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Protecting Egg Donors and Human Embryos—The Failure of the South Korean Bioethics and Biosafety Act

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PROTECTING EGG DONORS AND HUMAN EMBRYOS—THE FAILURE OF THE SOUTH KOREAN BIOETHICS AND BIOSAFETY ACT

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Abstract: Human embryonic stem cells have the potential to treat many physical and neurological disorders due to their unique ability to transform into any type of human cell. The process of deriving stem cells from human embryos, however, raises important ethical and regulatory issues. Embryonic stem cell research requires a steady source of human eggs to create embryos that are destroyed during stem cell extraction. International declarations and guidelines protect the two most vulnerable participants of embryonic stem cell research: women who donate eggs for research purposes and human embryos that are destroyed in the research.

In 2005, South Korea passed the Bioethics and Biosafety Act to regulate biotechnology research. In its current form, the Bioethics and Biosafety Act fails to adequately protect egg donors and human embryos. The Bioethics and Biosafety Act does not have adequate safeguards to protect egg donors, such as a requirement of voluntary consent and a requirement that egg donors understand the research and its potential risks. The Institutional Review Boards established by the Bioethics and Biosafety Act are not sufficiently removed from the research institution to guarantee that egg donors are not exploited. Additionally, this legislation fails to appropriately regulate the use of human embryos in scientific research as required by international guidelines. The Bioethics and Biosafety Act should include more detailed provisions dealing with the adequacy and quality of informed consent that is obtained from egg donors. Furthermore, Korea should amend its law to limit the use of human embryos in stem cell research so that the embryos are not unnecessarily destroyed.

I. INTRODUCTION

To realize its goal of becoming the "world-best science nation," the Republic of Korea ("Korea") is investing tremendous money and resources into scientific research and development.[1] Embryonic stem cell research is one specific area of study that the Korean government has encouraged and supported. In May 2006, the Korean government decided to invest 430 billion won,[2] or $454 million, into stem cell research over the next decade.[3]

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[1] *Korea Gears Up Efforts to Become Science Leader*, KOREA.NET, Dec. 20, 2007, http://www.korea.net (search for "Korea gears up efforts to become science leader") (last visited Apr. 26, 2008).

[2] Won is the official currency of South Korea. Central Intelligence Agency: The World Factbook, South Korea, https://www.cia.gov/library/publications/the-world-factbook/geos/ks.html (last visited Apr. 26, 2008).

The money was allocated to support research on adult and embryonic stem cells as well as to strengthen the ethical infrastructure underlying stem cell research.[4] Korea's strong support for stem cell research has required it to pass new legislation to guide this innovative, yet controversial, field. In 2003, Korea passed the Bioethics and Biosafety Act ("Bioethics Act") to deal with advances in biotechnology, particularly in stem cell research.[5] The Bioethics Act came into effect at the beginning of 2005.[6]

No binding international standards currently govern embryonic stem cell research. In 1998, the United Nations ("UN") passed a resolution banning all forms of human cloning that are "incompatible with human dignity and the protection of human life."[7] However, it is a non-binding declaration that was voted against by thirty-four member countries.[8] Korea voted against the UN resolution and the Korean representative to the UN General Assembly made it clear that the resolution will not affect Korea's policy of allowing therapeutic cloning.[9] As a result, the Korean Bioethics Act allows therapeutic cloning, yet places a ban on reproductive cloning.[10] Reproductive cloning creates an embryo with the aim of producing a new, genetically identical individual, whereas therapeutic cloning produces embryos to be used in research.[11] Thus, unlike reproductive cloning, therapeutic cloning has the potential to help patients by replacing or supplementing their damaged cells, tissues, or organs.[12]

Korea's continued support of therapeutic cloning and embryonic stem cell research arguably requires changes in the Bioethics Act to adequately protect egg donors and human embryos from exploitation and to bring the Act into compliance with international standards. Part II of this Comment provides a brief introduction to the Bioethics Act and addresses the highly

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[3] *Government to Spend $450 Million on Stem Cell Research*, KOREA.NET, May 30, 2006, http://www.korea.net (search for "Government to spend 450 million on stem cell research") (last visited Apr. 26, 2008).

[4] *Id.*

[5] UN JONG PAK, BIOETHICS, RESEARCH ETHICS, AND REGULATION 203 (Seoul National University Press 2005).

[6] Bioethics and Biosafety Act, Law No. 7150 of 2005 (an unofficial English translation), *available at* www.ruhr-uni-bochum.de/kbe/Bioethics&BiosafetyAct-SouthKorea-v1.0.pdf [hereinafter Bioethics Act].

[7] Declaration on Human Cloning, G.A. Res. 59/280, U.N. Doc. A/RES/59/280 (Mar. 23, 2005).

[8] U.N. GAOR, 59th Sess., 82nd plen. mtg. at 5, U.N. Doc. A/59/PV.82 (Mar. 8, 2005).

[9] *Id. See Korea: Korea to Continue Cloning Research*, TODAY'S STEM CELL RESEARCH, Feb. 21, 2005, http://www.stemnews.com/archives/000362.html (last visited Apr. 26, 2008).

[10] *See* Bioethics Act, *supra* note 6, art. 11.

[11] Human Genome Project Information, Cloning Fact Sheet, http://www.ornl.gov/sci/techresources/Human_Genome/elsi/cloning.shtml (last visited Apr.26. 2008).

[12] Alan Colman & Alexander Kind, *Therapeutic Cloning: Concepts and Practicalities*, 18 TRENDS IN BIOTECHNOLOGY 192, 192 (2000).

publicized stem cell research scandal that took place in Korea after the Bioethics Act became law. Part III argues that the Bioethics Act falls short of international guidelines, such as the Declaration of Helsinki and the Nuremberg Code, because it does not require voluntary informed consent or comprehension of the research by egg donors. Additionally, the institutional review boards ("IRB") lack the independence necessary to monitor the quality of informed consent obtained. Part IV raises questions about a human embryo's status as a potential human being and argues that Korea's legislation fails to protect human embryos by not limiting their use in embryonic stem cell research. Part V recommends several approaches to strengthen the protections for human research subjects and place limitations on the use of human embryos in stem cell research. This Comment ultimately concludes that Korea should make the necessary changes to the Bioethics Act to stay consistent with international standards and ensure that scientists are conducting ethical and legal research.

II. JUST TWO YEARS AFTER THE BIOETHICS ACT CAME INTO EFFECT, KOREA RECOGNIZED THE NEED TO AMEND IT

After several unsuccessful attempts, Korea finally passed the Bioethics Act on December 29, 2003; it became effective on January 1, 2005.[13] The Bioethics Act aims to promote biotech research that can be "used to prevent or cure human diseases."[14] The Bioethics Act allows scientists to conduct research on human embryos, but prohibits the production of embryos for purposes other than pregnancy.[15] The uncovering of Korea's infamous stem cell research scandal attracted the world's attention to the regulation of embryonic stem cell research in Korea. The scandal prompted the Korean government to examine the effectiveness of the Bioethics Act in preventing future ethical breaches by scientists and protecting research subjects who participate in embryonic stem cell research.[16]

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[13] PAK, *supra* note 5, at 203.

[14] Bioethics Act, *supra* note 6, art. 1.

[15] Bioethics Act, *supra* note 6, art. 13.

[16] *See* Kim Tae-gyu, *Korea Mulls Allowing Research Using Cloned Embryos*, KOREA TIMES, Jan. 20, 2007.

A. The Legislative History of the Bioethics Act Sheds Light on the Struggles in Drafting a Bioethics Act that Promotes Scientific Research and Protects Human Dignity

Between 1997 and 2003, Korea attempted to legislate a bioethics law twelve times.[17] In 2000, Korea's Ministry of Science and Technology ("MOST") formed the Korean Bioethics Advisory Commission ("KBAC") to draft the first version of a bioethics law.[18] KBAC completed and submitted the framework for the Basic Law on Bioethics to MOST.[19] KBAC recommended prohibiting both reproductive and therapeutic cloning.[20] This commission also suggested temporarily allowing stem cell research on surplus frozen embryos from in vitro fertilization ("IVF").[21] MOST was not satisfied with these recommendations and did not submit its version of the bioethics law to the Korean National Assembly.[22]

Instead, in May 2002, MOST proposed the Bill on the Prohibition of Human Cloning and Stem Cell Research.[23] Another government ministry, the Ministry of Health and Welfare ("MHW"), also took up the issue of drafting the bioethics bill.[24] In contrast to MOST's bill, which sought to foster research and development of biotechnologies, MHW's bill focused on the issues of human dignity and safety.[25] To consolidate the bills proposed by the two governmental ministries, MHW formulated the Act on Bioethics and Safety in July 2002.[26] An associated gathering of citizen groups made changes to MHW's Act on Bioethics and Safety and drafted its own bill entitled "Bioethics and Biosafety Act," which amended the MHW bill.[27] The changes made by the citizen groups included complete prohibition of embryonic cloning and interspecies hybridization, as well as elevation of the National Bioethics Committee's status and function.[28] The government

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[17] Sung-Goo Han, Young Je Yoo & Wha-Joon Rho, *New Cloning Technologies and Bioethics Issues: The Legislative Process in Korea*, 13 EUBIOS J. ASIAN & INT'L BIOETHICS 205, 216 (2003).

