
Stem Cell Research in Korea: A Legislative Aspect

Kangchan Jeong *

1. An Overview

Korea has been among the scientific leaders in the development of stem cell research and reproductive technologies. The fourth to succeed in producing an in-vitro fertilization (IVF) baby, Korea is leading in the culture of a stem cell line from an embryo created through a somatic-cell nuclear-transfer technology.¹ The progress in stem cell research in Korea, however, has sparked a vigorous ethical and legal debate. Korea finally adopted the regulations of stem cell research in December 2003 after a vigorous three-year debate triggered by Dolly the Sheep and the assertions of human cloning by Clonaid in Korea, originating from the United Kingdom. Korea passed Bioethics and Biosafety Act (BES Act), which regulates the use of embryonic stem cells for research purposes along with somatic-cell nuclear transfer (SCNT). In addition, Korea enacted Law on Bioethics and Safety and Law on Generative Cells.

BES Act came into effect on January 1, 2005. Its detailed regulations were released as either presidential decrees (BES Decree) or ordinances of the Ministry of Health and Welfare (BES Ordinance). Additional provisions and guidelines are still going through the legislative process.² As a special note, the current legislative process will be discussed herein.

2. What is Permissible?

Stem cell research in Korea could be carried out with a license. The Human Fertilization and Embryology(HFE) Act of 1990 provides that a research plan should be registered at and approved by the government.³ Reproducing clones without a license may

* Judge, The Seoul High Court. LL.B.(S.N.U.), Visiting Fellow(Oxon).

¹ See Hwang W.S., et al., *Stem cell research in Korea* 305 SCIENCE 944-45 (2004). See also T. Tamkins, *Human embryos cloned*, available at <http://www.biomedcentral.com/news/20040212/02> (last visited on Apr. 5. 2008).

² See Kim J.H., *A Critical study of Bioethics and Safety Law*, 7 BIO WAVE (2005), chapter 2 (available only in Korean).

³ HFE Act, sec. 3(1), sched. 2, par. 1(1) & 3. There are three kinds of licences: licences for treatment, licences for

constitute a criminal offence.⁴ Embryos, including those created by SCNT, can be used only before the appearance of the “primitive streak,” which ordinarily appears 14 days after the gametes are mixed.⁵ Korea does not allow payments for embryos or gametes apart from the reasonable expenses that may be incurred in their use for research purposes.⁶ The fertilization of sperms or eggs of the dead for pregnancy is also forbidden in Korea.⁷ Embryo creation for research is not even an issue in Korean legislation. In addition, only surplus embryos can be used for research, and embryos may not be created for any purpose other than IVF treatment.⁸

3. Authorities

There are three bodies that regulate stem cell research in Korea. The first is the Ministry of Health and Welfare (MHW), where researchers must register their stem cell or SCNT research plans for approval.⁹ The second is the National Bioethics Council (NBEC),¹⁰ which has the power to deliberate on important matters specified in BES Act of January 2005.¹¹ It may be pointed out that the NBEC covenant unites government representatives with those from the biotechnology or pharmaceutical industries, enabling them to drive the national policy on biotechnology. Legally, NBEC is only a deliberative council; its recommendations have no legal binding force on the President and on the rest of the executive branch of the government. The Report for BES Act Revision of October 2007(Report for BES Act Revision) provides that the council, however, could stimulate so much social or political pressure that it could determine the agenda for regulatory change and discussion.¹² The most significant bodies in Korea in relation to stem cell research are the research-institute-specific bioethics councils (IBECs). All IBECs should have at least one outside member who will review the research’s ethics.¹³ Meanwhile, the World Stem Cell Hub (WSCH) was established in Seoul National University (SNU) Hospital on October 19, 2005. WSCH comes up with systematic regulations or guidelines for the quality control of stem cells. Korea’s stem

storage, and licences for research (sec. 11, sched. 2).

⁴ BES Act, arts. 11① & 49.

⁵ HFE Act, sec. 3(4); BES Act, art. 17.

⁶ BES Act, art. 13 ③; HFE Act, sec. 12(e).

⁷ BES Act, art. 13 ②.

⁸ *Id.* art. 13 ①.

⁹ *Id.* arts. 14①, 18, 23①, 19① & 22①.

¹⁰ *Id.* art. 7③.

¹¹ *Id.* art. 6.

¹² See REPORT FOR BES ACT REVISION, 10.

¹³ BES Act, arts. 9 & 10; see also BES Ordinance, art. 2; see also BES Decree, art. 10 ④.

cell bank is expected to offer cloned embryonic-stem-cell lines to researchers around the world. This notwithstanding, there is yet no general or widespread high-level expertise on bioethics. Ethical compliance has been left to the researchers themselves.

The Korean government recently tried to revise BES Act. According to the Report for BES Act Revision, there is a proposal to appoint one member of the Ethics Committee and one of the Science Committee respectively to replace the two government representatives so as to strengthen the Ethics Committee.¹⁴ The report mentions the autonomous formation of an organ committee in addition to mandatory departments. It also allows the Minister of Health and Welfare to examine, supervise, evaluate, and educate the researchers' activities to strengthen the autonomous control.¹⁵

4. Criteria

In Korea, fellows relating to infertility treatments and contraception technologies are permitted to conduct research with embryos or to engage in SCNT research. In addition, the permissible research includes the treatment of rare or obstinate diseases specified in BES Decree.¹⁶ To be approved, the research plan must focus on a treatment that is not yet available or that is expected to be vastly superior to the other available treatments.¹⁷

One aspect of the scope of research that attracts much attention is the range of transfer or implantation between humans and animals, the so-called "hybrid" issue. In Korea, experiments on crossing species (or hybridization) are prohibited. Researchers cannot implant a human embryo into the womb of an animal, and vice versa; they cannot mix human germ cells with those of an animal; they cannot transfer animal somatic cells into a human egg that lacks a nucleus; and neither can they mix human and animal embryos.¹⁸ A human somatic cell may be transferred, however, to the nucleus-free egg of an animal. This raises concerns about the possibility of animal eggs being used broadly when human eggs are not readily available, and creates the risk of creating hybrids.¹⁹ According to BES Act Report, transplanting a human cell into an animal egg and blending human and human as well as human and animal embryos are

¹⁴ See *supra* note 12.

