifically to derive stem cell lines;
- research involving somatic cell nuclear transfer into human oocytes (cloning) or the stimulation of an unfertilized egg to produce a human embryo (parthenogenesis) for the purpose of developing human embryonic stem cell lines;
- research involving the direct donation of stem cell line;
- research in which human or non-human embryonic stem cells, embryonic germ cells or other cells that are likely to be pluripotent are combined with either a human embryo or a human fetus.

The *Tri-Council Policy Statement* particularly describes policies that promote ethical practices in research involving humans. This statement was jointly adopted by the Medical Research Council (MRC), the Natural Sciences and Engineering Research Council (NSERC), and the Social Sciences and Humanities Research Council (SSHRC). According to this policy statement, practices that are considered to be unethical include:

- The creation of embryos specifically for the research purposes.
- Research that involves cloning human beings by any means, including somatic cell nuclear transfer (SCNT).

CHINA

- Bioethics Committee, Southern China National Human Gene Research Center, *Ethical Guidelines for Human Embryo Stem-Cell Research*, (October 2001).
- Government of the Hong Kong Special Administrative Region, *The Human Reproductive Technology Ordinance, An Ordinance No. 47* (Gazette, Legal Supplement No. 1 to No. 26, Vol. 4, June 2000, pp. A1691-A1777, amended 2002), <http://www.hkllii.org.hk/hk/legis/ord/561/>
- Ministry of Health, *Guidelines on Assisted Reproductive Technologies for Human Beings*, (July 2003).
- Chinese Ministry of Science and Technology and Ministry of Health, *Ethical Guidelines on Human Embryonic Stem Cell*, (January 2004), http://www.chinaphs.org/bioethics/regulations_&_laws.htm#_Toc113106142

Descriptive Synopsis

Legislative acts

The *Human Reproductive Technology Ordinance* enacted by the Government of the Hong Kong Special Administrative Region, though not yet in operation, regulates the

creation, use and manipulation of an embryo, whether or not the embryo is to be implanted into the body of a woman. The ordinance defines an embryo as, “a live human embryo where fertilization is complete; and references to an embryo include an egg in the process of fertilization, and, for this purpose, fertilization is not complete until the appearance of a 2 cell zygote.” The creation of embryos for research, somatic cell nuclear transfer and embryo cloning are all procedures that are prohibited by the ordinance under section 15 (1).

Other normative measures

The *Ethical Guidelines on Human Embryonic Stem Cell* regulate the derivation of embryonic stem cells used for research. According to these guidelines, human reproductive cloning is prohibited while cloning for therapeutic or research purposes is allowed. Furthermore, the creation of embryos for stem cell research is not permitted. The guidelines state that human embryonic stem cells used for research be derived only from “spared (sic) gamete or blastula after IVF,” “fetal cells after natural or voluntarily selective abortion,” “blastula or monosexual split blastula by somatic cell nucleus transfer technique,” and “germ cells voluntarily donated” (art. 5). The *Guidelines on Assisted Reproductive Technologies for Human Beings* adopted by the Ministry of Health also ban reproductive cloning explicitly.

FRANCE

- *Code Civil*, (1804),
http://ledroitcriminel.free.fr/la_legislation_criminelle/lois_speciales/code_civil.htm
(certain extracts - in French only)
- *Code de la propriété intellectuelle* (Code of Intellectual Property), (2001),
<http://www.copyrightfrance.com/hypertext/cpi1.htm>
- *Loi no. 94-654 du 29 juillet 1994 relative au don et à l'utilisation des éléments et produits du corps humain, à l'assistance médicale à la procréation et au diagnostic prénatal*, (Law no. 94-654 governing the donation and use of elements and products of the human body, medically assisted reproduction, and prenatal diagnosis), (July 1994),
<http://www.legifrance.gouv.fr/WAspad/UnTexteDeJorf?numjo=SPSX9400032L>,
revised by the *Loi no. 2004-800 du 6 août 2004 relative à la bioéthique* (Bioethics Law), (August 2004),
<http://www.legifrance.gouv.fr/WAspad/UnTexteDeJorf?numjo=SANX0100053L>
- National Consultative Ethics Committee, *Opinion on a preliminary draft law incorporating transposition into the Code of intellectual property, of a European Parliament and Council Directive 98/44/CE dated July 6, 1998, on the legal protection of biotechnological inventions*, (1998).

- National Consultative Ethics Committee, *Opinion (No. 67) on the Preliminary Draft Revision of the Laws on Bioethics*, (January 2001), <http://www.ccne-ethique.fr/english/start.htm>
- *Decree No. 2006-121 regarding embryo research and on embryonic cells, and modifying the Code of Public Health*, (2005), <http://www.admi.net/jo/20060207/SANP0524383D.html> (in French)
Press release by the French Biomedicine Agency regarding the decree, (July 2006), <http://www.agence-biomedecine.fr/fr/presse/doc/Decret-embryon-VA.pdf> (in English)

Descriptive Synopsis

Legislative acts:

Under the *Bioethics Law* it is prohibited to create embryos for research purposes or for the creation of stem cells. Therapeutic cloning is thus prohibited while reproductive cloning is considered a “crime against the human race.” Both procedures are criminalized under the law, but there is discussion in France of reconsidering the prohibition on therapeutic cloning.

