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Korean Regulation of Stem Cell and Human Genetic Research

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Abstract

This paper deals with Korean regulations on embryonic stem cell research and genetic research. It explains Bioethics and Safety Act in detail related to embryonic research and genetic test, research, and therapy including gene bank. In addition, some limitations of the Act and some issues in its interpretation are mentioned. Korea has legally allowed SCNT embryonic stem cell research as well as embryonic research under the Act since 2005. The Act has regulations about informed consent, review system, protection of personal information, anonymization, and prohibition of discrimination based on genetic information. From the perspective of the regulative approach, Korea has strong regulations on embryonic stem cell research and genetic test, research, and therapy in that it runs an act like Bioethics and Safety Act, not any guidelines. However, there may be some difficulties in regulating bioethical issues by an act because it is likely not to be easy to revise. In addition, the Act includes lots of contents that had better be regulated by Presidential decree or enforcement, or even just guidelines made by professional societies. In order to make

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bioethical issues regulated by an act, ethical guidelines based on consensus should have established. Establishing bioethics policies is a process to reach consensus through deliberative democracy, where the use of "public reason" is required. This should be also applied to global bioethics policies. Different policies in bioethics may give a wrong message to scientists and laypersons that ethics is relative to countries and cultures although we reach lots of ethical agreements across countries and cultures.

Keywords

embryonic stem cell research, genetic research, gene therapy, Bioethics and Safety Act, global bioethics policy,

I. Introduction

The advance of life and medical sciences has raised several ethical, legal and social problems. Especially ethical debate on embryonic stem cell research was one of the hot issues in most countries. A few years ago, SCNT(somatic cell nuclear transfer) embryonic stem cell research was one of them. Some countries ban SCNT embryonic stem cell research others allow. Korea has legally allowed SCNT embryonic stem cell research as well as embryonic research under Bioethics and safety Act since 2005.[1]

In addition, recent biology and medicine have, through genome project, focused on genetic research. One of hot issues involved in genetic research is about protection of personal information. Korea has the strong

1. For the English version of Bioethics and Safety Act and its Enforcement Decree and Rule, visit www.bprc.re.kr. You can also download the full text.

regulation in that such researches are regulated by Bioethics and Safety Act beyond just guidelines. The Act regulates gene bank as well as genetic test and therapy.

I will here explain Bioethics and Safety Act in detail related to embryonic research and genetic test, research, and therapy including gene bank. I will mention some limitations of the Act and some issues in its interpretation, too.

II. Bioethics and Safety Act

1. Bioethics and Safety Act and the Scope of Its Application

Bioethics and Safety Act in Korea concentrates on embryo production and embryonic research and genetic test, research and therapy including genetic bank although the title seems to cover general issues in bioethics. Thus this act does not cover human subject research in general, which may be roughly divided into invasive and non-invasive research. 45CFR46 in U.S.A. is applied to human subject research, whether it is invasive or non-invasive. If a research is one that obtains identifiable personal data or data through intervention and interaction, it should be reviewed by institutional review board.[2] While 45CFR46 covers research using directly human material, Bioethics and Safety Act regulates only research using directly human material for genetic research. However, non-genetic research also belongs to human subject research according to the Declaration of Helsinki (2008).[3] Thus Bioethics and Safety Act should be revised to include those researches too.

2. 45CFR46 Protection of Human Subjects. §46.101 (To what does this policy apply?), §46.102 (Definitions).