[18] Sang-yong Song, *The Rise and Fall of Embryonic Stem Cell Research in Korea*, ASIAN BIOTECHNOLOGY & DEV. REV., Nov. 2006, at 65, 66.

[19] *Id.*

[20] *Id.*

[21] *Id.* For a discussion of in vitro fertilization, see COLUMBIA ENCYCLOPEDIA (6th ed. 2007), *available at* http://www.encyclopedia.com/doc/1E1-invitro.html.

[22] Song, *supra* note 18, at 66.

[23] PAK, *supra* note 5, at 192.

[24] *Id.*

[25] Kim Mikyung, *An Overview of the Regulation and Patentability of Human Cloning and Embryonic Stem Cell Research in the United States and Anti-Cloning Legislation in South Korea*, 21 SANTA CLARA COMPUTER & HIGH TECH. L. J. 645, 684 (2005).

[26] *Id.* at 684-85.

[27] *Id.* at 685-86.

[28] *Id.*

reviewed the bills and finally produced a single bill to be considered by the National Assembly.[29] After a year-long discussion, on October 14, 2003, the government bill, "Bioethics and Biosafety Act," was referred to the Korean National Assembly, the assembly that ultimately passed the Bioethics Act in December 2003.[30]

B. The Bioethics Act Establishes an Ethics Committee and Creates the Requirement of IRBs to Oversee Embryonic Stem Cell Research

Although some of its provisions became applicable in 2003, the Bioethics Act did not take effect until January 1, 2005.[31] In March 2004, MHW established the Bioethics and Biosafety Task Force Team ("Task Force Team"), which was entrusted with the responsibility to "provide an institutional framework on stem-cell research in order to ensure its transparency and ethical integrity."[32] The Task Force Team was also responsible for establishing and running the National Bioethics Committee ("NBC"),[33] the reviewing body responsible under the Bioethics Act for overseeing bioethics and safety in the life sciences and biotechnologies.[34]

The Bioethics Act stipulates a ten-member NBC, made up of scientists, ethicists, and government officials, to monitor any requested research on human embryos for a period of ninety days after receiving the request.[35] Other important provisions of the Act include the following: creation of IRBs,[36] a total ban on human cloning,[37] a ban on embryonic cloning using somatic cell nuclear transfer ("SCNT") except where the Committee permits such research,[38] and conditions and criteria for utilizing embryos in scientific research.[39]

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[29] *Id.* at 686.
[30] *Id.*
[31] *See* Bioethics Act, *supra* note 6.
[32] Press Release, Ministry of Health and Welfare, Bioethics and Safety Task Force Team Has Been Launched (Mar. 4, 2004), http://english.mohw.go.kr/ (search for "Bioethics and Safety Task Force Team") (last visited Apr. 26, 2008).
[33] *Id.*
[34] Bioethics Act, *supra* note 6, art. 6.
[35] *Korea Okays Stem Cell Research*, KOREA TIMES, Aug. 1, 2005.
[36] Bioethics Act, *supra* note 6, art. 9.
[37] *Id.* art. 11.
[38] *Id.* art. 22.
[39] *Id.* arts. 11-21.

C. The Hwang Embryonic Stem Cell Research Scandal and the Circumstances Surrounding It Attracted International Attention

Under the newly enacted Bioethics Act, MHW approved the stem cell research that Professor Hwang Woo-Suk had started at the Seoul National University before the Bioethics Act came into effect.[40] Less than four months after the Bioethics Act came into effect, Professor Hwang announced that he had made a breakthrough invention in stem cell research. In May 2005, Professor Hwang announced that his lab had been able to create eleven human embryonic stem cell lines that were patient-specific.[41] This was the second major invention in less than one year made in Professor Hwang's lab.[42] Just one year prior, in 2004, Professor Hwang had announced that his team was able to create a stem cell line from a cloned human embryo.[43] The Korean government had reacted to this news by issuing a stamp commemorating Professor Hwang's achievements[44] and investing millions of dollars in his research lab.[45]

Some commentators have argued that under the strict requirements of the Bioethics Act, only Professor Hwang was eligible to conduct stem cell research at the time the Bioethics Act came into effect;[46] the Additional Provisions of the Act allowed someone who was engaged in embryonic stem cell research prior to January 2005 to continue his research only if he had worked in the field for more than three years or had published a paper in an international journal.[47] This provision allowed Professor Hwang, who had published his 2004 scientific results in *Science*,[48] to continue his work on embryonic stem cell research uninterrupted, even after the Bioethics Act came into effect. Although MHW allowed Professor Hwang to continue his

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[40] *Korea Okays Stem Cell Research*, *supra* note 35.

[41] Erika Check, *Korea's Accelerating Stem-cell Work Prompts Calls for Global Ethical Rules*, 435 NATURE 393 (2005). Patient-specific stem cells are created by taking genetic material from the patient such that the resulting cells are a perfect match for the patient and there are no problems of rejection. *Stem Cells Tailored to Patients*, BBC NEWS, May 20, 2005, http://news.bbc.co.uk/2/hi/health/4555023.stm (last visited Mar. 16, 2008).

[42] Chris Mason, *The Korean Stem Cell Fiasco: Shifting the Focus*, MEDICAL DEVICE TECHNOLOGY, Mar. 2006, at 24, 24, *available at* http://www.devicelink.com/mdt/archive/06/03/002.html.

[43] *Id.*

[44] *S. Korea Takes Lead in Stem Cell Research*, NEWSDAY.COM, May 20, 2005, http://www.newsday.com/news/health/ny-hsclon0521,0,2813316.story (last visited Apr. 17, 2008).

[45] *See* Susan Watts, *South Korea's Cloning Controversy*, BBC NEWS, July 11, 2006, http://news.bbc.co.uk/2/hi/programmes/newsnight/4602490.stm (last visited Feb. 17, 2008).

[46] Tae-gyu, *supra* note 16.

[47] *Id.*; Bioethics Act, *supra* note 6, Additional Provisions.

[48] Tae-gyu, *supra* note 16.

work on stem cells, it did not approve any other scientist's stem cell research project under the Bioethics Act until August 2005.[49]

After the successes in embryonic stem cell research reported by Professor Hwang and endorsed by the Korean government, the entire world was shocked to hear that Professor Hwang's research data had been fabricated.[50] In his 2004 and 2005 papers, Professor Hwang fabricated results and manipulated photographs to claim that he had cloned the first human embryo and had derived patient-specific stem cells from cloned embryos.[51] By January 2006, a committee at Seoul National University had confirmed that the data reported by Professor Hwang in his 2004 and 2005 papers were fabricated.[52] Several other reports of ethical violations were also brought against Professor Hwang,[53] and he finally admitted in November 2005 that two of his research assistants had donated eggs for his research on embryonic stem cells and he had paid other egg donors for their donations.[54]

The knowledge that Professor Hwang's research was doctored created an uproar in the scientific community.[55] Public faith in embryonic stem cell research decreased as a result of the scandal.[56] The ethical irregularities of the Hwang scandal can be used as "ammunition [by] activists who are opposed to the technology on moral grounds."[57] Following the news of the scandal, the stock prices in the Korean biotech industry fell dramatically, and the news shook the whole biotech industry.[58]

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[49] *Korea Okays Stem Cell Research*, *supra* note 35.

[50] Steve Connor, *Inquiry Finds Korea's Human Cloning Was All Fraud*, INDEPENDENT (London), Jan. 11, 2006, at 25.

[51] *Id.*

[52] Dennis Normile, Gretchen Vogel & Jennifer Couzin, *South Korean Team's Remaining Human Stem Cell Claim Demolished*, SCIENCE, Jan. 13, 2006, at 156, *available at* http://www.sciencemag.org/cgi/reprint/311/5758/156.pdf.

[53] *See generally* Sei Chong, *Investigations Document Still More Problems for Stem Cell Researchers*, SCIENCE, Feb. 10, 2006, at 754, *available at* http://www.sciencemag.org/cgi/reprint/311/5762/754.pdf (referring to reports stating that Hwang violated ethical principles in his collection of human oocytes and that the government auditor "could not account for $2.6 million in research funds that Hwang had received").