The French medical association the *Conseil de l'Ordre des Medecins* has released a statement criticizing the adopted Bioethics Law because the law does not protect the legal status of the embryo. The association protests that the law would lead to regarding an embryo “as an object that could be disposed of and subjected to manipulations” (BMJ - <http://bmj.bmjournals.com/cgi/content/full/309/6968/1534>).

Other normative measures:

According to its various opinion statements, the National Consultative Ethics Committee (CCNE) is unanimously in favor of explicitly prohibiting reproductive cloning in French law. Regarding therapeutic cloning, the members of the CCNE have not come to a consensus on whether to ban this type of research due to the difficult ethical questions associated with the topic. However, the majority is in favor of therapeutic cloning under controlled conditions.

It is the CCNE’s view that the production of stem cell lines from embryos must only be derived using aborted fetuses, surplus in vitro fertilization (IVF) embryos, or cell nuclear replacement embryos. Furthermore, the committee declares that the human embryo must, as soon as it is formed, receive the respect owed to its status. The creation of embryos solely for the purpose of research is thus prohibited, with the exception in the context of evaluation of new medically assisted reproductive techniques.

The *Code of Intellectual Property* dictates at article 611-17 that, “the human body, its elements, and its products, as well as knowledge of the total or partial structure of the human gene, cannot as such be the subject of a patent.” This article adds a list of inventions that are excluded, and whose publication, implementation, or commercial exploitation would be contrary to public order. This list includes processes for cloning human beings. The basis for these prohibitions is consecrated in the French *Civil Code*, which states: “The human body, its elements, and its products cannot be the object of any rights of patrimony” and “conventions with a view to confer rights of patrimony to the human body, its elements, or its products, are null and void.”

GERMANY

- *The Embryo Protection Law*, (1990).
- *Act ensuring the protection of embryos in connection with the importation and utilization of human embryonic stem cells* (Stem Cell Act), (June 2002), <http://217.160.60.235/BGBL/bgb11f/BGB1102042s2277.pdf> (in German)
- German National Ethics Council, *Cloning for reproductive purposes and cloning for the purposes of biomedical research*, (September 2004), http://www.ethikrat.org/english/publications/Opinion_Cloning.pdf

Descriptive Synopsis

Legislative acts:

Under German Law, human cloning (therapeutic or reproductive) is criminalized by the *Embryo Protection Law*. Furthermore, the use of human embryos for research purposes is not allowed.

Article 6 of this law states, “any person who artificially causes a human embryo to develop with the same genetic information as another embryo, fetus, living person, or deceased person shall be punished by up to five years’ imprisonment or by a fine. The same penalty shall be imposed on a person who transfers an embryo...into a woman.”

Finally, for the purpose of the *Embryo Protection Law*, the term “embryo” is defined as a “human egg cell, fertilized and capable of development, from the time of fusion of the nuclei, as well as each totipotent cell removed from an embryo that is capable, in the presence of other necessary conditions, of dividing and developing into an individual.”

Other normative measures:

The German National Ethics Council expresses, in its opinion statement *Cloning for reproductive purposes and cloning for the purposes of biomedical research*, support for an absolute ban on reproductive cloning and also recommends that research cloning should not be permitted in Germany at the present time.

INDIA

- Indian Council of Medical Research, *Consultative Document on Ethical Guidelines for Biomedical Research on Human Subjects*, (2000), <http://icmr.nic.in/ethical.pdf>
- Department of Biotechnology, Ministry of Science and Technology, *Ethical Policies on the Human Genome, Genetic Research and Services*, (June 2001), <http://dbtindia.nic.in/publication/publicmain.html>
- Indian Council of Medical Research, *National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India*, (2004), http://www.icmr.nic.in/art_clinic/art_clinic.htm
- Department of Biotechnology, Ministry of Science and Technology, Government of India, *Ethical Issues and Consent Process Pertaining to Stem Cell Research*, (2004), <http://dbtindia.nic.in/publication/publicmain.html>
- Indian Council of Medical Research and the Department of Biotechnology, *Draft Guidelines for Stem Cell Research and Therapy*, (2006), http://www.icmr.nic.in/stem_cell/Stem_cell_guidelines.pdf

Descriptive Synopsis

Cloning in India is not regulated by legislation but by ethical guidelines adopted by authoritative bodies. The Department of Biotechnology of the Ministry of Science and Technology has adopted ethical policies on the human genome, which have laid down *inter alia* India's position on cloning. The text, "*Ethical Policies on the Human Genome, Genetic Research and Services*," states that, "as a principle, human cloning shall not be permitted."

