

### Laws and guidelines

#### 1. Constitutional law

#### Basic Law for the Federal Republic of Germany

The Basic Law is the Constitution of the Federal Republic of Germany. It is the basis for the essential government system and value decisions. It stands above all other German legal norms.

#### Article 1

Human dignity shall be inviolable. To respect and protect it shall be the duty of all state authority. The German people therefore acknowledge inviolable and inalienable human rights as the basis of every community, of peace and of justice in the world. The following basic rights shall bind the legislature, the executive and the judiciary as directly applicable law.

#### Article 2

Every person shall have the right to free development of his personality insofar as he does not violate the rights of others or offend against the constitutional order or the moral law. Every person shall have the right to life and physical integrity. Freedom of the person shall be inviolable. These rights may be interfered with only pursuant to a law.

#### Article 3

All persons shall be equal before the law. Men and women shall have equal rights. The state shall promote the actual implementation of equal rights for women and men and take steps to eliminate disadvantages that now exist. No person shall be favoured or disfavoured because of sex, parentage, race, language, homeland and origin, faith, or religious or political opinions. No person shall be disfavoured because of disability.

#### Article 4

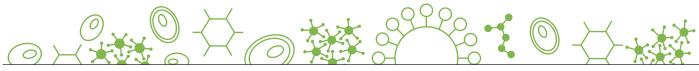
Freedom of faith and of conscience, and freedom to profess a religious or philosophical creed, shall be inviolable.

The undisturbed practice of religion shall be guaranteed. No person shall be compelled against his conscience to render military service involving the use of arms. Details shall be regulated by a federal law.

#### Article 5

Every person shall have the right freely to express and disseminate his opinions in speech, writing and pictures, and to inform himself without hindrance from generally accessible sources. Freedom of the press and freedom of reporting by means of broadcasts and films shall be guaranteed. There shall be no censorship.

These rights shall find their limits in the provisions of general laws, in provisions for the protection of young persons, and in the right to personal honour. Arts and sciences, research and teaching shall be free. The freedom of teaching shall not release any person from allegiance to the constitution.





#### 2. Simple Right

## 2.1. Act for the Protection of Embryos (The Embryo Protection Act)

The Embryo Protection Act regulates the artificial insemination and the handling of human embryos. The purpose of the law is to protect human life from the beginning.

§ 8 of the Embryo Protection Act already defines the fertilized, viable oocyte as an embryo. An egg cell can be developed within 24 hours after the merger (§ 8 para. 1). In addition, every cell taken from an embryo is considered an embryo itself if it could develop into a complete individual (totipotency). In §1 is enumerated which abusive applications of the reproductive techniques are punished. This includes, for example, the artificial insemination of oocytes for a purpose other than to induce a pregnancy (§ 1 Abs. 1 No. 2). Also, no more egg cells may be fertilized than can be transmitted to a woman in a cycle. By doing so, the legislator is preventing high-grade multiple pregnancies that would jeopardize the life of the mother and children. The maximum number of embryos that can be transferred is set at three (§ 1 (1) no. 3). This regulation has the consequence that in Germany with artificial inseminations no so-called "surplus embryos" arise, since all manufactured embryos (maximum three) are always transferred.

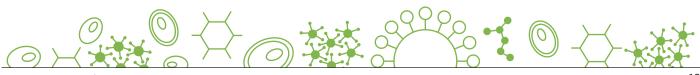
§ 2 deals with the misuse of the human embryo.
Here the trade with embryos is forbidden (§ 2 exp.
1). In addition, further treatment of an embryo outside the womb is only permitted if the embryo is subsequently transferred to the mother (§ 2 (2)).
Source: Federal Law Gazette, Date: November 2011

# 2.2. Law ensuring the protection of embryos in connection with the import and use of human embryonic stem cells (German Stem Cell Act – StZG)

In accordance with the constitutional obligation of the state, the German Stem Cell Act seeks to respect and protect human dignity and the right to life, and to guarantee freedom of research (§ 1 Para. 1). The German Stem Cell Act is a ban with reservation of permission. It fundamentally prohibits the import and use of embryonic stem cells. It is intended to prevent the commissioning of overseas production of embryos for stem cell research or the production of embryonic stem cells from existing embryos for stem cell research or the production of stem cell research or the production of stem cells from existing embryos in Germany is already banned by the German Embryo Protection Act.

However, the German Stem Cell Act also lays down the conditions under which the import and use of embryonic stem cells for research purposes may be authorized in exceptional cases (§ 1 and § 4). These conditions include the condition that embryonic stem cells were obtained abroad from surplus embryos before the deadline of May 1, 2007 and are no longer needed to induce pregnancy. And that no money was paid for the transfer of these embryos (§ 4 Para. 2 No. 1).

The law prescribes strict criteria for research on embryonic stem cells in Germany. For example, the research must serve high-ranking research goals and must not be feasible using other cell types (§ 5).





#### 3. Institutions

## The German Central Ethics Committee for Stem Cell Research

The German Central Ethics Committee for Stem Cell Research (ZES) is an interdisciplinary commission of experts in the fields of ethics, theology, biology and medicine. It is based at the Robert Koch Institute, the responsible federal institute in the field of biomedical research. The committee examines applications under the German Stem Cell Act and clarifies whether a derogation can be granted. The following questions are clarified: How important is the research objective? How well has the research project been prepared and clarified? How great is the necessity for the use of human embryonic stem cells (hES cells)? The committee assesses whether the research project is ethically acceptable within the context of the German Stem Cell Act. It submits an opinion to the Robert Koch Institute for each research project in which hES cells are to be used. The German Central Ethics Committee for Stem Cell Research was first appointed on July 1, 2002, when the Stem Cell Act came into force.