[54] Constance Holden, *Korean Cloner Admits Lying About Oocyte Donations*, SCIENCE, Dec. 2, 2005, at 1402, *available at* http://www.sciencemag.org/cgi/reprint/310/5753/1402.pdf.

[55] *See* Lawrence K. Altman & William J. Broad, *Global Trend: More Science, More Fraud*, N.Y. TIMES, Dec. 20, 2005, at F5, *available at* http://www.nytimes.com/2005/12/20/science/20rese.html?pagewanted=print.

[56] Paul Elias & Malcolm Ritter, *Science Fraud Shakes Stem Cell Field*, LIVESCIENCE, Dec. 24, 2005, http://www.livescience.com/strangenews/ap_051224_stem_cells.html (last visited Apr. 28, 2008).

[57] *See* David Cyranoski, *Korea's Stem-Cell Stars Dogged by Suspicion of Ethical Breach*, 429 NATURE 3 (2004), *available at* http://www.nature.com/nature/journal/v429/n6987/pdf/429003a.pdf.

[58] *See* Ichiko Fuyuno, *Hwang Scandal Hits Korean Biotech Hard*, 439 NATURE 265 (2006), *available at* http://www.nature.com/nature/journal/v439/n7074/pdf/439265a.pdf.

D. Korea Recognized the Need to Amend the Bioethics Act in the Aftermath of the Hwang Scandal

After the Hwang scandal, Korea practically prohibited research on cloned human embryos.[59] Then, in January 2007, NBC began to reconsider whether to allow research on cloned human embryos.[60] NBC recognized that if it permitted this research, the government would have to revise bills to qualify more local institutions to get involved in embryonic cloning research.[61] In March 2007, NBC lifted the ban on embryonic stem cell research on the condition that scientists only use embryos that would otherwise be discarded instead of creating new embryos for research.[62]

A few months later, in October 2007, Korea passed an Amendment to the Executive Ordinance of the Bioethics Act ("Amendment").[63] Among other procedural changes, the Amendment describes the process to call the Council of National Bioethics Committee into action and the process to create new committees for particular areas of bioethics.[64] With regard to embryonic stem cell research, the Amendment lists the parts of an embryo research plan that require approval before they can be changed.[65] These parts include changes in the purpose of embryological research, the time span of the research, and the number of embryos used.[66] Article 12(2) of the Amendment limits the permitted sources of eggs used for somatic cell nucleus transplantation.[67] These procedural amendments, however, do not address the major shortcomings of the Bioethics Act. Primarily, the amendments do not address the Act's failure to require voluntary informed consent to ensure that an egg donor understands her role in the research. Also, they do not address the Act's failure to adequately protect human embryos from undue harm. Another amendment with more extensive changes to the Bioethics Act has already been submitted to the Korean National Assembly.[68]

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[59] Tae-gyu, *supra* note 16.

[60] *Id.*

[61] *Id.*

[62] Kim Yoon-mi, *Panel Approves Limited Research on Stem Cells*, KOREA HERALD, Mar. 24, 2007.

[63] Enforcement Ordinance of Bioethics and Biosafety Act, Executive Order No. 20316, partly amended Oct. 4, 2007, *available at* http://likms.assembly.go.kr/law/jsp/Law.jsp?WORK_TYPE=LAW_BON&LAW_ID=B3684&PROM_NO=20316&PROM_DT=20071004& (unofficial translation on file with author) [hereinafter Enforcement Ordinance].

[64] *Id.* arts. 2, 3.

[65] *Id.* art. 12.

[66] *Id.*

[67] *Id.* art. 12(2).

[68] E-mail from Dr. Young-Mo Koo, Assistant Professor, University of Ulsan College of Medicine Asan Medical Center to author (Dec. 4, 2007, 20:50 PST) (on file with author). Specific information about

III. THE BIOETHICS ACT DOES NOT ADEQUATELY MEET INTERNATIONAL STANDARDS FOR PROTECTING EGG DONORS IN EMBRYONIC RESEARCH

Although the Bioethics Act addresses egg donations made by women, it does not have enough safeguards to protect egg donors from exploitation. Women may be motivated by altruistic intent to further scientific research when they donate their eggs.[69] However, it is equally plausible, if not more so, that egg donors are pressured into donating their eggs,[70] especially in Korea where egg donors receive no financial benefit from the donation or compensation for the trouble of donating their eggs.[71] Due to the absence of monetary incentive to donate, many women may not willingly donate their eggs, creating a situation where scientists are forced to procure eggs through unethical or illegal means.[72] Recognizing the need to protect these egg donors, the Bioethics Act requires researchers to obtain written consent from the donors before using their eggs in research.[73] International standards, however, have more stringent guidelines that govern research on human subjects, such as the requirement that research participants understand the aim and scope of the research study, and give their informed and voluntary consent.[74] Korea's Bioethics Act falls short of the international standards because it does not have adequate protections for women who donate their eggs for stem cell research.

A. International Standards Governing Research on Human Subjects Apply to Women Egg Donors

The Nuremberg Code and the World Medical Association's Declaration of Helsinki are the foremost authorities on human subject research.[75] The International Bioethics Committee ("IBC"), which advises

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the changes is very limited, in English as well as in Korean. The Assembly is expected to make a decision on the amendment later this year. *Id*.

[69] *See* Human Fertilisation & Embryology Authority, Donor Motivation in the UK, http://www.hfea.gov.uk/docs/donor_motivation_literature_review.pdf (last visited Feb. 17, 2008).

[70] For a discussion of women being forced to donate their eggs, see *infra* Part III.B.

[71] Bioethics Act, *supra* note 6, art. 13.

[72] *See infra* Part III.B.

[73] *See* Bioethics Act, *supra* note 6, arts. 5, 9, 15.

[74] *See infra* Part III.B.

[75] *See* Bernard A. Fischer IV, *A Summary of Important Documents in the Field of Research Ethics*, 32 SCHIZOPHRENIA BULL. 69, 69-70 (2006); *see also* World Medical Association, Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects (1964) (amended in 2000 and clarified in 2002 and 2004), *available at* http://www.wma.net/e/policy/pdf/17c.pdf [hereinafter Declaration of Helsinki]; 2 TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW NO. 10 181-82 (U.S. Govt. Printing Office, 1949), *reprinted in* Office of Human Subjects

the United Nations Educational, Scientific and Cultural Organization ("UNESCO") on ethics in science and technology, has issued a report on the necessity and quality of consent obtained from research participants.[76] The World Health Organization ("WHO") incorporated the requirements for ethical review established in the above-mentioned international guidelines and issued the Operational Guidelines for Ethics Committees that Review Biomedical Research.[77] Though many of these standards are not binding, they are aspirational standards, and are widely accepted in the world.[78]

Most national as well as international regulations treat women who donate their eggs for scientific research as research subjects. Under the Declaration of Helsinki, for instance, biomedical research involving human participants includes research on "identifiable human material and data."[79] Similarly in the United States, under the federal regulations, persons who provide biological materials for research are research subjects.[80] Women who donate eggs for embryonic stem cell research donate human biological material, i.e. their eggs, for research. Thus, the women who donate eggs for stem cell research should be characterized and treated as "research participants."[81] This classification is important because the Declaration of Helsinki applies to "human subjects"[82] involved in medical research; if women who donate their eggs for scientific research are considered human

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Research, Nuremberg Code, http://ohsr.od.nih.gov/guidelines/nuremberg.html (last visited Apr. 26, 2008) [hereinafter Nuremberg Code].

[76] *See* U.N. Educ., Sci. and Cultural Org. [UNESCO], International Bioethics Committee, *Report of the International Bioethics Committee of UNESCO (IBC) on Consent*, SHS/EST/CIB-13/06/CONF.505/2 Rev 2 (May 19, 2007) [hereinafter UNESCO International Bioethics Committee].

[77] World Health Organization [WHO], *Operational Guidelines for Ethics Committees that Review Biomedical Research*, at v, TDR/PRD/ETHICS/2000.1 (2000), *available at* http://www.who.int/tdr/publications/publications/pdf/ethics.pdf [hereinafter WHO Operational Guidelines].

[78] *See* Bryan Christie, *Doctors Revise Declaration of Helsinki*, 321 BMJ 913, 913 (2000), http://www.bmj.com/cgi/reprint/321/7266/913 (last visited Feb. 17, 2008); *see* International Compilation of Human Research Protections, Office of Human Research Protections, U.S. Dept. of Health & Human Services 4 (2008), *available at* http://www.hhs.gov/ohrp/international/HSPCompilation.pdf. The United States National Institutes of Health has recognized the Nuremberg Code and the Declaration of Helsinki as forming the legal foundation for its policies and procedures governing research on human participants. U.S. Dept. of Health & Human Services, Guidelines for the Conduct of Research Involving Human Subjects at the National Institutes of Health 15 (Aug. 2004), http://ohsr.od.nih.gov/guidelines/GrayBooklet82404.pdf (last visited Apr. 26, 2008) [hereinafter Guidelines for the Conduct of Research Involving Human Subjects]. The Korean Medical Association is a member of the World Medical Organization. World Medical Association, WMA Medical Ethics Manual, http://www.wma.net/e/ethicsunit/resources.htm (last visited Feb. 21, 2008).