Consistent with this policy document, the Indian Council of Medical Research has developed "*Ethical Guidelines for Biomedical Research on Human Subjects*." One of the concerns in these guidelines is respect for embryos with regards to research. It is established that "respect for the embryo's moral status can be shown by careful regulation of conditions of research, safeguards against commercial exploitation of embryo research, and limiting the time within which research can be done to 14 days, i.e., when the primitive streak appears...At this time, the development of the nervous system

begins and the embryo begins to become a distinct individual.” Special attention is given to the prohibition of cloning (through nuclear transplantation or embryo splitting). The Council states, “since its [cloning’s] safety, success, utility and ethical acceptability is not yet established, research on cloning with the intent to produce an identical human being...is prohibited.”

Finally, the Indian Council of Medical Research and the Department of Biotechnology have recently drafted guidelines for stem cell research in which they recommend that embryos should not be generated for the sole purpose of obtaining stem cells. Any research related to reproductive cloning and the transfer of human blastocysts generated by somatic cell nuclear transfer into a human or non-human uterus is also prohibited under the draft guidelines.

ISRAEL

- *Law on the Prohibition of Genetic Intervention Act 1999-5759 (Human Cloning and Genetic Manipulation of Reproductive Cells)*, (1999, renewed 2004), <http://www.academy.ac.il/bioethics/english/DocPage3-e.html>
- Report from the Bioethics Advisory Committee of the Israel Academy of Sciences and Humanities, *The use of Embryonic Stem Cells for Therapeutic Research*, (August 2001), http://www.academy.ac.il/bioethics/english/PDF/Embryonic_stem_Cells.pdf

Descriptive Synopsis

Legislative acts:

The *Law on Genetic Interventions in Humans* prohibits the creation of a “complete human being” by reproductive cloning; however, this law does not rule out producing cloned embryos that will not be implanted. For the purpose of the law, “human reproductive cloning” is defined as “(1) the creation of a human embryo by means of transferring the nucleus from a somatic cell into an ovum or a fertilized ovum from which the nucleus has been extracted (in this law – a “cloned embryo”), in order to create a person who is genetically and chromosomally identical to another person or fetus, living or dead; (2) the insertion of a cloned embryo into the uterus of a woman or another womb or body.”

The purpose of the *Law on Genetic Interventions in Humans* is to prescribe a five year period during which certain types of genetic research are not permitted, allowing for an assessment of the moral, legal, social and scientific implications of these research procedures for human dignity. The law will remain in force until March 1st 2009 and any person who violates its provisions is subject to criminal sanctions.

Other normative measures:

The Bioethics Advisory Committee of the Israel National Academy of Sciences and Humanities adopted a recommendation on August 8, 2001, stating that it is ethically permissible to experiment with new technologies such as nuclear transfer (therapeutic cloning) to produce ES cells. The committee adds, “the ethical consideration in the creation of such cloned embryonic forms for therapeutic research is that they do not result from sperm and intact ova, and are not meant to be used in any process of complete fetal development since cloning is presently not admissible for reproductive purposes.” Finally, it 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 stated that it would, in principle, authorize applications to conduct those two types of research.

JAPAN

- Ministry of Education, Culture, Sports, Science and Technology, *Guidelines for Handling of a Specified Embryo*, (January 2001),
http://www.mext.go.jp/a_menu/shinkou/seimei/2001/hai3/31_shishin_e.pdf
- *Law Concerning Regulation Relating to Human Cloning Techniques and Other Similar Techniques*, (June 2001),
http://www.mext.go.jp/a_menu/shinkou/seimei/eclone.pdf
- Ministry of Education, Culture, Sports, Science and Technology, *Guidelines to the 'Law concerning Regulation Relating to Human Cloning Techniques and Other Similar Techniques,'* (December 2001),
http://www.mext.go.jp/a_menu/shinkou/seimei/2001/hai3/17_shishin.pdf (in Japanese)
- Japanese Government, *Commentaries to the Guidelines to the 'Law concerning Regulation Relating to Human Cloning Techniques and Other Similar Techniques,'* (December 2001),
http://www.mext.go.jp/a_menu/shinkou/seimei/2001/hai3/20_shishin.pdf (in Japanese)
- Bioethics Committee of Council for Science and Technology, *Report on Research Cloning*, (June 2004).

Descriptive Synopsis

Legislative acts:

“*The Law Concerning Regulation Relating to Human Cloning Techniques and Other Similar Techniques*” prohibits the transfer of embryos created by human cloning techniques as well as those created by xenotransplantation. However, it allows the application of these techniques, and other similar ones for research purposes, as long as the embryo created is not transplanted into a human or an animal. The guidelines impose criminal sanctions for the violation of their provisions.

