

International Initiatives

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Prohibitive Approach

Austria

The *Reproductive Medicine Law*, 1992:

- Creation of embryos for reproductive purposes only (art. 9) (only as many oocytes may be fertilized as is necessary)
- Stem cell research prohibited since embryo may be subjected to examination and treatment only if such action is necessary in order to achieve pregnancy. (art. 9)

Ireland

Constitution of Ireland (art. 40 (3°)):

Stem cell and embryo research prohibited because of the following conditions:

- Right to life of the unborn protected in the Constitution so: no destructive research on embryo.
- Perform IVF: creation of embryo for reproductive purposes only.
- Absence of specific law for embryo research due to above (but experimentation is considered unacceptable).

Victoria, Australia

Infertility Treatment Act, 1995:

- No research that would destroy the embryo: non-destructive research on/with embryos permitted (subject to authorization by the Infertility Treatment Authority) (art. 24, art. 25)

- No new stem cell lines created since 1995: researchers work with old lines or,
- Importation of stem cells not prohibited by the Infertility Treatment Act 1995 (stem cells cannot come from embryos developed in the state of Victoria).
- Stem cell research prohibited.

Criticisms of Prohibitive Approach

- *General prohibitions slow down scientific advances not anticipated by law at the time of adoption.*
- *Encourages forum shopping*
- *Difficult to change general law*

“Bogus” Approach

United States (federal)

President Bush’s criteria for federal funding:

- On existing stem cell lines as long as prior to this announcement (August 9, 2001): derivation process had been initiated, and the embryo no longer had the possibility of development as a human being.
- Stem cell lines can only be derived from an embryo created for reproductive purposes.
- The embryo was no longer needed for this purpose.
- Informed consent must have been obtained for the donation of embryo for research.
- No financial inducements were provided for donation of the embryo for research.

- Creation of a Human Embryonic Stem Cell Registry at NIH that will list the human embryonic stem cell lines that meets the eligibility criteria (embryo created for reproductive purposes, embryo no longer needed for this purpose, informed consent, no financial inducement).
- The stem cell lines created prior to August 9, 2001 can have been produced by the private sector so: public funds for research on “prohibited activities” results.

Germany

Embryo Protection Law, 1990:

- Specific penal law for the protection of the embryo *in vitro*.
- Embryo research and stem cell line creation prohibited.
- *Act Ensuring Protection of Embryos in Connection with the Importation and Utilisation of Human Embryonic Stem Cells (Stem Cell Act, 2002):*
- Stem cell research on imported lines only.
- Stem cell research on such imported lines is considered an exception (section 1 art. 3).
- Research has to generate scientific knowledge to increase medical knowledge for the development of diagnostic, preventive or therapeutic methods (section 5 art. 1).
- The results cannot be obtained by using cells other than embryonic stem cells (section 5, art. 2 (b)).
- Creation of an Agency to approve importation and use of stem cells (section 6 art. 1): Robert Koch Institute.
- Central Ethics Commission on Stem Cell: reviews applications to import embryonic stem cells and issue statement to RKI on ethical justification of a research project (section 6 art. 3).

Criticism of “Bogus” Approach

Acceptance of importation or utilization of stem cells derived from embryos, which were destroyed abroad or created in private sector, without questioning the moral arguments serving to prohibit performing or financing research on embryos.

Cautious Approach

Canada

Bill C-13, *An Act Respecting Human Reproduction:*

- Embryo and stem cell research permitted on surplus embryos: creation of embryos for research purposes prohibited (s. 5(1)(b)).
- Subject to licence by the Assisted Human Reproduction Agency of Canada (ss. 10(2) and 24(1)(a)).
- Licence authorizing the use of an *in vitro* embryo may be issued only if the use is necessary for the purpose of the proposed research (s. 40(2)).

CIHR Guidelines:

- These Guidelines apply to all proposals for human pluripotent stem cell research submitted to CIHR.
- Research on surplus embryos only (Guideline 7.1, section 7.1.1(1)).

- Creation of embryo for research purposes ineligible for funding (Guideline 7.4, section 7.4.1)
- No funding for therapeutic cloning (Guideline 7.4, section 7.4.2)
- All new cell lines created using CIHR funds will be listed at an electronic registry and will be available to all Canadian academic researchers. Participation in this registry will be a prerequisite to obtain CIHR funding.

France

Projet de loi relatif à la bioéthique (tel qu'adopté par l'assemblée nationale le 22 janvier 2002) :

- Research on surplus embryos permitted: medical goal, no alternative method, according to the state of the art. (art. L-2151-3)
- Subject to licence by the « Agence de la procreation, de l'embryologie et de la génétique humaine » (art. L-2151-3)
- In a prior version of this bill, therapeutic cloning was envisaged.
- Creation of embryos for research purposes is prohibited (art. L-2152-3). Therapeutic cloning is prohibited (art. 16-4 al. 3)

Commonwealth of Australia

Research Involving Embryos and Prohibition of Human Cloning (Bill) 2002:

- This Act is not intended to exclude the operation of any law of a State, to the extent that the law of the State is capable of operating currently with this Act (art. 56).
- Stem cell and embryo research on surplus embryos created before April 5, 2002 even though it may destroy or damage the embryo (art. 36(3) b)).
- Subject to licence by the National Health and Medical Research Council (NHMRC licensing committee).
- Creation of embryos for research purposes is prohibited (art.13).

