Act ensuring protection of embryos in connection with the importation and utilization of human embryonic stem cells

– Stem Cell Act – (Stammzellgesetz – StZG)

of 28 June 2002

(amended by the "Act amending the Stem Cell Act" of August 14th 2008)

(Unofficial Translation)

The Bundestag has adopted the following Act:

Section 1

Purpose of the Act

In consideration of the State's obligation to respect and protect human dignity and the right to life and to guarantee the freedom of research, the purpose of the present Act is

1. to ban, as a matter of principle, the importation and utilization of embryonic stem cells,
2. to prevent demand in Germany from causing the derivation of embryonic stem cells or the production of embryos with the aim of deriving embryonic stem cells, and
3. to determine the requirements for permitting, as an exception, the importation and utilization of embryonic stem cells for research purposes.

Section 2

Scope

The present Act shall apply to the importation of embryonic stem cells and the use of embryonic stem cells within Germany.

Section 3

Definitions

For the purpose of the present Act

1. stem cells mean all human cells which have the potential to multiply by cell division if in a suitable environment and which by themselves or through their daughter cells are capable, under favourable conditions, of developing into specialized cells, but not, however, into a human being (pluripotent stem cells),
2. embryonic stem cells mean all pluripotent stem cells derived from embryos which have been produced in vitro and have not been used to induce pregnancy or which have been taken from a woman before completion of nidation,
3. embryonic stem cell lines mean all embryonic stem cells which are kept in culture or those which are subsequently stored using cryopreservation methods,

4. embryo means any human totipotent cell which has the potential to divide and to develop into a human being if the necessary conditions prevail,

5. importation means the importation of embryonic stem cells into the territorial scope of the present Act.

Section 4

Importation and utilization of embryonic stem cells

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

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

1. the competent agency has satisfied itself that
   a) the embryonic stem cells were derived before 1 May 2007 in the country of origin in accordance with relevant national legislation there and are kept in culture or are subsequently stored using cryopreservation methods (embryonic stem cell line),
   b) the embryos from which they were derived have been produced by medically-assisted in vitro fertilization in order to induce pregnancy and were definitely no longer used for this purpose and that there is no evidence that this was due to reasons inherent in the embryos themselves,
   c) no compensation or other benefit in money's worth has been granted or promised for the donation of embryos for the purpose of stem cell derivation and if
2. other legal provisions, in particular those of the German Embryo Protection Act , do not conflict with the importation or utilization of embryonic stem cells.

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

Section 5

Research involving embryonic stem cells

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

1. such research serves eminent research goals to generate scientific knowledge in basic research or to increase medical knowledge for the development of diagnostic, preventive or therapeutic methods to be applied to humans and that,
2. according to the state-of-the-art of science and technology,
   a) the questions to be studied in the research project concerned have been clarified as far as possible through in vitro models using animal cells or through animal experiments and
   b) the scientific knowledge to be obtained from the research project concerned can only be expected to be gained by using embryonic stem cells.

Section 6

Approval

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

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

1. Name and professional address of the person in charge of the research project concerned,
2. a description of the research project including scientific reasons showing that the research project meets the requirements set forth in section 5 above,
3. a documentation about the embryonic stem cells to be imported or used showing that the requirements set forth in no. 1 of para 2 of section 4 above have been complied with or equivalent evidence that
   a) the embryonic stem cells to be imported or used are identical with those registered in a scientifically recognized, publicly accessible registry maintained by government agencies or agencies authorized by the government and that,
   b) by way of such registration, the requirements set forth in no. 1 of para 2 of section 4 above have been complied with.

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

(4) Approval shall be given if

1. the requirements set forth in para 2 of section 4 above have been complied with,
2. the requirements set forth in section 5 above have been complied with and, accordingly, the research project is ethically acceptable, and if
3. an opinion by the Central Ethics Commission on Stem Cell Research has been submitted following a request by the competent agency to this effect.

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

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

Section 7

Competent agency

(1) The Federal Ministry for Health shall determine by ordinance which authority in its portfolio shall be the competent agency. The agency shall discharge – as federal administrative tasks – the duties assigned to it by virtue of the present Act and shall be supervised by the Federal Ministry for Health.