3. World Medical Association, Declaration of Helsinki (2008), 1 and 25.

Current Korean regulations are as follows if embryonic research may be also considered.[4]

Types		Name of IRB	Relevant act or guideline
research through physical intervention (invasive research)	research through intervention using drug, etc.	IRB for clinical trial in hospital.	Standard for the Control of Drug Clinical Trial under Enforcement Rule of Pharmaceutical Affairs Act
		IRB(or IBC) for gene therapy	Bioethics and Safety Act
research using directly human material (intervention in the case of obtaining human material)	genetic research using human material	IRB(or IBC) for genetic research	Bioethics and Safety Act
	embryonic research	IRB(or IBC) for embryonic research and SCNT embryonic research	Bioethics and Safety Act
	non-genetic research using human material	IRB for clinical trial in hospital. But this is not legally required.	None
research through interaction or using identifiable personal data(non-invasive research)	research using medical record, survey, interview, and observation accomplished in hospital	IRB for clinical trial in hospital. But this is not legally required.	None
	research using survey, interview, and observation in academic area like universities except for hospital and medical school	Bioethics Review Committee or IRB (There is no legal proper name to call this committee in Korea)	None

As we can see in the above table, there is no comprehensive act in Korea to cover human subject research in general.[5]

2. The Outline of the Act

While Bioethics and safety Act does not cover human subject research in general, the Act has some important infrastructure for bioethics in Korea. We have to note that Article 6 of the Act requires the establishment of National Bioethics Committee. The Committee reviews, according to Article 6, the following items concerning "bioethics and safety in life sciences and biotechnologies":

> 1. Establishing policies concerning national bioethics and safety; 2. The type, subject, and extent of research involving spare embryos under Article 17-3; 3. The type, subject, and extent of research involving somatic cell nuclear transfer under Article 22-②; 4. The types of genetic tests that are prohibited under Article 25-①; 5. The types of diseases for which gene therapy can be performed under Article 36-①-3; and 6. Other issues of social or moral significance concerning the research, development, and utilization of life sciences and biotechnologies that the Chairperson of the National Committee formally submits to the National Committee for its deliberation.

4. Kyungsuk Choi, "Korean Law Relevant to Bioethical Issues and Its Problem," *Biomedical Law & Ethics*, Vol.4. No.1. Ewha Institute for Biomedical Law & Ethics, June 2010. pp.67-68. I used this table with correcting some typos and reflecting the revision of relevant regulations.

5. Now the Government's bill to entirely revise the Bioethics and Safety Act is under review in the Korean Congress. The Bioethics and Safety Act was enacted in 2004 and implemented in 2005.

Because of the expression of "bioethics and safety in life sciences and biotechnologies," the role of National Bioethics Committee is often interpreted to have limitation on the review and discussion of bioethical issues related to medical practice in general such as abortion and life-sustaining treatment. In addition, the expression of "the research, development, and utilization of life sciences and biotechnologies" makes us to interpret that the role of National Bioethics Committee is directly involved in bioethical issues related to research. In fact, the Act does not have any articles about bioethical issues in general such as abortion and life-sustaining treatment, etc. As the above citation shows, most of items are focused on embryonic research, genetic test and research, and gene therapy.

Article 9 requires the establishment of Institutional Bioethics Committees[6] in the following institutions:

> 1. Medical institution designated as an Embryo Producing Medical Institution by the Minister of Health and Welfare according to Article 14-①; 2. Embryo Research Institutions registered with the Minister of Health and Welfare according to Article 18; 3. SCNT Embryo Research Institutions registered with the Minister of Health and Welfare according to Article 23; 4. Genetic Testing Institutions reported to the Minister of Health and Welfare according to Article 24-①; 5. Gene Bank permitted by the Minister of Health and Welfare

6. The name of 'Institutional Bioethics Committee' is a proper name. Some of Institutional Bioethics Committees have the same function as Institutional Review Board in America in that they review research protocols. But some are not the same as IRB. For example, the main jobs of Institutional Bioethics Committee in Embryo Producing Medical Institution, Genetic Testing Institution, and Gene Bank are not to review protocols, but to supervise their practice.

according to the provisions of Article 32-①; 6. Gene Therapy institutions reported to the Minister of Health and Welfare according to Article 37-①; and 7. Other research institutions designated by the Ordinance of the Ministry of Health and Welfare that study, develop or utilize life sciences and biotechnologies that may have significant moral or social consequences.