[79] Declaration of Helsinki, *supra* note 75, ¶ 1.

[80] Guidelines for the Conduct of Research Involving Human Subjects, *supra* note 78, at 4 (citing 45 C.F.R. §46 (1991)).

[81] *See* David Magnus & Mildred K. Cho, *Issues in Oocyte Donation for Stem Cell Research*, SCIENCE, June 17, 2005, at 1747, *available at* http://www.sciencemag.org/cgi/reprint/308/5729/1747.pdf.

[82] Declaration of Helsinki, *supra* note 75, ¶ 1.

research subjects, then the protections of the Declaration of Helsinki must apply to them as well.

B. The Bioethics Act Does Not Have Enough Safeguards to Protect Women Who Donate Their Eggs for Embryonic Stem Cell Research

With the worldwide acceptance of the Declaration of Helsinki,[83] informed consent has become a must-have requirement in the field of biomedical research.[84] As the international guidelines point out, it is equally important to ensure that the research subjects are participating in research voluntarily.[85] To that end, Korea joined other nations in implementing ways to protect human research subjects from exploitation, such as by establishing the IRB review system.[86] However, women who donate their eggs for stem cell research are not adequately protected from possible exploitation because the Bioethics Act falls short of fulfilling international mandates designed to ensure voluntary and uncoerced consent. Although the Bioethics Act contains provisions that lay out the information that should be included in the consent form, it does not require that egg donors actually understand the purpose of the research being conducted or appreciate the risks involved. The IRBs set up by the Bioethics Act have the responsibility of ensuring that embryonic stem cell research is conducted ethically,[87] but the administration of IRBs under the Bioethics Act makes it difficult for the IRBs to conduct an independent and unbiased review of the research study.

1. Because Egg Donors Derive No Personal Benefit from the Research, Scientists May Unduly Influence Them to Donate Their Eggs

The Bioethics Act expressly prohibits any financial reward in exchange for egg donations.[88] Paying women money in exchange for their

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[83] *See* Jeff Blackmer & Henry Haddad, *The Declaration of Helsinki: An Update on Paragraph 30*, 173 CANADIAN MED. ASS'N J. 1052, 1052 (2005), *available at* http://www.cmaj.ca/cgi/reprint/173/9/1052; Tyebkhan G., *Declaration of Helsinki: The Ethical Cornerstone of Human Clinical Research*, 69 INDIAN J. DERMATOLOGY VENEREOLOGY LEPROLOGY 245 (2003), *available at* http://www.ijdvl.com/text.asp?2003/69/3/245/1013; Christie, *supra* note 78.

[84] Nuremberg Code, *supra* note 75, ¶ 1; CONTEMPORARY ISSUES IN BIOETHICS 505 (Tom L. Beauchamp & LeRoy Walters eds., 1978).

[85] *See* Council for International Organizations of Medical Sciences [CIOMS] and the World Health Organization [WHO], International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002), http://www.cioms.ch/frame_guidelines_nov_2002.htm (last visited Apr. 26, 2008) [hereinafter CIOMS Guidelines].

[86] *See* Editorial, *Stages of Institutional Review Board Activities*, 18 J. KOREAN MED. SCI. 1, 2 (2003), *available at* http://jkms.kams.or.kr/2003/pdf/02001.pdf.

[87] Bioethics Act, *supra* note 6, art. 9.

[88] Bioethics Act, *supra* note 6, art. 13.

eggs may unduly influence them into becoming donors.[89] Still, given that egg donation is an arduous process which exposes donors to several different types of risks ranging from infertility to cancer,[90] some bioethicists argue that egg donors should be compensated on the basis of time and discomfort associated with the egg donation process.[91] The Bioethics Act, however, does not even allow women to get reimbursed for their time, pain and suffering in donating eggs, or for medical treatments for complications resulting from these procedures.[92] Furthermore, at the present time no successful treatment exists that utilizes embryonic stem cells.[93] Even if a cure for the disease being researched is developed using a woman's eggs, she may not be able to afford the treatment, especially if she is from a lower socio-economic class.[94]

With no monetary or medical benefit from the donation, it is possible that many women will have no incentive or motivation to go through the trouble of donating their eggs. If there are not enough egg donors available, scientists involved in embryonic stem cell research may have to secretly pay donors or engage in other "problematic practices" to get the required eggs for research.[95] This has already happened in Korea where investigations during the Hwang scandal revealed that Professor Hwang had engaged in unethical practices and had unduly influenced women to obtain their eggs for research.[96]

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[89] Bonnie Steinbock, *Payment for Egg Donation and Surrogacy*, 7 MOUNT SINAI J. MED. 255, 262 (2004).

[90] Sarah B. Angel, *The Value of the Human Egg: An Analysis of Risk and Reward in Stem Cell Research*, 22 BERKELEY J. GENDER L. & JUST. 183, 203 (2007).

[91] Robert Steinbrook, *Egg Donation and Human Embryonic Stem-Cell Research*, 354 NEW ENG. J. MED. 324, 326 (2006), *available at* http://content.nejm.org/cgi/reprint/354/4/324.pdf.

[92] *See* Bioethics Act, *supra* note 6.

[93] Wolfgang Lillge, *The Case for Adult Stem Cell Research*, 21ST CENTURY SCIENCE AND TECHNOLOGY MAGAZINE, 2001-2002, http://www.21stcenturysciencetech.com/articles/winter01/stem_cell.html (last visited Feb. 17, 2008).

[94] *See* Anne McLaren, *Insight Commentary, Ethical and Social Considerations of Stem Cell Research*, 414 NATURE 129, 131 (2001), *available at* http://www.nature.com/nature/journal/v414/n6859/pdf/414129a0.pdf; *see also* Thomas A. Shannon, *Ethical Issues in Stem Cell Therapy From the Micro to the Macro*, WPI TRANSFORMATIONS (2003), http://www.wpi.edu/News/Transformations/2003Spring/stemcell.html ("the product of such research will also be costly because investors will be seeking an adequate return on their investment"); *see generally* Greg Nelson, *Man Travels to Russia for Stem Cell Treatment*, MORNING SUN, Jan. 27, 2008, http://www.themorningsun.com/stories/012708/loc_russia.shtml (last visited Feb. 17, 2008) (narrating a man's trip to Russia to obtain adult stem cell treatment which cost him "more than $25,000" for the first trip and $10,000 for the second).

[95] Steinbrook, *supra* note 91, at 326.

[96] Diane Beeson & Abby Lippman, *Egg Harvesting for Stem Cell Research: Medical Risks and Ethical Problems*, 13 RBM ONLINE, http://www.humanebiotech.com/images/RBMOnline-Eggharvestingforstemcellres....pdf (last visited Feb. 29, 2008).

Professor Hwang had paid women money in exchange for their eggs.[97] Between November 2002 and December 2005, Professor Hwang's laboratory had monetarily compensated more than ninety-seven women for their egg donations.[98] The Bioethics Act expressly prohibits any "financial reward" in exchange for eggs.[99] Any payments for egg donations made after January 2005 violated the Bioethics Act.[100] Professor Hwang had also obtained eggs from junior scientists in his laboratory, which, according to some commentators, constituted coercion.[101] As one critic points out, "in the strict hierarchy of a scientific laboratory in a Confucian society like South Korea, junior members often feel great pressure to please their superiors."[102] In fact, one researcher from Professor Hwang's laboratory who had donated her eggs later wrote in an email, "I shouldn't have done it this way, not giving up [my position in the research team] until the end, not fighting against the professor."[103] In light of the Hwang scandal and the very real possibility that Korean women may feel pressured or coerced into donating their eggs, it is important that egg donors are adequately protected from exploitation.

2. The Bioethics Act Does Not Require that Egg Donations Be Made Voluntarily and Free of Coercion

Before allowing research on human subjects, international standards require that research participants give voluntary and informed consent to participate in the research.[104] Informed consent and voluntary consent are

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[97] Aera Han, The Ethical and Regulatory Problem in the Stem Cell Scandal, 21-22 (2006) (unpublished LL.M dissertation, Harvard University), http://leda.law.harvard.edu/leda/data/769/Han06.rtf (last visited May 10, 2008).

[98] *Id.* at 25.