The law defines an embryo as “a cell (except for a germ cell) or cells which has/have potential to grow into an individual through the process of development *in utero* of a human or an animal and has/have not yet begun formation of a placenta.”

Supplementary provisions of the law have established a three-year moratorium during which the legislation surrounding cloning and similar techniques will be re-examined. In June 2006, a press release by the *Japan Times* reported that the Japanese government is expected to lift its ban on research on cloned human embryos for use in regenerative medicine as early as the beginning of 2007, with restrictions on the source of eggs used to clone the embryos. It is reported that the Council for Science and Technology Policy will begin discussions on lifting the ban on human cloning after the Ministry of Education, Culture, Sports, Science and Technology completes its guidelines on the issue. A preliminary report issued by the ministry, and complied by the ministry’s life ethics and safety panel, proposes allowing researchers to use surplus eggs from fertility treatments and those surgically extracted from ovaries. However, it recommends that the use of eggs from healthy female volunteers remain banned.

MEXICO

- *General Health Law of 7 February 1984* (amended June 2006), <http://info4.juridicas.unam.mx/ijure/tcfed/159.htm?s=> (in Spanish)
- *Regulation of the General Health Law on Scientific Research*, (January 1987), http://www.respyn.uanl.mx/iv/3/contexto/reglamento_investigacion.htm (in Spanish)

Descriptive Synopsis

Mexican legislation does not regulate explicitly cloning for reproductive and/or therapeutic purposes. The *General Health Law* and its *Regulation on Scientific Research*

have been interpreted as implicitly prohibiting human reproductive cloning. The article on which this interpretation is based stipulates that research on embryos can only be conducted for the benefit of the embryo and then only when its “security/integrity is guaranteed” (art. 56). For the purpose of this law, an embryo is “the product of conception from fertilization to the end of the 12th week of gestation” (art. 314). This definition is consistent with the *Regulation of the General Health Law on Scientific Research*, which contains the same definition for an embryo in its article 40.

Several bills have been introduced in both parliamentary chambers and are currently under debate. While the debate remains polarized, most legislative proposals call for a ban on both human reproductive and therapeutic cloning.

THE NETHERLANDS

- The Health Council, *IVF-related research*, (1998), <http://www.gezondheidsraad.nl/pdf.php?ID=617&p=1>
- *Act containing rules relating to the use of gametes and embryos (Embryos Act)*, (September 2002), http://www.minvws.nl/images/eng-embryowettekst_tcm20-107819.pdf
- *Explanatory Notes to the Embryos Act*, (2002), http://www.minvws.nl/images/explanatory-notes-to-the-embryos-bill_tcm20-108037.pdf
- The Health Council, “*Stem cells for tissue repair. Research on therapy using somatic and embryonic stem cells*,” (June 2002), <http://www.gr.nl/pdf.php?ID=429>

Descriptive Synopsis

Legislative acts:

The *Embryos Act*, which contains rules relating to the use of human gametes and embryos, allows the use of spare embryos for scientific research (including obtaining stem cells from such embryos for the purposes of research), subject to review of the research protocol by the Central Committee on Research Involving Human Subjects and Embryo Research (CCMO). The Act prohibits the creation of embryos for purposes other than reproduction (s. 24a), which applies to therapeutic cloning using human stem cells. However, there is a sunset clause (s. 33 sub 2) of five years, at which point the matter will be revisited. Article 24 of the Act prohibits the creation of embryos specifically for scientific research or for purposes other than the generation of a pregnancy; performing

procedures with gametes or embryos with the goal of the birth of genetically identical human individuals is also forbidden.

The Act also prohibits human reproductive cloning. Article 11 of the act prohibits the performance of scientific research with embryos specifically created for this purpose. However, this prohibition does not apply to scientific research that is reasonably likely to lead to the identification of new insights in the field of fertility, in the field of artificial reproduction techniques, in the field of congenital diseases or in the field of transplant medicine.

Under the Embryos Act, an embryo is defined as “a cell or a complex of cells with the capacity to develop into a human being.”

The Act already contains provisions for the handling of embryos created for purposes other than reproduction, which would come into force after the lifting of the ban (section 11). This complex construction was chosen in order to allow reservations to Article 18 of the European Convention on Human Rights and Biomedicine (which forbids the creation of embryos for research purposes) when the Netherlands ratified the convention.

In a recent statement (June 2004), the Dutch government decided, following the recommendations of the Health Council of the Netherlands, that research involving all types of stem cells, including embryonic stem cells, should continue; the claim that adult stem cells are sufficient to address current scientific needs was rejected. The Health Council has recommended that entities resulting from the transfer of a human nucleus into an enucleated animal egg can best be considered as *human* embryos. According to the statement from the Dutch government, however, these embryos are *not* human embryos as these embryos are probably not viable.