In addition, according to Article 2 of Enforcement Rule of the Act, "Institutions which have filed a report to the Minister of Health and Welfare according to Article 24-① of the Act in order to obtain specimens directly and do genetic research on them," this is, Genetic Research Institution must also establish Institutional Bioethics Committee.

As the listed institutions shows, any institution for non-genetic research to use human material and for clinical trials is not mentioned. Although the limitation in the scope of the Act, however, we have to note that the Act sets up the self-regulative review system for individual research units.

Especially, the Act mentions about the role of national or regional governments for bioethics and safety. Article 4 says, "National or regional governments shall arrange all necessary measures to deal effectively with problems concerning bioethics and safety that may arise during the process of developing and utilizing life sciences and biotechnologies." This Article shows that governments should have responsibility for bioethics and safety.

3. The principles in the Act

The Act declares some basic principles. Article 4 says, "Anyone who intends to study, develop or utilize life sciences and biotechnologies shall

endeavor to safeguard human dignity and the value of human life and to carry out their work in accordance with the principles of bioethics and safety." It declares the values of human dignity and human life. And Article 5 says about right to self-determination as follows: "Anyone who becomes a subject of research or experimentation in the area of life sciences and biotechnologies shall have the right to be fully informed of his or her involvement in the research and shall also have the right to consent, or refuse consent, after being fully informed of his or her involvement in the research." We have to note that this Article does not only emphasize on self-determination, but also informed consent.

The Act does not directly declare other values and ethical principles such as principle of justice and protection of vulnerable peoples. However, it does not imply such values and principles are not important. Even if legal acts are not likely to include abstract declaration of values, the bill to revise the Bioethics and Safety Act, which is under reviewing in the Congress, includes some Articles about ethical principles and values.

III. Stem Cell Research

1. Stem Cell Research the Act Covers and Bans on Human Cloning and Chimera

The Act covers embryonic stem cell researches. It does not, however, cover adult stem cell researches. Adult stem cell researches are regulated by Standard for the Control of Drug Clinical Trial under Enforcement Rule of Pharmaceutical Affairs Act and Rule for the Management of Producing and Selling Biological Medicine. Supreme Court judged cells from human body are drug according to Pharmaceutical Affairs Act as long as cells are used for treatment.[7] Pharmaceutical Affairs Act defines drugs as articles

used for the purpose of diagnosis, medical care, alleviation, treatment or prevention of diseases of human beings or animals, excluding appliances, machinery or equipment.

The Act provides some restrictions to embryonic stem cell research. Article 11 prohibits human cloning, saying "No one shall implant a SCNT embryo into a uterus, maintain a cloned embryo within a uterus, or give birth when the pregnancy results from the act of implanting a SCNT embryo into a uterus"[8] and "No one shall induce or assist in" the above activities. Article 12 deals with issues of chimera. It says "No one shall implant a human embryo in the uterus of an animal; nor shall anyone implant an animal embryo into a human uterus."

Article 12-② deals with bans on making chimera as follows;

> No one shall perform any of the following acts: 1. The act of fertilizing a human oocyte with an animal sperm, or vice versa, for any purpose other than that of testing human sperm cells; 2. The act of implanting an animal somatic cell nucleus into an enucleated human oocyte, or a human somatic cell nucleus into an enucleated animal oocyte; 3. The act of fusing a human embryo with an animal embryo; 4. The act of fusing a human embryo with another embryo of non-identical genetic information.

In Article 12-③, the following ban is added; "No one shall transfer the products of any of the acts described in paragraph ② above into the uterus of a human being or animal."

7. The Korean Supreme Court Case, 2007DA3162 Decided October 14, 2010.

8. International Society for Stem Cell Research, Guidelines for the Conduct of Human Embryonic Stem Cell Research (2006), 6.1.

