

# [South Korea's Bioethics and Biosafety Act \(2005\)](#) <sup>[1]</sup>

By: Clay, Anne Safiya Keywords: [Bioethics](#) <sup>[2]</sup> [Stem cells](#) <sup>[3]</sup> [Fertilization](#) <sup>[4]</sup>

The South Korean government passed the Bioethics and Biosafety Act, known henceforth as the Bioethics Act, in 2003 and it took effect in 2005. South Korea's Ministry of Health and Welfare proposed the law to the South Korean National Assembly to allow the progress of biotechnology and life sciences research in South Korea while protecting human research subjects with practices such as [informed consent](#) <sup>[5]</sup>. The Bioethics Act establishes a National Bioethics Committee in Seoul, South Korea. The Bioethics Act is the first law in South Korea to regulate research on [embryonic stem cells](#) <sup>[6]</sup> and [in vitro](#) <sup>[7]</sup> [fertilization](#) <sup>[8]</sup>. Most South Korean bioethical policies rely on this act and its provisions.

Two years after the birth of Dolly the [sheep](#) <sup>[9]</sup> in 1997 in the UK, Woo-suk Hwang, a scientist at Seoul National University, in Seoul, South Korea, cloned a [cow](#) <sup>[10]</sup> named Chini in 1999. Hwang's achievement gained national attention and South Korea became the fifth country in which researchers cloned mammals. Chini's birth also provoked ethical concerns from many South Korean scientists, bioethicists, and nongovernmental organizations. These groups, concerned by the prospect of human [cloning](#) <sup>[11]</sup>, demanded a national bioethics regulatory commission. By 2003, Hwang had moved from [cloning](#) <sup>[11]</sup> animals to attempting to clone human embryos for their [stem cells](#) <sup>[12]</sup>. Although some laws applied to medical malpractice in South Korea, no laws addressed human [embryonic stem cell research](#) <sup>[13]</sup>. Hwang's research prompted the two governmental organizations headquartered in Seoul, South Korea to draft the Bioethics Act to regulate research on [embryonic stem cells](#) <sup>[6]</sup>. The first [organization](#) <sup>[14]</sup> was the South Korean Ministry of Science and Technology, integrated into the Ministry of Education, Science and Technology in 2008, and the second [organization](#) <sup>[14]</sup> was the Ministry of Health and Welfare.

The Bioethics Act relies on existing regulations related to biotechnology and bioethics in South Korea. One of these regulations included the 1983 Genetic Engineering Promotion Act, later revised as the 1995 Biotechnology Promotion Act, an act that promoted progress in biotechnology in South Korea. The Bioethics Act accommodates South Korea's 1994 strategic fourteen-year research and development program known called Biotech 2000. The 1990 Human Fertilization and Embryology Act, which forbade the purchase of [egg](#) <sup>[15]</sup> cells or gametes for research, also influenced the development of the Bioethics Act.

In 2000 South Korea's Ministry of Science and Technology organized the Korean Bioethics Advisory Commission to draft a bioethics law. Ten scientists from the biotechnological and medical fields and ten non-scientists from philosophical, social sciences, religious, and non-governmental organizations comprised the Advisory Commission. The Advisory Commission drafted a law suggesting that the South Korean government prohibit both reproductive and therapeutic [cloning](#) <sup>[11]</sup> and allow stem cell research on surplus frozen embryos from [in vitro](#) <sup>[7]</sup> [fertilization](#) <sup>[8]</sup> treatments. Neither liberals nor conservatives approved of the draft, and it was discarded.

The Ministry of Science and Technology proposed another legislative act in May 2002 called The Bill on the Prohibition of Human Cloning and Stem Cell Research. The bill dealt with the promotion of biotechnology research. At the same time, the Ministry of Health and Welfare drafted a bioethics bill on the rights of human research subjects. In July 2002, Ministry of Health and Welfare combined its bill with the Ministry of Science and Technology's bill. This combination resulted in the Act on Bioethics and Safety. Some non-governmental organizations also amended the Ministry of Health and Welfare's bill. The groups added provisions prohibiting interspecies hybridization and human embryonic [cloning](#) <sup>[11]</sup>, as well as raising the National Bioethics Committee's level of ethical oversight and its official functions in biotechnological [regulation](#) <sup>[16]</sup>. Over the next year, the South Korean government combined the provisions from the citizens' groups with the Act on Bioethics and Safety to form the Bioethics Act, which was submitted to the South Korean National Assembly in October 2003.

After three years of drafts and discussion, the Bioethics Act passed on 29 December 2003 and went into effect a year later on 1 January 2005. The law establishes the National Bioethics Committee, which became one of the three primary organizations that regulate stem cell research in South Korea. The other two organizations are the Ministry of Health and Welfare, which gives researchers permission to do human embryonic research, and the World Stem Cell Hub at Seoul National University, which sets guidelines for the management of [stem cells](#) <sup>[12]</sup>. The National Bioethics Committee is the main [organization](#) <sup>[14]</sup> that addresses the Bioethics Act and reviews bioethics policy at the national level. The [organization](#) <sup>[14]</sup>, however, lacks direct authority over the executive government to regulate scientific research.

In addition to establishing the National Bioethics Committee, The South Korean Bioethics Act legally defines terms such as the embryo, biotechnology, and [somatic cell nuclear transfer](#) <sup>[17]</sup> (SCNT). The Bioethics Act bans human [cloning](#) <sup>[11]</sup>, bans [cloning](#) <sup>[11]</sup> via SCNT except under special circumstances, and sets standards for using human embryos in research. The act also requires every South Korean research institute and university to create an Institute of Biological Research and Biotechnology to regulate areas such as genetics, [stem cells](#) <sup>[12]</sup>, and embryo-related research. The Bioethics Act describes restrictions on human [cloning](#) <sup>[11]</sup>, one of which outlaws human and animal hybrid experiments. In addition, the act stipulates several requirements that

hospitals must meet to become embryo-research institutions, forbids researchers to pay for [egg](#)<sup>[15]</sup> cells, and requires researchers to provide adequate information to [egg](#)<sup>[15]</sup> cell donors before they give their consent. Such information includes details on the storage and disposal of embryos, whether the use of remaining embryos for implementation is allowed or disallowed, and whether it requires donor consent. Finally, the Bioethics Act establishes guidelines for gene banks, genetic testing, and other scientific and ethical issues related to human genetic information.

Policy-makers revised the Bioethics Act five times between 2005 and 2009 to amend the restrictions on stem cell research. Some of these amendments responded to what many scientists consider a scandal in 2005. The stem cell researcher Woo-Suk Hwang, at Seoul National University at the time, admitted in 2005 to pressuring his young female colleagues to donate their [egg](#)<sup>[15]</sup> cells for his experiments. This revelation led to revisions in the Bioethics Act to strengthen the [regulation](#)<sup>[16]</sup> of [egg](#)<sup>[15]</sup> donations. After the Hwang incident in 2005 and until 2009, the National Bioethics Commission did not approve any experiments that used human [embryonic stem cells](#)<sup>[6]</sup>. The Bioethics Act has become a primary reference for South Korean bioethics as of 2013. The act attempts to navigate both ethics and scientific innovation, and to protect individuals from the exploitation that may happen in a laboratory setting.

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