Other normative measures:

The Health Council of the Netherlands believes that the argument that an embryo has a relative right to protection cannot be used to prevent the creation of an embryo by means of somatic cell nuclear transfer (the transfer of a cell nucleus to an ovum, or another cell, from which the nucleus has been removed). The council is not convinced that allowing therapeutic cloning (defined by the council as “cloning with the aim of obtaining stem cells for the treatment of diseases”) will lead to reproductive cloning (defined by the council as “cloning with the aim of creating an organism”). Therefore, the council recommended that therapeutic cloning not be banned. In the June 2002 report released by the council, reproductive cloning is considered to be “medically extremely irresponsible” at the present time.

Consistent with this view, the council states that the legal option of generating embryos specifically for research purposes should be left open in the interest of acquiring important new knowledge that cannot be achieved by any other means. The council recommends “no ban (statutory or non-statutory) in advance on research into the

possibility of nuclear transplants and the creation of new embryonic stem cell lines.” In ethical terms, the council states, the distinction between conducting research on spare embryos and on embryos created specifically for research is comparatively small.

SOUTH AFRICA

- Medical Research Council of South Africa, *Guidelines on Ethics for Medical Research: Reproductive Biology and Genetic Research*, (2002), <http://www.sahealthinfo.org/ethics/book2.htm>
- *National Health Act*, (December 2003), http://www.parliament.gov.za/pls/portal/web_app.utl_output_doc?p_table=acts&p_doc_col=act_doc&p_mime_col=mime_type&p_id=606077

Descriptive Synopsis

Legislative acts:

The *National Health Act* prohibits both human reproductive and therapeutic cloning (the latter allowed only from adult or cord blood stem cells) as well as the genetic manipulation of gametes, zygotes or embryos (“a human embryo is a human offspring in the first eight weeks from conception”). Under the Act, “reproductive cloning of a human being means the manipulation of genetic material in order to achieve the reproduction of a human being and includes nuclear transfer or embryo splitting for such purpose,” whereas therapeutic cloning is understood as the manipulation of genetic material from either adult, zygotic or embryonic cells in order to alter, for therapeutic purposes, the function of cells or tissues. The Act also establishes criminal sanctions for its violation.

Other normative measures:

The Medical Research Council of South Africa states that the “pre-embryo” must be treated with utmost respect because it is a genetically unique and a viable human entity. Therefore, the creation of embryos for the sole purpose of research is discouraged. The MRC recommends that human stem cells used for therapeutic cloning should only come from cadaveric fetal tissue and ‘surplus’ embryos remaining from infertility treatments. In regards to reproductive cloning, the council recommends that the best interests of the child produced should always take precedence. Because the potential harms of reproductive cloning outweigh the potential benefits, the council recommends that the use of human nuclear transfer cloning to create a new life be prohibited. Finally,

the MRC recommends the creation of a new expert supervisory body to provide advice and grant approval (in conjunction with a properly constituted Research Ethics Committee) to cloning-related research.

SOUTH KOREA

- Ministry of Health and Welfare, *Guidelines on the Safety of Biotechnology Research*, (December 2000).
- South Korean Bioethics Advisory Commission, *Recommendations for Biotechnological Research and Application*, (May 2001).
- *Bioethics and Biosafety Act*, (January 2005).

Descriptive Synopsis

Legislative acts:

The Bioethics and Biosafety Act regulates research development in biotechnology in accordance with principles of bioethics. The Act defines an embryo as “a fertilized egg (or segmented cell) from the moment of fertilization to the point of time at which all organs of the given organism have developed embryologically.” The Act bans both human cloning (with no specific distinction between reproductive or therapeutic cloning) (s. 11) and the creation of embryos for research purposes (s.13). In particular, article 11 of the Act states, “[n]o 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.” Under the Act, a somatic cell embryo clone is defined as an embryo formed by “the transfer of a human somatic cell nucleus to a human or animal oocyte from which the nucleus has been removed.”

However, somatic cell nucleus transfer (SCNT) is allowed for the purpose of conducting research aimed at curing rare or currently incurable diseases (art. 22). The type, subject, and extent of allowed research using SCNT shall be decided by the president after it has been reviewed by the National Bioethics Committee. In addition, the research institution conducting SCNT must meet the standards established by the Ministry of Health and Welfare and be registered with the ministry as an “Embryo Research Institution” (art. 23).

SINGAPORE

- Licensing and Accreditation Branch, Ministry of Health, *Guidelines for Private Healthcare Institutions Providing Assisted Reproduction Services: Regulation 4 of the Private Hospitals and Medical Clinics Regulations* (Cap. 248, Rg. 1), (September 2001).
- Bioethics Advisory Committee of Singapore, *Ethical, Legal and Social Issues in Human Stem Cell Research, Reproductive and Therapeutic Cloning*, (June 2002), <http://www.bioethics-singapore.org/resources/reports1.html>
- *Human Cloning and Other Prohibited Practices Act*, (September 2004), <http://www.moh.gov.sg/corp/systems/acts/GG.pdf>

Descriptive Synopsis

Legislative acts:

The *Human Cloning and Other Prohibited Practices Act* prohibits placing a human embryo clone in the body of a human or the body of an animal. It also prohibits the import and export of any human embryo clone into or out of Singapore. Under this Act, a human embryo is defined as having “been developing for less than 8 weeks since the appearance of 2 pro-nuclei or the initiation of its development by other means.”