Thus, the Act has stronger position than ISSCR Guidelines because the Guidelines mention just the review, approval, and ongoing monitoring of SCRO(Stem Cell Research Oversight), not bans on all of the above acts.[9]

2. Regulations on Producing Embryos

Producing embryos except for SCNT embryos is allowed only for reproduction. Article 13 says, "No one shall produce embryos other than for the purpose of pregnancy." The article continues to say;

> In producing embryos for the purpose of pregnancy, no one shall perform any of the following acts: 1. Fertilizing an oocyte, when the oocyte and/or sperm have been specially selected for the purpose of producing offspring of a particular gender, 2. Fertilizing an oocyte, when the oocyte and/or sperm are those of a non-living human; or 3. Fertilizing an oocyte, when the oocyte and/or sperm are those of an under-aged human. However, this shall be allowed when married under-aged parents wish to conceive a child.

The Act prevents the abuse of IVF for the selection of a male or

9. International Society for Stem Cell Research, Guidelines for the Conduct of Human Embryonic Stem Cell Research (2006), 8.1 and 10.3. 10.3 is about researches of Category 3, which are "research that should not be pursued at this time because of broad international consensus that such experiments lack a compelling scientific rationale or raise strong ethical concerns." Such forms of research include: "10.3a) *In vitro* culture of any post-fertilization human embryos or organized cellular structures that might manifest human organismal potential, regardless of derivation method, for longer than 14 days or until formation of the primitive streak begins, whichever occurs first. 10.3b) Research in which any products of research involving human totipotent or pluripotent cells are implanted into a human or non-human primate uterus. 10.3c) Research in which animal chimeras incorporating human cells with the potential to form gametes are bred to each other."

female child. The Act seriously considers the welfare of a future child in that it tries to prevent a child born without genetic father or mother alive although sperms or oocytes are donated.[10]

Whereas producing embryos is allowed only for reproduction, producing SCNT embryos is allowed only for research. Article 22 says, "No one shall conduct somatic cell nuclear transfer other than for the purpose of conducting research aimed at curing rare or currently incurable diseases." This shows we have different attitudes to embryos and SCNT embryos although both have theoretically the same potentiality to become a person. Such difference in attitude is not only true of Korea, but of other countries where SCNT embryo stem cell research is allowed.

Any sale of sperm and oocytes is legally prohibited in Korea. The Article 13 declares "No one shall provide or utilize sperm or oocytes, or induce or assist in providing or utilizing them for the purpose of receiving monetary benefits, property interests or other personal benefits in return." In Korea, any sale of organs is of course legally prohibited. But Article 15.4 allows Embryo Producing Medical Institution to compensate the actual cost for oocyte donors.

3. The Government Oversight of Stem Cell Research Institution

The Korean government oversees Embryo Producing Medical Institutions, that is, a medical institution that wishes to collect and preserve sperm or oocytes for artificial fertilization or to generate embryos through fertilization. Such medical institutions, according to Article 14, "should be designated as an Embryo Producing Medical Institution by the Minister of

10. UK allows the fertilization to use the sperms or oocytes of the dead persons if they wanted.

Health and Welfare." And "Any medical institution that wishes to be designated as an Embryo Producing Medical Institution should meet the facility and manpower requirements set by the Ordinance of the Ministry of Health and Welfare." In addition, according to Article 18, "Any one who wishes to do research on spare embryos under the provisions of Article 17 should meet the facility and manpower requirements set by the Ordinance of the Ministry of Health and Welfare and be registered with the Minister of Health and Welfare as an Embryo Research Institution." Likewise, according to Article 23, "Any one wishing to produce or research SCNT embryos shall register with the Minister of Health and Welfare only after satisfying the requirements concerning facilities and personnel set by the Ministry of Health and Welfare." Therefore, infertility clinics, embryonic research units, SCNT embryonic stem cell research units are overseen by the Government. In addition, such clinics and research units must give a regular report regulated by Bioethics and Safety Act to the Government.