¹⁵ *Id.* 1.

¹⁶ BES Act, art. 13. BES Decree, art. 11. This provision specifies 17 diseases as follows: (1) Rare diseases: Multiple sclerosis, Huntington's disease, hereditary ataxia, amyotrophic lateral sclerosis, cerebral palsy, spinal cord injury, AIDS, aplastic anemia, leukemia, and osteogenesis imperfecta; (2) Obstinate diseases: Myocardial infarction, liver cirrhosis, Parkinson's disease, cerebral apoplexy, Alzheimer's disease, optic nerve disease, and diabetes mellitus.

¹⁷ BES Ordinance, art. 10.

¹⁸ *Id.* arts. 12, 50 & 51 ①.

¹⁹ See Kim J.H., *supra* note 2.

prohibited. If this is violated, the research plan will be cancelled.

5. Consent and Counselling

In Korea, those who want to create embryos are required to formalize the matter by acquiring a written consent from the providers of gametes, the subjects of IVF treatment, and their spouses before creating an embryo.²⁰ The written consent should contain the following: acknowledgement of the purpose of creating the embryo, the storage period, the manner of disposal of the embryo, the use of the embryo for purposes other than IVF treatment, any withdrawal of consent, a statement of the rights of the persons whose consent is required to create an embryo, and the protection of their information.²¹ The institutes in Korea should explain all these points fully to the donors before acquiring their consent.²² If the storage period of an embryo is less than five years, the institute must obtain a new written consent for the proposed use of that embryo after the initial period.²³

The genetic examination of an embryo or fetus is allowed only for the purpose of the diagnosis of a genetic disease specified in BES Decree. Article 25, provision 2 of BES Act and the Chart 1 annex of BES Decree specify 62 genetic diseases. The genetic examination of stem cells, however, is not stipulated therein. There are no specific provisions relating to information about the immortality of stem cells, the possibility of genetic examination, traceability, and feedback regarding any result, including the choice of the donor of the embryo. When a stem cell research institute entrusts genetic examination to a genetic examination institute, it should eliminate all information about the identity of the donor, including name and the date of birth, to protect the donor's confidentiality.²⁴

BES Act Report states that genetic testing should be accompanied by a written consent. Furthermore, the genes that had been tested should be immediately abolished to maintain the anonymity of the gene bank.²⁵

In the meantime, Legislative Bill on Generative Cells provides that a gamete donor should be given due explanation of the side effects of the extraction of a generative cell.²⁶ Furthermore, the onerous extraction of a generative cell and embryo is

²⁰ HFE Act, sched. 3, secs. 1 & 2.

²¹ BES Act, art. 15②.

²² *Id.* art. 15③.

²³ *Id.* art. 16①.

²⁴ BES Ordinance, Article 17③.

²⁵ *See supra* note 12 at 3.

²⁶ Legislative Bill on Generative Cells 1-2.

prohibited.²⁷ Moreover, the legislative bill allows only medical institutes to extract generative cells and to produce embryos for the creation of embryos.²⁸ The detailed regulations cover the period of preserving and abandoning generative cells and the procedure for such.²⁹

The legislative bill restricts the extraction of generative cells from, and the donation of such to, physically and mentally healthy and multiparous women aged above twenty. Moreover, only the use of a surplus egg is permissible, except when the donor has a rare and incurable disease.³⁰ It also restricts the period of extracting eggs and the frequency of such.³¹ Furthermore, the protection and management of all information regarding the registering donators, recipients, and generative cells is mandatory.³²

6. Conclusion

Korea recently adopted legislation on stem cell research. They are on the modification process. This development, nonetheless, is significant because such legislation may spare the nation from the suspicion of unregulated research.³³ As was seen in the incident involving Dr. Hwang Woo-suk, he conducted each research according to his own set of ethical standards. There is still much work to be done, however, and some of it urgently. For example, certain issues have yet to be fully addressed, such as informed consent and counselling, especially with respect to the immortality and gene inclusion of stem cells. These issues point back to confidentiality, traceability, and feedback regarding abnormal results. Most of these issues can be resolved by revising the subordinate statutes of BES Act or the relevant regulations issued by the Ministry of Health and Welfare. ISBC may have successfully blended its internal onsite oversight with external reviews, and may offer efficiency in regulation. This short-term strategy may be the way to harmonize the needs of the researchers and the industry with the concerns of the religious circles and NGOs. The long-term goal must be maintaining the efficiency of and support for research while addressing the overwhelming related ethical issues that emerge. It is worth noting that Korea is now trying to adopt detailed and comprehensive laws regarding stem cell research control.

²⁷ *Id.*

²⁸ *Id.* at 3.

²⁹ *Id.* at 4.

³⁰ *Id.*

³¹ *Id.* at 5.

³² *Id.*

³³ A guideline was set by Korea Medical Doctors Association before the legislation.