The Act also bans certain practices associated with reproductive cloning activities, such as developing human embryos created other than by fertilization of human egg by human sperm for a period of more than 14 days, and developing a human embryo outside the body of a woman for more than 14 days. In addition, the removal of human embryos from the body of the woman for the purpose of collecting a viable human embryo is forbidden.

Anyone who infringes on the provisions of the Act is subject to fines or criminal sanctions.

Other normative measures:

The guidelines, which pertain to private healthcare institutions providing assisted reproduction services issued by the Ministry of Health, prohibit the creation of human embryos solely for the purpose of research.

The Bioethics Advisory Committee (BAC), a governmental advisory body, has also adopted an intermediate position that supports the special status of the human embryo. The BAC bans reproductive cloning but supports therapeutic cloning, provided that there

is strong scientific merit in, and potential medical benefit from, such research. The BAC acknowledges the concern that the creation of embryos by cloning techniques may lead to the cloning of a whole human being and states that the only way to prevent this is by banning the implantation of any cloned embryo into a womb. The creation of human embryos specifically for research is permitted provided that: (1) there is strong scientific merit in, and potential medical benefit from, such research; (2) there is a lack of acceptable alternatives; and, (3) the research is selected on a case-by-case basis with specific approval by a statutory body.

The BAC also recommends that there should be a legislative and regulatory framework that prohibits the commercialization of donated materials, especially surplus embryos. In addition to the observance of ethical principles (i.e. informed consent), the BAC supports the establishment of a statutory authority to license and closely monitor all human embryo research.

SWITZERLAND

- *Federal Constitution of the Swiss Confederation*, (1999, revised September 2001), <http://www.admin.ch/ch/itl/rs/1/c101ENG.pdf>
- Centre for Technology Assessment (TA-Swiss), *Cells that are causing a political stir - Embryonic and Adult Stem Cells: Opportunities and Hurdles Surrounding the Development of New Treatments*, (February 2003), http://www.ta-swiss.ch/www-remain/reports_archive/publications/2003/030217_KF_Stammzellen_e.pdf
- *Federal Act on Research on Surplus Embryos and Embryonic Stem Cells (Embryonic Research Act)*, (Approved by Referendum November 2004), <http://www.admin.ch/ch/f/ff/2003/7481.pdf> (in French)
Press release on the results of the referendum, http://www.admin.ch/cp/f/4200919c_1@fwsrvg.html (in French)
- Swiss National Advisory Commission on Biomedical Ethics, *Research Involving human embryos and fetuses*, Opinion no. 11/2006, (January 2006), http://www.nek-cne.ch/en/pdf/Embryo_engl.pdf

Descriptive Synopsis

Legislative acts:

The *Federal Constitution* of Switzerland, at article 119, protects persons against abuse related to assisted procreation and gene technology. This article stipulates that the Swiss Constitution will ensure “the protection of human dignity, of personality, and of family, and in particular it shall respect [that]...all forms of cloning and interference with genetic material of human reproductive cells and embryos is prohibited.”

The *Embryonic Research Act* also prohibits cloning and other practices related to embryo research at article 3. According to this article, it is forbidden to produce an embryo for research purposes, create a clone, produce embryonic stem cells from a clone, or to import or export cloned embryos. The goal of the Act is “to prevent all abusive uses of excess embryos and of embryonic stem cells and to protect human dignity” (art. 1). The forbidden practices are sanctioned with imprisonment (art. 24).

The Act prohibits the creation of embryos for research purposes and the production and use of stem cells from such embryos. The procurement of embryonic stem cells from a clone is also forbidden.

The Act was accepted by nation-wide referendum on November 28, 2004. The Federal Council adopted a decree on the application of the *Federal Act on Research on Surplus Embryos and Embryonic Stem Cells* stating that the Act would come into force March 1, 2005.

Other normative measures:

In a recent opinion statement, the Swiss National Advisory Commission on Biomedical Ethics adopts certain recommendations on the regulation of embryo research in Switzerland. The majority of the commission’s members sees no convincing ethical grounds that would justify the maintenance of the current prohibition on therapeutic cloning over the long-term, but sees no compelling argument in favor of lifting the ban at the present time. It is the commission’s opinion that “from the beginning of the fertilization process, the embryo has an ethical claim to protection – which becomes increasingly strong in parallel with the growth and development of the fetus.”