4. The Limitation of Embryonic Stem Cell Research

Research on embryos is, according to Article 17, allowed only for "spare embryos that have passed the storage period." But Article 17 continues to say, "in order to utilize a spare embryo that has been stored for less than 5 years, a new consent, for this new purpose, is required from the Consenters." Thus, the default storage period is 5 years although the period may be changed by consenters.

In addition, Article 17 says that spare embryos that have passed the storage period "may be utilized ⋯ only until the embryological primitive streaks appear in their developmental process" for the following purposes; "1. To conduct research aimed at developing contraception and infertility treatments; 2. To conduct research aimed at curing rare or incurable

diseases, as decided by the Presidential Decree."

If one of the above purposes is satisfied, embryonic research may be allowed. In fact, the real purpose of most embryonic research is to establish an embryonic stem cell line. The purpose of curing rare or incurable diseases is a further purpose after the establishment of embryonic stem cell lines.

5. Review System

The Act mentions the conditions for the approval of embryonic research. When an embryo research institution wishes to do research on embryos, Article 19 says, "it shall submit an Embryo Research Protocol for the approval of the Minister of Health and Welfare." Article 19 continues to say that the Embryo Research Protocol "should include documents showing the review results of that Embryo Research Institution's Institutional [Bioethics] Committee."

Thus each of the approvals of the Minister of Health and Welfare and Embryo Research Institution's Institutional Bioethics Committee[11] is required for an embryonic research. It means that Korea runs a system of double approvals although it does not mean a system of double IRB reviews.

6. Informed Consent

The Act also requires a written informed consent on the reproductive production of embryos and whether spare embryos may be utilized for

11. Embryonic Research Institution's Institutional Bioethics Committee can be considered to be SCRO in ISSCR Guidelines.

research. Article 15 says that when an Embryo Producing Medical Institution collects sperm or oocytes in order to produce an embryo, "they shall obtain written consent from both the sperm and oocyte donors as well as the artificial insemination patient and her spouse." In the interpretation of "and her spouse," it is not clear whether an artificial insemination patient must be a married woman or the consent from her spouse is necessary when such a patient is married. Here the word "artificial insemination" is not appropriate because patient for IVF must be included. This inappropriate translation comes from the misleading expression in Bioethics and Safety Act written in Korean.

In addition, Article 15 says about what contents should be informed. They are as follows:

> 1. The details of the purpose of producing an embryo; 2. The details of the deposit period and maintenance of embryos; 3. The details of the disposal of embryos; 4. Indication of whether or not consent is given to utilize the spare embryos for purposes other than pregnancy; and 5. Information on the procedures for the withdrawal of consent, the protection of consenters' rights and information, and other necessary information set by the Ordinance of the Ministry of Health and Welfare.

If consenters decide to allow spare embryos to be utilized for research, they should give a separate informed consent on the use of spare embryos.

But this consent on an embryonic research is obtained by Embryo Producing Medical Institution, not by Embryo Research Institution. Thus, a kind of blanket consent on embryonic research is given because consenters do not know a specific embryonic research purpose.

7. Storage and Management of Embryos

The Act also provides practical procedures such as of the storage and management of embryos. Article 16 says, "The storage period of embryos shall be 5 years; shorter storage periods are possible when the Consenters request it." It continues to say, "Embryo Producing Medical Institutions shall dispose of all embryos approaching the end of their period of storage, except for those that are to be utilized for the purpose of research."

The Act also includes regulations about supplying and maintaining spare embryos. Article 20 says that when an Embryo Producing Institution supplies a spare embryo to an Embryo Research Institution, "it shall be supplied for free." However, according to Article 20, the Embryo Producing Institution may "request that the Embryo Research Institution provide reimbursement for the expenses of storing and providing the spare embryo." In addition, Article 20 asks Embryo Producing Institution and Embryo Research Institution to regularly "report all details concerning the storage and supply of spare embryos to the Minister of Health and Welfare."