[99] Bioethics Act, *supra* note 6, art. 13.

[100] It is true that some of the payments made by Professor Hwang's research took place before the Bioethics Act came into effect in 2005. Yet, the purchasing of eggs, even if not illegal under the Bioethics Act, still violated other guidelines applicable to Professor Hwang's research. For instance, the Korean Medical Association's Guidelines on Research of Cloning Lives, issued in 1999, prohibit trading of eggs. Han, *supra* note 97, at 21-22.

[101] *See* Holden, *supra* note 54, at 1402; Jin Hyun-joo, *Ethical Issues Surface Over Cell Research: Junior Researcher Says She Was Forced to Donate Eggs*, KOREA HERALD, Jan. 3, 2006; Gary Younge, *Embryo Scientist Quits Team Over Ethics Fear*, GUARDIAN (London), Nov. 14, 2005.

[102] James Brooke, *Korean Leaves Cloning Center in Ethics Furor*, N.Y. TIMES, Nov. 25, 2005, at A1, *available at* http://www.nytimes.com/2005/11/25/international/asia/25clone.html?_r=1&oref=slogin.

[103] Han, *supra* note 97, n. 89 (citing Hwang Woo Suk Gyosu-Ui Yunlimunje-E Daehan Jungganbogoseo [The Intermediary Report on the Ethical Problems of Dr. Woo Suk Hwang's Research]).

[104] *See* Nuremberg Code, *supra* note 75, ¶ 1; Declaration of Helsinki, *supra* note 75, ¶ 20; UNESCO International Bioethics Committee, *supra* note 76, art. 5.

two distinct requirements.[105] Informed consent deals with the physician or researcher's duty to provide adequate information to the patient or research subject. Voluntariness of consent deals with the patient's decision-making ability to give free consent to participate.[106] Recognizing this difference, international guidelines require informed as well as voluntary consent from human subjects involved in the research. For instance, the Nuremberg Code requires that, along with being fully informed of the extent of their involvement in research, human research participants should be in a position to "exercise free power of choice" to participate.[107] Similarly, the Declaration of Helsinki requires physicians to pay special attention to vulnerable research participants who might be "subject to giving consent under duress" or "who will not benefit personally from the research."[108]

The Bioethics Act does not require that the consent obtained from research participants be voluntary. Unlike the Guidelines for Korean Good Clinical Practice which require physicians to pay special attention to trials involving vulnerable subjects—those who may be unduly influenced by expectation of benefits, or those who may be afraid to refuse consent due to a retaliatory response from a senior member[109]—Article 5 of the Bioethics Act only guarantees a research participant the right to "consent, or refuse consent" to participate in the research after being "fully informed" of his or her involvement.[110] It is true that the Bioethics Act allows egg donors to withdraw their consent,[111] but withdrawal of consent is only meaningful if the Bioethics Act requires voluntary consent in the first place.

Because the Bioethics Act does not require women to voluntarily consent to egg donations, it does not protect women from the various sources of duress that may force them to donate their eggs. By expressly prohibiting any sort of monetary compensation for egg donations, the Bioethics Act tries to ensure that women are not swayed to donate their eggs because of money. As commentators have pointed out, however, payment for eggs is only one of many ways women donors can be unduly influenced into donating their eggs.[112] Societal and familial pressures and the

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[105] Helen J. Kahn, *Voluntary Consent for Participation in Research in the Twenty-First Century*, 71 BRAIN & LANGUAGE 110, 110 (2000).
[106] *Id.*
[107] Nuremberg Code, *supra* note 75, ¶ 1.
[108] Declaration of Helsinki, *supra* note 75, ¶ 8.
[109] Han, *supra* note 97, at 23 (citing the Guidelines for Korean Good Clinical Practice, art. 7 §1).
[110] Bioethics Act, *supra* note 6, art. 5.
[111] *Id.* art. 15.
[112] Josephine Johnston, Editorial, *The Women Behind Cloning*, WASH. POST, Mar. 8, 2004, at A19.

authoritative presence of someone in a hierarchy are other causes of duress and coercion that may make a woman's consent to donate involuntary.[113]

The Bioethics Act, however, is quiet on these other possible sources of duress. For example, it is not clear whether egg donations made by junior researchers in Professor Hwang's laboratory would have constituted coercion under the Bioethics Act,[114] even though the donations undoubtedly violated the Declaration of Helsinki[115] which states that "special attention is also required for those who cannot give or refuse consent for themselves, for those who may be subject to giving consent under duress."[116] The Bioethics Act's silence on the issue of voluntary consent highlights its failure to protect vulnerable subjects who might not be in a situation to deny consent to stem cell research participation.[117] By addressing only monetary compensation as a potential form of duress and by not expressly requiring that a woman voluntarily consent to donate her eggs, the Bioethics Act falls short of the international guidelines and fails to adequately protect the autonomy of egg donors.

3. The Bioethics Act Violates International Standards by Not Requiring that Egg Donors Understand the Research and Associated Risks

The International Bioethics Committee states that "it is necessary [in scientific research] to make the [research subject] aware of the aim of the research, the methodology and the duration, expected benefits for him/her or for other persons concerned and the risks involved."[118] As a member state of UNESCO,[119] Korea is expected to follow the guidelines set forth by the International Bioethics Committee.

The Korean Bioethics Act does not require researchers to inform the research subjects of the potential risks involved in the research study. The Bioethics Act only mandates that the written consent form state the purpose of producing an embryo, details regarding the storage and disposal of

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[113] Russell Korobkin, *Buying and Selling Human Tissues for Stem Cell Research*, 49 ARIZ. L. REV. 45, 53 (2007).

[114] *See generally* Bioethics Act, *supra* note 6 (denying financial reward for donating oocytes, but not protecting an egg donor from other possible sources of coercion or undue influence).

[115] *See* Han, *supra* note 97, at 23; *Hwang Admits In-House Egg Donations*, KOREA TIMES, Nov. 25, 2005.

[116] Declaration of Helsinki, *supra* note 75, ¶ 8.

[117] The Guidelines for Korean Good Clinical Practice do not apply to protect the women who donate their eggs for embryonic stem cell research because the Guidelines are not laws and the Bioethics Act states that only "other laws concerning bioethics" may be relied upon. Bioethics Act, *supra* note 6, art. 3.

[118] UNESCO International Committee of Bioethics, *supra* note 76, ¶ 13.

[119] UNESCO, Member States, http://erc.unesco.org/cp/MSList_alpha.asp?lg=E (last visited Feb. 20, 2008).

embryos, whether remaining embryos can be used for purposes other than pregnancy, information about the procedures for withdrawal of consent, and other information regarding consenters' rights or any other information the MHW finds necessary.[120] The Act's inherent vagueness as to what constitutes "other necessary information"[121] is compounded by the Act's failure to require scientists to disclose information about "expected benefits" of the research and the "risks involved" as required by UNESCO guidelines.[122]

After a full disclosure of expected benefits and potential risks of a particular research study, the international standards place a further burden on researchers and physicians. The Declaration of Helsinki requires that research subjects understand the information presented to them by the physician.[123] Thus, scientists can only utilize a subject in a research study after a full disclosure of expected benefits and risks involved and after making sure that the subject understands the information presented to him or her. The Korean Bioethics Act does not require that research subjects understand the information presented to them before allowing them to participate in stem cell research.

"Embryo producing medical institutions," facilities that "collect sperms or oocytes in order to produce an embryo," are required under the Bioethics Act to "explain in detail the contents of [the consent form to the oocyte donors] before obtaining a written consent."[124] Requiring a signed, written consent from oocyte donors is an important first step in ensuring that research subjects are not exploited. However, as one commentator points out, compliance with research ethics should move away from "checking off boxes" and towards a "culture of conscience."[125] The use of "readability tests" and other measures to ensure that the consent form uses simple words and sentences such that a woman with little formal education can understand it is one way of creating that culture of conscience.[126] Instead of the researcher providing large amounts of complicated information to egg donors, it might be helpful to have a counselor present at the meetings who

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[120] Bioethics Act, *supra* note 6, art. 15(2).

[121] *Id.*

[122] UNESCO International Committee of Bioethics, *supra* note 76, ¶ 13.

[123] Declaration of Helsinki, *supra* note 75, ¶ 22.

[124] *See* Bioethics Act, *supra* note 6, art. 15(3).

[125] David Perlman, *Putting the "Ethics" Back into Research Ethics: A Process for Ethical Reflection for Human Research Protection*, 37 J. RES. ADMIN. 13, 14 (2006).