UNITED KINGDOM

- *Human Fertilisation and Embryology Act* (c.37), (1990), http://www.hms.gov.uk/acts/acts1990/Ukpga_19900037_en_1.htm
- *Human Reproductive Cloning Act* (“An Act to prohibit the placing in a woman of a human embryo which has been created otherwise than by fertilisation”), (December 2001), <http://www.legislation.hms.gov.uk/acts/acts2001/20010023.htm>

- *The Human Fertilisation and Embryology (Research Purposes) Regulations No.188*, (2001), <http://www.hmso.gov.uk/si/si2001/20010188.htm>
- House of Commons, *Developments in Human Genetics and Embryology, Fourth Report of Session 2001-02*, (July 2002), <http://www.parliament.the-stationery-office.co.uk/pa/cm200102/cmselect/cmsctech/791/791.pdf>
- The Human Fertilisation and Embryology Authority, *Code of Practice*, 6th Edition, (2003), <http://www.hfea.gov.uk/HFEAPublications/CodeofPractice/Code%20of%20Practice%20Sixth%20Edition%20-%20final.pdf>
- Royal Society, *Human Reproductive Cloning: A Statement by the Royal Society*, (January 2003), <http://www.royalsoc.ac.uk/files/statfiles/document-212.pdf>
- House of Commons Science and Technology Committee, *Inquiry into Human Reproductive Technologies and the Law*, Eighth Spec. Rep. Sess. 2004-2005, <http://www.publications.parliament.uk/pa/cm200405/cmselect/cmsctech/491/491.pdf>
- UK Stem Cell Initiative, *Reports & Recommendations*, (November 2005), <http://www.advisorybodies.doh.gov.uk/uksci/uksci-reportnov05.pdf>
- Human Genetics Commission, *Making Babies: Reproductive Decisions & Genetic Technologies*, (2006), <http://www.hgc.gov.uk/UploadDocs/DocPub/Document/Making%20Babies%20Report%20-%20final%20pdf.pdf>

Descriptive Synopsis

Legislative acts:

Embryo research is regulated by both the *Human Fertilisation and Embryology Act 1990*, which makes general provisions in connection with embryo research, and the *Human Reproductive Cloning Act 2001*, which bans human reproductive cloning by and renders it a criminal offense. Article 1 of this Act considers an offender “a person who places in a woman a human embryo which has been created otherwise than by fertilization.”

Under the *Human Fertilisation and Embryology Act 1990*, an embryo is defined as “a live human embryo where fertilisation is complete.” This definition includes reference to “an egg in the process of fertilisation,” where fertilization is not complete until the appearance of a two-cell zygote. This Act prohibits the creation or use of an embryo without a license issued by the Human Fertilisation and Embryology Authority. A license may be issued for research involving the creation or use of human embryos for the purpose of:

- (1) promoting advances in the treatment of infertility;
- (2) increasing knowledge about the causes of congenital disease;
- (3) increasing knowledge about the causes of miscarriage;
- (4) developing more effective contraceptive techniques;
- (5) developing methods for detecting genetic or chromosomal abnormalities in pre-implantation embryos.

In January 2001, regulations were made which extended the purposes for which embryo research could be licensed. These purposes include:

- increasing knowledge about the development of embryos;
- increasing knowledge about serious disease;
- enabling such knowledge to be applied in developing treatments for serious disease.

UNITED STATES

- Balanced Budget Downpayment Act, I, Pub. L. No. 104-199, § 128, 1.10 Stat. 34 (first enactment of Dickey-Wicker amendment), (1996).
- Federal Food, Drug & Cosmetic Act, Title 21 § 201 et. seq.
- Public Health Service Act, Title 42 § 201 et. seq.
- Department of Health and Human Services, Food and Drug Administration, Letter to Institutional Review Boards, (October 1998), <http://www.fda.gov/oc/ohrt/irbs/irbletr.html>
- *President Bush's position on stem cell research*, (August 2001), <http://www.whitehouse.gov/news/releases/2001/08/20010809-2.html>
- National Academy of Sciences, *Scientific and Medical Aspects of Human Reproductive Cloning*, (2002).
- The President's Council on Bioethics, *Human Cloning and Human Dignity: An Ethical Inquiry*, (2002).
- The President's Council on Bioethics, *Reproduction and responsibility: the regulation of new biotechnologies*, (2004), <http://www.bioethics.gov/reports/reproductionandresponsibility/index.html>
- The President's Council on Bioethics, *Monitoring Stem Cell Research*, (January 2004),

http://www.bioethics.gov/reports/stemcell/pcbe_final_version_monitoring_stem_cell_research.pdf

- National Academy of Sciences, *Guidelines for Human Embryonic Stem Cell Research*, (April 2005), <http://newton.nap.edu/catalog/11278.html>

Descriptive Synopsis

Federal legislation and other non-normative measures:

In the United States there is no federal legislation prohibiting cloning for either reproductive and therapeutic purposes. However, under the 1996 Dickey-Wicker amendment it is illegal to use federal funds to support research “in which human embryos are created, destroyed, discarded, or knowingly be subjected to risk of injury or death greater than allowed for research on fetuses in utero under 45 CFR 46.204 and 46.207, and subsection 498(b) of the Public Health Service Act.” Moreover, the Dickey-Wicker amendment defines a human embryo as “any organism, not protected as a human subject under 45 CFR 46 as of the date of enactment of the governing appropriations act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.”