According to Article 20.2, established in Korea or imported stem cell lines shall be registered with the Minister of Health and Welfare before they are provided or used. Article 20.4 says "The stem cell lines registered in accordance with Article 20.2 shall be used in vitro." There is an issue of whether the use of stem cell lines includes that of clinical grade stem cell from stem cell lines or not.

Regulations of approving embryonic research protocol, registering stem cell lines, and supplying and maintaining spare embryos are applied to research on SCNT embryos.

IV. Genetic Test, Research, and Therapy Including Gene Bank

1. Human Genetic Research and No Discrimination based on Genetic Information

Bioethics and Safety Act covers only a part of research using human material, that is, a genetic research. Non-genetic research using human material is guided by such international guidelines as the Declaration of Helsinki. The Act regulates the operation of gene bank as well as genetic test and therapy. The Act focuses on genetic test because this test is basically involved in both genetic research and therapy and further in the use of human material from gene bank. Thus the regulations on genetic test are applied to genetic research and therapy.

The Act does not allow discrimination based on genetic information. Article 31 says, "No one shall be discriminated against in educational opportunities, in employment or promotion, or in eligibility for insurance coverage on the basis of his or her genetic information"[12] and continues to say "Unless specifically stated otherwise in a different law, no one shall force others to take genetic tests or to submit genetic test results."

2. Some limitations on Genetic Test

In addition, there are some legal restrictions to genetic tests. Article 25 says, "Genetic Testing Institutions shall not conduct genetic tests

12. UNESCO, Universal Declaration on the Human Genome and Human Rights (1997), Article 6 also says, "No one shall be subjected to discrimination based on genetic characteristics that is intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity."

concerning physical characteristics or personality traits that may mislead subjects due to a lack of scientific evidence; nor shall they conduct tests that have been prohibited by the Presidential Decree after being reviewed by the National Committee."[13] It continues to say, "Genetic Testing Institutions shall not conduct genetic tests on embryos or fetuses for purposes other than that of diagnosing muscular dystrophy or other gene-related diseases as stipulated by the Presidential Decree." The number of genetic diseases stipulated by the Presidential Decree and the Minister of Health and Welfare Note is 138.

The Presidential decree lists which genetic tests are allowed for embryos and fetuses as well as which genetic tests are prohibited because they lack scientific evidence. Listing approach itself is not bad in that it clearly indicates which genetic tests are prohibited and allowed. However, this approach may not reflect special features of a particular case and cannot be fully sensitive to the advance of genetic technology.

In addition, even if a fetus has a genetic disease on the list, the abortion of this fetus is not legally allowed only on the basis of such a disease. Mother and Child Health Act, which lists conditions under which abortion is legally allowed, mentions just the health condition of a fetus's mother and father.[14] Korea has not been able to make Mother and Child Health Act consistent with the recent biotechnology because opinions on abortion are sharply split and we cannot reach a consensus on the condition of abortion. Thus the old fashioned regulations have kept going without any realistic revision.

In addition, Article 25 says, "No Genetic Testing Institution shall conduct genetic tests for the diagnosis of disease, unless it either is a

13. This regulation may look paternalistic.

14. This Act was originally enacted and implemented in 1973. For the English version of Korean Acts, visit http://elaw.klri.re.kr/.

medical institution or is requested by a medical institution to conduct such tests." Thus a business venture on biotechnology cannot conduct genetic tests for the diagnosis of disease.

3. The Government Oversight of Genetic Testing Institution, and Etc.

Like Embryonic Research Institutions, according to the Act, the government oversees Genetic Testing Institution, Genetic Research Institution, Gene Therapy Institution including one doing a clinical trial of gene therapy, and Gene Banks. According to Article 24, Genetic Testing Institutions and Genetic Research Institutions should report the following details to the Minister of Health and Welfare:

> The location of the institution in which the tests or research are carried out, the name of the head of the institution, the type of genetic tests or research topics carried out, and other details required by the Ordinance of the Ministry of Health and Welfare.