[126] Family Health International, *Choices Must be Informed, Voluntary*, 21 ETHICS AND REPRODUCTIVE HEALTH (2001), http://www.fhi.org/en/RH/Pubs/Network/v21_2/NW21-2informconst.htm #informedcons (last visited Mar. 15, 2008).

uses visual aids to explain the contents of the consent form.[127] Egg donors may feel more comfortable asking the counselor questions regarding the research and stating their unwillingness to participate. Moreover, the counselor likely has more experience than a scientist in communicating information. The Bioethics Act lacks "conscience" because it takes no steps to ensure that only women who truly understand the manifold risks of donating their eggs are allowed to donate eggs.

The text of the Bioethics Act also warrants the requirement of comprehension of the information presented to research participants. Allowing scientists to conduct research when a research subject fails to understand the "aims, [and] methods" of the study contradicts the purpose of the Bioethics Act.[128] The Bioethics Act aims to "protect human dignity and to prevent harm to human beings."[129] How can the Bioethics Act prevent harm to human beings if it does not require that the human subjects who volunteer to participate in a research study actually understand the potential risks and harms arising from the research? For instance, a woman may decide to go to an embryo producing medical institution to donate her eggs to embryonic stem cell research thinking that the procedure will not be any different from donating blood. To prevent unnecessary harm to egg donors, it is important that the woman understand all the risks associated with donating eggs, risks that include Ovarian Hyperstimulation Syndrome, future infertility, and cancer.[130] It is only after a woman understands and appreciates the risks involved in donating eggs and the purpose of the research study that she can give a truly informed and voluntary consent.

The dangers present when a research subject does not understand the purpose of the research are heightened in embryonic stem cell research. Women who donate eggs entirely for research purposes are not seeking any personal medical or reproductive benefit from the donation, but are taking risks for the potential benefit to others and may be mistaken about the use of the resulting embryo.[131] Therapeutic misconception has been pointed out as a real and significant danger of embryonic stem cell research.[132] A

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[127] Daniel W. Fitzgerald, Cécile Marotte, Rose Irene Verdier, Warren D. Johnson & Jean William Pape, Research Letters, *Comprehension During Informed Consent in a Less-Developed Country*, 360 LANCET 1301, 1301-02 (2002).

[128] Declaration of Helsinki, *supra* note 75, ¶ 22; *see* NEIL C. MANSON & ONORA O'NEILL, RETHINKING INFORMED CONSENT IN BIOETHICS 9 (Cambridge University Press 2007) ("many research subjects fail to understand common features of prospective research design").

[129] Bioethics Act, *supra* note 6, art. 1.

[130] Angel, *supra* note 90, at 203-07.

[131] Magnus, *supra* note 81, at 1748.

[132] David Magnus & Mildred K. Cho, *A Commentary on Oocyte Donation for Stem Cell Research in South Korea*, AM. J. BIOETHICS W23, W23-24 (Jan. 2006).

description of the potential uses of stem cells along with reasons why stem cell research is so promising can make it confusing for the donor to understand that there are no "embryonic stem-cell based therapies currently available."[133] Egg donors must understand the nature of embryonic stem cell research so they can make an informed decision about whether they want to become research subjects. The Bioethics Act "aims to prevent harm to human beings,"[134] which includes preventing harm to egg donors. Requiring that egg donors actually understand the research, its goals, and inherent risks in donating their eggs is an internationally accepted way of preventing this type of harm.

4. The Bioethics Act Fails to Heed WHO's Guidelines that Require IRBs to Function Independently of the Research Institution

International organizations have recognized the importance of having ethics committees that review research that is conducted on human subjects. The Declaration of Helsinki requires that the protocol of research involving human subjects "should be submitted for consideration, comment, guidance, and where appropriate, approval to a[n] [independent] specially appointed ethical review committee."[135] It further states that the researcher should submit and the committee should review "information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest and incentives for subjects."[136] WHO has also published the Operational Guidelines for Ethics Committees That Review Biomedical Research.[137] These guidelines establish "an international standard for ensuring quality in ethical review" of biomedical research.[138]

Recognizing the international importance of having ethics committees review biomedical research, Korea enacted the Korean Good Clinical Practice ("KGCP") in 1995.[139] In January 2001, the Korean government revised the KGCP based on the International Conference on Harmonization of Good Clinical Practice, an international ethics guideline for clinical

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[133] *Id.*
[134] Bioethics Act, *supra* note 6, art. 1.
[135] Declaration of Helsinki, *supra* note 75, ¶ 13.
[136] *Id.*
[137] WHO Operational Guidelines, *supra* note 77.
[138] *Id.* at 1.
[139] Ock-Joo Kim, Byung-Joo Park, Dong-Ryul Sohn, Seung-Mi Lee & Sang-Goo Shin, *Current Status of the Institutional Review Boards in Korea: Constitution, Operation, and Policy for Protection of Human Research Participants*, 18 J. KOREAN MED. SCI. 3, 3 (2003), *available at* http://jkms.org/fulltext/pdf/jkms-18-3.pdf.

trials.[140] This revision required that legal and institutional bases be established to ensure that the constitution and operation of IRBs are standardized and upgraded to international levels.[141] In March 2002, IRB members in major hospitals, biomedical researchers, medical directors of pharmaceutical companies and officers from health authorities founded the Korean Association of Institutional Review Boards ("KAIRB") under the auspices of the Korean Academy of Medical Sciences.[142] The main mission of the KAIRB is to help Korean IRBs build up ethical review capacity to the international level.[143]

Against this backdrop, the Korean Bioethics Act stipulates that every embryo research institution set up its own IRB.[144] The law describes the organization and administration of IRBs[145] and lays out their role in reviewing biomedical research. However, the Bioethics Act falls short of international standards, particularly the WHO Operational Guidelines, because it does not require that the IRB act independently of the research institution.

International standards guiding the organization and functioning of ethics committees are much more stringent than the Korean Bioethics Act. WHO Operational Guidelines require a member of the ethics committee to "withdraw from the meeting for the decision procedure concerning an application where there arises a conflict of interest."[146] "Conflict of interest" exists when a board member has "financial, material, institutional, or social ties to the research" or there are other factors present that may "jeopardize his/her (their) ability to provide a free and independent evaluation of the research focused on the protection of the research participants."[147]

Compared to the WHO Guidelines, the Bioethics Act takes a narrower approach to determine when an IRB member may be ineligible to participate in the review process. Article 10 of the Bioethics Act states that each IRB will be made up of five to nine people, and will include one person who is "not engaged in the fields of life science or medical science, as well as one person [who is] external to the institution."[148] Members who are "involved in research, development, or utilization of life sciences and biotechnologies"

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[140] *Id.* at 4.
[141] *Id.*
[142] *Id.*
[143] *Id.*
[144] Bioethics Act, *supra* note 6, art. 9(1).
[145] *See* Bioethics Act, *supra* note 6, art. 10.
[146] WHO Operational Guidelines, *supra* note 77, at 14.
[147] *Id.* at 21.
[148] Bioethics Act, *supra* note 6, art. 10.

that are being reviewed by the Board are barred from participating in the review process.[149]

The Bioethics Act does not define what it means by the phrase "involved in research, development, or utilization" of biotechnology. Webster's Dictionary defines the verb "involve" as "to engage as a participant."[150] So the Bioethics Act bars participants of embryological stem cell research from being on the committee that reviews the research. Even though "involved" can cover a broad range of relationships that might be problematic to a fair assessment of biomedical research, the use of the phrase "in research, development, or utilization of life sciences and biotechnologies" restricts its reach. Only members who have a scientific, institutional or financial interest in the research or utilization of a biotechnology can be said to be "involved" so as to bar them from participating in the review process. Members who are not "involved" in the research, development, or utilization of the technology, but have other "social ties"[151] with the research or development of the biotechnology would not be barred under the Bioethics Act from being on the IRB that reviews the research protocol.[152] The international guidelines, however, explicitly prohibit an ethics committee member from having any "social ties" or any other relationship that might jeopardize their decision-making ability from being on the review board.[153] For example, some of the members of the IRB that reviewed Professor Hwang's research were alleged to have been originally nominated by Professor Hwang's team.[154] Under the international guidelines, this social relationship between Professor Hwang and the IRB members he nominated would prevent those members from reviewing his research. However, under the Bioethics Act, the members were allowed to review Professor Hwang's research because they were not "involved" in the study. International standards ensure that a research proposal or protocol will face an independent review process, whereas there is no such guarantee under the Bioethics Act in Korea.

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[149] *Id.* art. 10(3).

[150] MERRIAM WEBSTER'S COLLEGIATE DICTIONARY 617 (10th ed. 1995).

[151] WHO Operational Guidelines, *supra* note 77, at 21.