The Food and Drug Administration (FDA) has asserted jurisdiction over clinical research using cloning technology to create a human being. According to FDA, clinical research using cloning technology to create a human being is subject to FDA regulation under the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act. This authority is based on the agency’s oversight authority over all products intended to treat or prevent disease. Furthermore, FDA has indirect oversight authority over research cloning, as data obtained from such research may be used to support an application for new therapy procedures. The agency has further indirect oversight authority over the laboratory procedures that would be used to create cloned embryos “as part of a determination of the safety and effectiveness of the end product” (Javitt G, Suthers K, and K Hudson. *Cloning: A Policy Analysis*. Washington, DC: Genetics and Public Policy Center, 2005). It is important to note that the FDA has explicitly stated that it would not permit the use of cloning technology to create a human being due to “major unresolved safety questions” pertaining to the use of such technology.

President Bush announced in August 2001 that for the first time federal funds would be used to support research on human embryonic stem cells, while stating his strong opposition to “human cloning.” Although not mentioned specifically in his speech, a fact sheet on the White House Web site states that federal funds will not be used for “the cloning of human embryos for any purpose.” However, it is important to note that there is no current federal legislation prohibitions or restrictions on the use of private funds for either reproductive and therapeutic cloning research.

Following the president's announcement, in July of 2002 the President's Council on Bioethics released its report *Human Cloning and Human Dignity*, in which the council unanimously recommended a ban on reproductive cloning, and, by a vote of 10 to 7, a four-year moratorium on cloning for medical research purposes.

The current U.S. administration supports a comprehensive cloning ban; however, its efforts to adopt federal legislation on the subject have yet to be successful. In the past years the U.S. Congress, which remains polarized on the issue of cloning, has considered numerous bills – including one supported by a bipartisan majority – also without success.

In the 2002 report *Scientific and Medical Aspects of Human Reproductive Cloning*, the National Academy of Sciences recommended that “human reproductive cloning should not now be practiced. It is dangerous and likely to fail.” The NAS also recommended that an enforceable ban, subject to a sunset clause of five years, be adopted by the federal government. Regarding cloning for therapeutic or research purposes, the NAS recommended that cloning to produce stem cells should be permitted because of the potential for developing new therapies and advancing biomedical knowledge. While the NAS's 2005 *Guidelines for Human Embryonic Stem Cell Research* do not specifically address human reproductive cloning or apply to reproductive uses of nuclear transfer, the NAS continues to support the view that research aimed at human reproductive cloning should not be conducted at this time.

State human cloning laws:

- States with statutes specifically banning human reproductive and therapeutic cloning:
 - ❑ Arkansas, [2003 SB 185]; Ark. Code § 20- 16-1001 et. seq. (2004)
 - ❑ Indiana, Ind. Code § 16-18-2-5.5. -56.5, -128.5, -183.5 (2005)
 - ❑ Iowa, Iowa Code §§ 707B.1-.4 (2004)
 - ❑ Michigan, Mich. Comp. Laws §§ 333.26401-06, 333.16274, 16275, 20197, 750.430a (2004)
 - ❑ North Dakota, [2003 HB 1424]; N.D. Cent. Code §§ 12.1-39-01, 12.1-39-02 (2004)
 - ❑ South Dakota, 2004 SB 184
 - ❑ Virginia, Va. Code Ann. §§ 32.1-162.21- .22 (2004) (unclear whether therapeutic cloning is included in the ban)

- States with statutes specifically banning human reproductive cloning:
 - ❑ Maryland, 2006 SB 144

- States banning the use of public monies for reproductive and/or therapeutic cloning:
 - ❑ Arizona, HB 2221 (2005) (human reproductive and therapeutic cloning)

- Missouri, Mo. Rev. Stat. § 1.217 (2004) (human reproductive cloning)
- States with statutes specifically allowing therapeutic cloning:
 - California, Cal. Bus. & Prof. §§ 16004, 16105; Cal. Health & Safety §§24185-24187 (2004)
 - Missouri, Mo. Rev. Stat. § 1.217 (2004)
 - New Jersey, [2003 SB 1909/2003 AB 2840]; N.J. Stat. § 2C:11A-1 (2004)
 - Rhode Island, R.I. Gen. Laws §§ 23-16.4-1 - .4-4 (2004) (Sunset provision: July 7, 2010)
 - Connecticut, Public Act 05-149 (2005)

For more information, see National Conference on State Legislatures, State Human Cloning Laws (updated April 2006) <http://www.ncsl.org/programs/health/Genetics/rt-shcl.htm>