In addition, the government controls the quality of Genetic Testing Institutions according Article 24. It says that the Minister of Health and Welfare may require Genetic Testing Institution "to be evaluated for the accuracy of its genetic tests and make the results of this evaluation public."

Gene Bank must, according to Article 32, "receive licensing of the Minister of Health and Welfare." But we have to note here that the regulation is not applied to biobank in general. Bioethics and Safety Act regulates only biobanks which wishes to collect human materials for

15. The Government's bill to entirely revise the Bioethics and Safety Act includes regulations on biobanks in general.

genetic research.[15] Gene Therapy Institution also must, according to Article 37, "register with the Ministry of Health and Welfare."

The institutions mentioned in the above must establish Institutional Bioethics Committees according to Article 9 of the Act and Article 2 of the Enforcement Rule of the Act. Institutional Bioethics Committee in Genetic Testing Institutions has the role to oversee the practice of their own institution. Thus this committee is not the same as IRB. But Institutional Bioethics Committees in Genetic Research Institutions and Gene Therapy Institutions are IRB. Institutional Bioethics Committee in Gene Banks has the same roles of steering committee in a biobank.

4. Informed Consent

Informed consent following the principle of autonomy is important to genetic test and research like other human subject research in general. Article 26 contains several necessary procedures for informed consent for genetic tests and research. It says:

> Before a Genetic Testing Institution or anyone conducting gene research obtains, either directly or indirectly, specimens or materials to be utilized in the research, a written consent, which includes the following details, should be obtained from the test subject: 1. The purpose of the genetic test or gene research; 2. Indication of whether or not consent is given for the use or provision of specimens and their extent other than for purposes mentioned in subparagraph 1 above; 3. Indication of whether or not personal information will be revealed when specimens are provided to others, in accordance with subparagraph 2 above; 4. Information on the maintenance and

storage period of specimens; and 5. Information on the right and manner of withdrawing consent, the rights and protection of test subjects, and any other details stipulated by the Ordinance of the Ministry of Health and Welfare.[16]

We have to note that the above regulation includes whether or not test subjects will consent to secondary uses of specimens. Consent to secondary uses may be generally understood to be blanket consent because particular purposes of researches are not yet specified when consent should be obtained. It is natural that withdrawing consent should be always respected like consent on other human subject researches.

5. Non-Commercialism in Providing Specimens

Genetic information and others such as specimens, according to Article 34, should be provided free of charge. This regulation keeps the principle of non-commercialism because test subjects provide their specimens for free. However, Article 34 says, "The head of Gene Bank may request compensation for the cost of maintaining and providing genetic information and others."[17] Researchers who collect specimens cannot, unlike Gene Banks, request expenses of storage and providing when they provide specimens. This difference is a policy to foster Gene Banks.

Article 33 regulates procedures for a Gene Bank's providing genetic information and others. It says, "any one wishing to use genetic information and others from a Gene Bank shall submit a plan on how the

16. Personal information in the Bioethics and Safety Act means identifiable personal information. See Article 9-② -3.

17. Here "genetic information and others" means genetic information including specimens, genes or personal information. See Article 2-8.

genetic information and others are to be used to the head of the Gene Bank." It continues to say "The head of the Gene Bank shall decide whether or not to release genetic information and others only after that institution's Institutional [Bioethics] Committee, under Article 9, reviews the plan on how the information will be used." As I mentioned earlier, this shows that Institutional Bioethics Committee in Gene Banks has the same role as a steering committee in biobank.

6. Protections of Personal Information and Ethnic Genetic Information

In order to protect personal information, Article 27 says, "Genetic Testing Institutions shall not include personal information in the specimens" unless test subjects have agreed to the inclusion of personal information in a written consent." In addition, Article 35 says:

> In the absence of legitimate reasons for doing so, neither the head of a Gene Bank nor its employees shall provide others with genetic information and others obtained through their work; nor shall they use such genetic information and others for inappropriate purposes.