[152] It was uncovered during the investigations that Yang Sam-sung, the head of South Korea's National Bioethics Committee, had participated in panel meetings while he was still Professor Hwang's lawyer. Herbert Gottweis & Robert Triendl, Commentary, *South Korean Policy Failure and the Hwang Debacle*, 24 NATURE BIOTECHNOLOGY 141, 143 (2006), *available at* http://www.nature.com/nbt/journal/v24/n2/pdf/nbt0206-141.pdf.

[153] *See* WHO Operational Guidelines, *supra* note 77, at 21.

[154] IRB Forum, http://www.irbforum.org/forum/read/2/113/113Vt?PHPSESSID=230a474bc7424d4f5ee07fffb85d5ad5 (last visited Apr. 26, 2008) (citing Jin Hyun-joo, *Ethics Panel Head to Quit in Alleged Involvement in Hwang's Scandal*, KOREA HERALD, Jan. 5, 2006).

IV. THE KOREAN BIOETHICS ACT FAILS TO SUGGEST AN APPROPRIATE TIMEFRAME TO USE HUMAN EMBRYOS IN SCIENTIFIC RESEARCH

Embryonic stem cell research raises important questions about the use of human embryos in scientific research.[155] On the one hand, embryonic stem cell research has the potential to cure diseases such as Alzheimer's and Parkinson's and treat conditions like spinal cord injury, heart disease, and diabetes.[156] On the other hand, the process of deriving stem cells from an embryo results in the embryo's destruction.[157] Ethics committees around the world, including in Korea, are struggling to determine the moral and legal status of human embryos that are used in stem cell research.[158] If an embryo is a potential human being, should it be granted all the protections that a human being enjoys? Any country that allows stem cell research to be conducted on human embryos should answer this question and justify the improvement in human health that results from the destruction of potential human beings. Unfortunately, the Korean Bioethics Act fails to do just that due to its inability to adequately protect human embryos from unnecessary destruction.

A. International Guidelines Require Special Attention Be Paid to the Use of Human Embryos in Scientific Research

International guidelines carefully regulate the use of human embryos in scientific research. Research involving human subjects includes "research on identifiable human material" under the Declaration of Helsinki.[159] This provision applies to identifiable human tissue, which includes human embryos.[160] This interpretation is consistent with the intent of the World Medical Association ("WMA") to extend the Declaration of Helsinki to human embryos as indicated in WMA Statement on In-Vitro Fertilization and Embryo Transplantation, which states that the Declaration of Helsinki will apply to "all clinical research in respect to . . . embryo

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[155] It is beyond the scope of this Comment to address the moral status of human embryos or the beginning of life.

[156] National Institutes of Health, Stem Cell Information, http://stemcells.nih.gov/info/health.asp (last visited Feb. 17, 2008).

[157] John Roach, *Stem Cell Breakthrough: No More Need to Destroy Embryos?*, NAT'L GEOGRAPHIC NEWS, Aug. 23, 2005, http://news.nationalgeographic.com/news/2005/08/0823_050823_stemcells.html (last visited Apr. 28, 2008).

[158] Harold T. Shapiro, *Ethical Dilemmas and Stem Cell Research*, SCIENCE, Sept. 24, 1999, at 2065, 2065, *available at* http://www.sciencemag.org/cgi/content/full/285/5436/2065.

[159] Declaration of Helsinki, *supra* note 75, ¶ 1.

[160] Jennifer Trueland, *Shake-up for Embryo Research Rules*, SCOTSMAN (United Kingdom), Sept. 26, 2000, at 1.

transplantation."[161] Thus a human embryo is considered a "human subject" under the Declaration of Helsinki, making it eligible for a "careful assessment of predictable risks and burdens in comparison with foreseeable benefits" to the embryo before allowing research.[162] In fact, the WMA's Statement on Assisted Reproductive Technologies expressly states that "research [on human embryos] should be carefully controlled and should be limited to areas in which the use of alternative materials will not provide an adequate alternative."[163] It also emphasizes the need to handle and manipulate human embryos in a manner that would "protect [them] from abuse."[164]

Many countries have closely traced the language of the Declaration of Helsinki and the WMA statements in laws that regulate research on human embryos. For instance, in Australia, before the Human Research Ethics Committee approves any proposal that involves research on human embryos, it must be satisfied that "the likely benefits of the proposed research cannot be achieved without using human embryos," and the potential benefit of the proposed research is enough and justifiable to allow harm to human embryos.[165] Similarly, the Singapore Bioethics Advisory Committee recognizes that "a human embryo has a special status as a potential human being" which is distinct from a living human being.[166] Like Australia, Singapore also utilizes a balancing of respect to the embryo with the benefits arising from proposed research.[167] The greater the promised medical benefit of the proposed research, the more likely that the Singapore Bioethics Committee would permit embryonic research.

The need to protect human embryos used in scientific experiments has been interpreted as a focus on the importance of the research goals and the way embryos are handled in research, instead of whether embryos may be

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[161] World Medical Association, Statement on In-Vitro Fertilization and Embryo Transplantation (adopted by the 39th World Medical Assembly, Madrid, Spain, Oct. 1987), *available at* http://www.wma.net/e/policy/e5.htm [hereinafter Statement on In-Vitro Fertilization and Embryo Transplantation]. The World Medial Association Statement on In-Vitro Fertilization and Embryo Transplantation was rescinded at the General Assembly in South Africa in 2006, but this fact does not change the author's analysis of the text.

[162] Declaration of Helsinki, *supra* note 75, ¶ 16.

[163] World Medical Association, Statement on Assisted Reproductive Technologies, ¶ 20 (adopted by the World Medical Association General Assembly, Pilanesberg, South Africa, Oct. 2006), *available at* http://www.wma.net/e/policy/r3.htm [hereinafter Statement on Assisted Reproductive Technologies].

[164] *Id.* ¶ 9.

[165] AUSTRALIAN GOV'T NAT'L HEALTH AND MED. RESEARCH COUNCIL, ETHICAL GUIDELINES ON THE USE OF ASSISTED REPRODUCTIVE TECH. IN CLINICAL PRACTICE AND RESEARCH 70 (revised June 2007).

[166] Catherine Tay Swee Kian & Tien Sim Leng, *The Singapore Approach to Human Stem Cell Research, Therapeutic and Reproductive Cloning*, 19 BIOETHICS 290, 292 (2005).

[167] *Id.*

destroyed.[168] Thus, for example, the Warnock Report in the United Kingdom prohibits "frivolous or unnecessary" use of human embryos in scientific research.[169] The international guidelines prohibiting misuse of human beings for research purposes are applied to human embryos in the United States as well.[170]

B. The Bioethics Act Lacks the Language Necessary to Ensure Appropriate Use of Human Embryos in Stem Cell Research

The Bioethics Act does contain some restrictions on the use of human embryos in stem cell research, but these limitations are not adequate. The Bioethics Act prohibits reproductive cloning,[171] while allowing therapeutic cloning of embryos.[172] Furthermore, any research on human embryos has to be performed before "the embryological primitive streaks appear in their developmental process."[173] In contrast to research on other human cells and tissues, any research involving human embryos must occur for one of the three enumerated purposes.[174] The research must be aimed at 1) developing "contraception and infertility treatments," 2) "curing rare or incurable diseases," or 3) any other research approved by the President.[175] Researchers are also required to follow specific guidelines regarding the storage, usage, and disposal of embryos.[176]

The above-mentioned safeguards put in place by the Bioethics Act to ensure proper use of human embryos in scientific research fall short of international standards. International standards require that stringent conditions be met before human embryos can be used in scientific research.[177] Yet the Korean Bioethics Act has no provisions that provide guidance as to when it would be appropriate to use embryos in stem cell research. Nowhere in the Bioethics Act does it require that, where possible,

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[168] Young-Rhan Um, Special Section, *South Korea: Human Embryo Research*, 12 CAMBRIDGE Q. HEALTHCARE ETHICS 268, 273 (2003).

[169] *Id.* (citing MARY WARNOCK, A QUESTION OF LIFE: THE WARNOCK REPORT ON HUMAN FERTILIZATION AND EMBRYOLOGY (Oxford 1985)).

[170] On Human Embryos and Stem Cell Research, The Founding Statement of Do No Harm: The Coalition of Americans for Research Ethics, July 1, 1999, http://www.stemcellresearch.org/statement/statement.htm#text28 (last visited Apr. 28, 2008).

[171] Bioethics Act, *supra* note 6, art. 11.

[172] Therapeutic cloning is not expressly addressed in the Bioethics Act. *See* Bioethics Act, *supra* note 6. However, South Korea has previously stated that it will allow therapeutic cloning. U.N. Doc. A/59/PV.82, *supra* note 8.

[173] Bioethics Act, *supra* note 6, art. 17.

[174] *Id.*

[175] *Id.*

[176] *See Id.* art. 16.