(2) Costs (fees and expenses) shall be charged for official acts performed by virtue of the present Act. The law on administrative costs shall apply. In addition to the exemption of the legal entities mentioned in para 1 of section 8 of the law on administrative costs, non-profit research organizations shall be exempt from paying any fees.

(3) The Federal Ministry for Health shall be authorized to determine, by ordinance and in agreement with the Federal Ministry of Education and Research, the acts which shall be subject to a fee, providing for fixed rates or tiered rates. In fixing such rates, the importance, the commercial value or any other benefit arising from approval for those having to pay fees shall be taken into account. The ordinance can provide for a fee to be charged for an uncompleted official act if the person who requested the official act is responsible for noncompletion.

(4) The applicants‘ own expenses incurred in the course of providing the information the agency requires to decide on approval shall not be reimbursed.

Section 8

The Central Ethics Commission on Stem Cell Research

(1) An independent, interdisciplinary Central Ethics Commission on Stem Cell Research shall be established at the competent agency; it shall be composed of nine experts from the disciplines of biology, ethics, medicine and theology. The experts to be nominated shall include four members from the disciplines of ethics and theology and five scientists from the fields of biology and medicine. The Commission shall elect a chair and a deputy chair from among its members.

(2) The members of the Central Ethics Commission on Stem Cell Research shall be appointed by the Federal Government for a three years’ term. Reappointment is possible. As a rule, a deputy shall be appointed for each member.

(3) The members and their deputies shall be independent and not bound by instructions. They shall be obliged to observe secrecy. Sections 20 and 21 of the Law on Administrative Procedures shall apply mutatis mutandis.

(4) The Federal Government shall be authorized to enact an ordinance specifying the details concerning the appointment of, and the procedure to be followed by, the Central Ethics Commission on Stem Cell Research, the invitation of external experts, and cooperation with the competent agency including deadlines.

Section 9

Duties of the Central Ethics Commission on Stem Cell Research

The Central Ethics Commission on Stem Cell Research shall examine and evaluate applications and accompanying documents in order to determine whether the requirements set forth in section 5 above have been complied with and, accordingly, the research project is ethically acceptable.

Section 10

Confidentiality

(1) The application documents referred to in section 6 above shall be treated as confidential.

(2) Notwithstanding para 1 above, the following data may be entered into the registry referred to in section 11 below:

1. the information to be provided on the embryonic stem cells in accordance with no. 1 of para 2 of section 4 above,
2. the name and official address of the person responsible for the research project,
3. basic data concerning the research project, in particular a brief description of the planned research specifying the reasons for its eminence, naming the institution where the research will be conducted and indicating its expected duration.

(3) If an application is withdrawn before a decision on approval has been made, the competent agency shall delete the data stored in connection with the application and return such application and accompanying documents.

Section 11

Registry

Information on the embryonic stem cells and basic data concerning approved research projects shall be registered by the competent agency in a publicly accessible registry.

Section 12

Obligation to notify

The person in charge of the research project has to notify the competent agency without delay of any major changes occurring after application which affect the permissibility of the importation or utilization of the embryonic stem cells in question. Section 6 shall remain unaffected.

Section 13

Penal provisions

(1) Any person who

1. imports embryonic stem cells or
2. uses embryonic stem cells within Germany

without having obtained approval pursuant to para 1 of section 6 above shall be punished with imprisonment of up to three years or shall be fined. Any person who obtains approval by deliberately giving false information shall be deemed to have acted without approval within the meaning of the preceding sentence. The attempt shall be punishable.

(2) Any person who fails to meet a binding requirement imposed pursuant to the first or second sentence of para 6 of section 6 above shall be punished with imprisonment of up to one year or shall be fined.

Section 14

Provisions on administrative fines

(1) An administrative offence shall be deemed to be committed by any person who,

1. contrary to the second sentence of para 2 of section 6 above, provides incorrect or incomplete information or,
2. contrary to the first sentence of section 12 above, does not notify changes or gives an incorrect, incomplete or belated notification.

(2) The administrative offence can be punished with an administrative fine of up to fifty thousand Euro.

Section 15

Report

The Federal Government shall submit to the Deutscher Bundestag a report presenting the experience gained with the implementation of the present Act every two years, beginning at the end of 2003. The report shall also describe the results of research using other types of human stem cells.

Section 16

Entry into force

The present Act shall enter into force on the first day of the month following promulgation.