This regulation is in a right way for the protection of personal information. The Act also has other protections of personal information. According to Article 35.2, "A Gene Bank shall render all of the genetic information and others collected anonymous before storage and maintenance."[18]

In addition, Article 35.2 says, "A Gene Bank shall designate an officer responsible for maintenance and security of information to protect

18. Article 35.2 was added in 2008.

personal information."

Recently, human materials are often moved into other countries for research. Korea does not have any regulation to prevent the export of Korean human material into other countries whereas China does. Koreans has relatively homogeneous genetic features. When Korean human materials are used in other countries, thus, protections of personal information alone are not enough to protect ethnic genetic information. I would like to argue that the use of ethnic information should be protected from its abuse. I would like to recommend each IRB in Korea and countries similar to Korea to review whether procedures to protect ethnic information as well as personal one are secure or not.

7. Disposal of Specimens

For the disposal of specimens, Article 28 says, "Genetic Testing Institutions and others shall dispose of specimens immediately after the storage period expires, unless the test subject or his or her legal guardian submits a written request not to dispose of the specimens." By saying "If the test subject or his or her legal guardian requests the disposal of his or her specimens at any point during the storage period, the Genetic Testing Institutions and others shall comply with the request," Article 28 strongly protects a donor's right to request the disposal at any time. Requesting the disposal of specimens is the key step that donors can take after they withdraw their consent. This regulation is also applied to genetic researchers and gene banks because "Genetic Testing Institutions and others" means Genetic Testing Institution, Genetic Research Institution, and Gene Bank, according to Article 27-③.

But the Act does not have any particular words about how research data obtained from specimens should be handled after withdrawing.

Generally, researchers want to use research date after the permanent anonymization of data.[19] If they want, they should explain such handing of data after withdrawing in their informed consent form.

8. The Scope of Gene Therapy

The scope of gene therapy is limited by Article 36. It says that gene therapy is allowed only in any of the following cases:

> 1. To treat or cure genetic disorders, cancer, Acquired Immune Deficiency Syndrome, and other life threatening or seriously damaging diseases; 2. To treat diseases for which there currently is no cure or when the expected results of gene therapy outweigh those of other therapies; or 3. To prevent or cure diseases that the Minister of Health and Welfare, after a review by the Institutional [Bioethics] Committee, targets for treatment by means of gene therapy.

This regulation, however, has a problem that trivial gene therapy like cosmetic gene therapy may be allowed. All of the above cases, not any of them, should be satisfied for gene therapy in order to protect patients from unnecessary risk.

In Korea, somatic cell gene therapy alone is allowed. Article 36 says, "gene therapy on sperm, oocytes, embryos, or fetuses is prohibited." This shows that germ-line gene therapy is prohibited. I cannot, however, find the reason gene therapy for fetuses is not allowed.

19. Anonymization may be classified into permanent and coded ones. The latter cannot be accepted as a procedure following the withdrawal of the consent.

V. Conclusion

From the perspective of the regulative approach, Korea has strong regulations on embryonic stem cell research and genetic test, research, and therapy in that it runs Bioethics and Safety Act, not any guidelines. However, there may be some difficulties in regulating bioethical issues by an act because it is likely not to be easy to revise. In addition, Bioethics and Safety Act includes lots of contents that had better be regulated by Presidential decree or enforcement, or even just guidelines made by professional societies. In order to make bioethical issues regulated by an act, ethical guidelines based on consensus should have established.

Establishing bioethics policies is a process to reach consensus through deliberative democracy, where the use of "public reason" is required.[20] This should be applied to global bioethics policies. It is easy to find that bioethics policies vary according to countries. Different policies in bioethics may give a wrong message to scientists and laypersons that ethics is relative to countries and cultures although we reach lots of ethical agreements across countries and cultures. We should give an effort to reach global consensus.

20. John Rawls emphasizes the importance of "public reason" when we legislate. See John Rawls, *Political Liberalism* (Columbia University Press, 1996), p.214.