[177] *See supra* Part IV.A.

researchers should use alternatives to human embryos as required by the WMA Statement on Assisted Reproductive Technologies.[178] The Bioethics Act allows NBC and the President to approve any research on human embryos.[179] The Bioethics Act fails to give effect to the Helsinki Declaration because it contains no provision requiring NBC or the President to weigh the risks of embryonic research against foreseeable benefits before approving the research under Article 17 of the Bioethics Act.[180] The Bioethics Act's silence on what constitutes appropriate use of human embryos for research contradicts the explicit requirements of the international standards.

V. KOREA SHOULD AMEND THE BIOETHICS ACT TO MAKE IT COMPATIBLE WITH INTERNATIONAL STANDARDS

Advances in biotechnology must be balanced against the legal and ethical risks to research subjects. The Bioethics Act should include mechanisms to ensure the adequacy and quality of informed consent received from egg donors, to review the circumstances under which informed consent is obtained, and to determine the ability of IRBs to effectively perform their role. It should also include provisions promoting alternatives to the use and destruction of human embryos. As Korea is considering amending its Bioethics Act, it can incorporate the aspects of international protections that would work in Korea to protect research subjects while advancing scientific research and development.

In August 2005, the Director of the Bioethics Policy Division of the MHW issued a statement claiming that South Korea has "concrete and comprehensive regulations on the scope of embryo research."[181] The Director pointed to the Bioethics Act to demonstrate that human embryo production and research is strictly regulated and written consent is required from sperm and oocyte donors.[182] The position of the Korean government changed in 2006, after the Hwang scandal became public knowledge. Since then, several different governmental organizations and entities have expressly stated the need for the government to "step up its efforts to assure proper ethical research standards" and "establish a scrupulous system for

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[178] *See* Statement on Assisted Reproductive Technologies, *supra* note 163.
[179] Bioethics Act, *supra* note 6, art. 17.
[180] *See id.*
[181] Kim Heonjoo, *Embryo Research in South Korea is Subject to Strict Laws*, FIN. TIMES (London), Aug. 25, 2005, at 14.
[182] *Id.*

donating human eggs for research purposes."[183] To that end, Korea should amend the Bioethics Act to ensure that higher ethical standards of scientific research are upheld in embryonic stem cell research.

A. The Bioethics Act Should Require IRBs to Ensure that the Informed Consent Obtained from Egg Donors Is Voluntary

Korea should incorporate adequate and effective ways to monitor the circumstances under which women are giving consent to donate eggs. One such way could be for the Korean Act to explicitly require researchers to obtain voluntary consent that is not obtained by coercion, undue influence or duress. The IRB should have the responsibility to make sure that women are not coerced into donating eggs due to their dependent status, monetary inducements, or their "compromised ability to offer fully voluntary consent."[184] IRB members could interview women donors to determine their motives in donating eggs and the circumstances in which they agree to donate.[185] An independent counselor not involved in the research project could also counsel egg donors on the various aspects of egg donation.[186]

Other amendments could include placing a maximum limit on the number of times a woman can donate eggs for research[187] and prohibiting women working in the lab from donating their eggs.[188] Furthermore, the Bioethics Act should require that women donors actually understand the research in which they are participating and truly appreciate the risks involved in donating eggs. The IRB should review the "adequacy, completeness, and understandability of written and oral information"[189] that is given to egg donors. Inclusion of a requirement that women undertand all the information that is presented to them is the first step in the right

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[183] Press Release, Korean Consulate General in Los Angeles, Statement on the SNU Investigation into Dr. Hwang (Jan. 18, 2006), http://www.koreanconsulatela.org/english/ (click on "Notice" then search for "Statement on the SNU Investigation into Dr. Hwang") (last visited Feb. 21, 2008).

[184] INTERNATIONAL SOCIETY FOR STEM CELL RESEARCH, GUIDELINES FOR THE CONDUCT OF HUMAN EMBRYONIC STEM CELL RESEARCH 8 (2006).

[185] *See* INSTITUTIONAL REVIEW BOARD GUIDEBOOK 29-30, *available at* http://www.hhs.gov/ohrp/irb/irb_chapter3.htm#e7.

[186] G. Pennings, G. de Wert, F. Shenfield, J. Cohen, B. Tarlatzis & P. Devroey, *ESHRE Task Force on Ethics and Law 12: Oocyte Donation for Non-Reproductive Purposes*, 22 HUMAN REPROD. 1210, 1213 (2007).

[187] In November 2006, the Ministry of Health and Welfare submitted a revised bill on life ethics which would allow a woman to donate her eggs for research purposes a maximum of three times. *Egg Donation for Research Limited to 3 Times*, KOREA.NET, Nov. 23, 2006, http://www.korea.net (search for "Egg donation for research limited to 3 times") (last visited Feb. 24, 2008).

[188] Kim Cheong-won, *Hwang's Team in Ethical Minefield Over Ova: Panel*, KOREA TIMES, Feb. 2, 2006.

[189] WHO Operational Guidelines, *supra* note 77, at 12.

direction—upholding and protecting their dignity. Where human research subjects are involved, the highest degree of ethics must be applied.

B. The Bioethics Act Should Include Provisions Assuring the Proper Use of Human Embryos in Stem Cell Research

Korea should follow Australia and Singapore's approach to regulating embryonic stem cell research to ensure that human embryos are not unnecessarily harmed.[190] The Bioethics Act should require MHW to weigh the potential benefits of a proposed research against the harm done to the embryos before approving any research on stem cells that are derived from human embryos. Following Singapore's approach, the Korean Bioethics Act could also require scientists to draw embryonic stem cells from existing stem cell lines before destroying more embryos to get stem cells.[191]

The Bioethics Act should also seek to promote technology that does not destroy human embryos. The Act already allows research on adult stem cells.[192] Adult stem cells are found in the tissues of a grown human being.[193] Derivation of adult stem cells does not harm the person from whom those cells are derived; neither does it harm an embryo.[194] Thus, instead of merely giving the national and regional governments an option of supporting research on adult stem cells, the Korean government should actively support research on adult stem cells. This is even more important in light of the fact that the benefits of embryonic stem cells are speculative, but adult stem cells have already been successfully used in numerous patients to allow them to regrow damaged tissues.[195]

Finally, the Korean Bioethics Act should include provisions that provide an incentive for scientists to engage in researching new biotechnologies. In late 2007, scientists were able to transform human skin cells into stem cells.[196] Then, in January of 2008, an Australian scientist was able to extract a single cell from an embryo, a technique which did not negatively affect the future development of the embryo.[197] Korea should

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[190] *See supra* Part IV.A.

[191] *See* Kian & Leng, *supra* note 166, at 293.

[192] Bioethics Act, *supra* note 6, art. 45.

[193] Lillge, *supra* note 93.

[194] Shilpa Gowda, *Adult Stem Cells May Eliminate Embryo-Related Controversies*, 18 J. YOUNG INVESTIGATORS (2008), http://www.jyi.org/news/nb.php?id=1345 (last visited Feb. 29, 2008).

[195] Lillge, *supra* note 93.

[196] Gowda, *supra* note 194; Terry Devitt, *UW-Madison Scientists Guide Human Skin Cells to Embryonic State*, U.WIS.-MADISON NEWS, Nov. 20, 2007, http://www.news.wisc.edu/14474 (last visited Feb. 29, 2008).

[197] *Embryonic Stem Cell Lines Created Without Destroying Embryo: Study*, AFP, Jan. 10, 2008, http://afp.google.com/article/ALeqM5hqybsR0NIR5yp_BubqSiDphlCkIQ (last visited Apr. 26, 2008).

invest money in and actively promote these approaches and the development of additional alternatives to destroying embryos to get stem cells.

VI. CONCLUSION

In recent years, Korea has continued to invest money and resources in embryonic stem cell research. Embryonic stem cell research poses unique challenges because egg donors and human embryos are harmed during a research study from which they do not receive any direct benefit. As it currently stands, the Bioethics Act is inadequate to protect women who donate their eggs for stem cell research because the Act does not require that women consent to the donation voluntarily and free of any undue influence. The Bioethics Act also does not require that the egg donors understand the research in which they are participating and its associated risks. Moreover, the Bioethics Act falls short of international standards because it does not limit the use of human embryos in scientific research.

To strengthen its protections of women and embryos, Korea's Bioethics Act should look to international standards and incorporate requirements that would protect women and embryos from being exploited. The Bioethics Act should require that egg donors understand the purpose of the research study and its associated risks before giving their voluntary consent. In addition, the Act should promote research that does not require the destruction of human embryos to obtain stem cells. Bringing the Bioethics Act into greater conformity with international standards will assure that Korea takes an ethical approach to embryonic stem cell research and will make it possible for Korea to fulfill the stated aims of the Bioethics Act while staying ahead in stem cell research.