- The bill has passed the Federal House of Representatives (September 2002) and a committee has already begun an inquiry into the bill in the Senate.

Criticisms of Cautious Approach

- *Criminal sanctions impede the evolution of social thinking re: embryo research.*
- *Relies on research done elsewhere.*

Pragmatic Approach

United Kingdom

The Human Fertilisation and Embryology Act, 1990:

- Embryo and stem cell research permitted, including embryos created for research (up to 14 days).
- Subject to licence by the Human Fertilisation and Embryology Authority (Schedule 2 para. 3(1)).
- Therapeutic cloning “controversy”: The HFE Act (section 3(3) (d)) expressly forbids one type of cloning, i.e. nuclear substitution of any cell whilst it forms part of an embryo. The Act also requires (section 3(1)) a licence for any creation of an embryo outside the body. The cell nuclear transplant technique involves nuclear substitution into an egg not an embryo. Thus is not specifically covered by section 3(3) (d). Some have argued that, as fertilization is not involved, section 3(1) does not apply. The HFE Authority and the Ministers are content that the Act does allow the HFE Authority to regulate cell nuclear replacement into an unfertilized egg through its licensing system.

The Human Fertilisation and Embryology (Research Purposes) Regulations 2001:

- The HFE Authority may issue a licence for research under Schedule 2 para. 3 for any of these purposes: increasing knowledge about development of embryos. about serious disease, enabling any such knowledge to be applied in developing treatments for serious disease (art. 2 (1) and (2)).

Singapore

Ethical, Legal and Social Issues in Human Stem Cell Research, Reproductive and Therapeutic Cloning (Bioethics Advisory Committee, June 2002). Recommends:

- “Research involving the derivation and use of ES cells is permissible only where there is a strong scientific merit in, and potential medical benefit from.” (Recommendation 3)
- “Where permitted, ES cells should be drawn from sources in the following order: (1) existing ES cell lines, originating from ES cells derived from embryos less than 14 days old; and (2) surplus human embryos created for fertility treatment less than 14 days old.” (Recommendation 4)
- “The creation of human embryos specifically for research can only be justified where (1) there is a strong scientific merit in, and potential medical benefit from such research; (2) no acceptable alternative exist, and (3) on a highly selective, case-by-case basis, with specific approval from the proposed authority.” (Recommendation 5 includes therapeutic cloning).
- “There should be a statutory body to license, control and monitor all human stem cell research conducted in Singapore, together with a comprehensive legislative framework and guidelines.” (Recommendation 8)

Israel

The Use of Embryonic Stem Cells for Therapeutic Research (Bioethics Advisory Committee of the Israel Academy of Sciences and Humanities, August 2001). Recommends in section 8:

- “Within the framework of IVF treatments, it will be permissible to donate supernumerary embryos that are no longer destined to implantation, and this specifically for the purpose of therapeutic research.” (research on surplus embryos only).
- “...the Committee considers it ethically permissible to experiment with new *in vitro* technologies to produce ES cells, such as reprogramming somatic cell nuclei by transfer into enucleated oocytes (so-called therapeutic cloning, without reproductive purposes)...” (therapeutic cloning permitted).

- Embryo creation for research purposes: “...the Israeli Law on Genetic Interventions in Humans, while prohibiting the creation of a “complete human being” by reproductive cloning, does not rule out producing cloned embryos that will not be implanted.”
- Research on embryos must be subject to strict supervision and to certain basic constraints (consent, benefit to humanity, confidentiality and privacy).
- Research involving the derivation of stem cells from human embryos should be scrutinized meticulously in order to avoid non-scientific or unethical aims. *In vitro* culturing of embryos after two weeks is *not* permitted
- A national committee established by the Ministry of Health to examine and approve specific research proposals using human supernumerary or cloned embryos for deriving stem cells, aborted fetuses and adult sources.

Japan

The Law Concerning Regulation Relating to Cloning and Other Similar Techniques, 2001:

- This law regulates artificial creation of embryos by cloning techniques (art. 1).
- Cloned embryos cannot be implanted in a uterus (art. 3) but can be used for research (art. 6).
- The production of such an embryo has to be the object of an ordinance of the Ministry of Education, Culture, Sports, Science and Technology (art. 6).

The Guidelines for Derivation and Utilization of Human Embryonic Stem Cells, 2001:

- Stem cell research on surplus embryos (art. 6).
- Stem cell research allowed when the following requirements are satisfied: purposes of research contribute to clarification of human development, differentiation, regeneration (art. 26(1), 1(a)) and the development of new methods to diagnose, prevent or treat diseases or of medicines and drugs (art. 26(1), 1(b)). The research is both scientifically necessary and rational (art. 26(1), 2).



- Stem cell derivation protocol acceptance: see attached scheme.

Advantages of Pragmatic Approach

- *This approach combines a legal and regulatory framework covering both the public and private sector.*
- *More flexible yet permits other large-scale prohibitions.*
- *Possibility of unforeseeable conservative interpretations.*
- *This approach favours scientific development and social change.*

Liberal Approach

United States (private sector) and every other country in the absence of professional guidelines and laws:

- No prohibition of stem cell or embryo research in private sector.
- Possibility of embryo creation specifically for research purposes.
- Stem cell lines derivation possible.

Criticisms of Liberal Approach

- *A “laissez-faire” approach is interpreted as lacking ethical boundaries in the field of embryonic and stem cell research.*