

## The Challenges of Governing Biotechnology in Korea

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**Abstract** This paper explores the development of biotechnology governance and current challenges to its improvement in Korea. It aims to identify what element would be crucial to foster an effectively working system of biotechnology governance in Korea. The analysis is focused on two cases, the legislation of the Bioethics and Biosafety Act, and the development of ethical, legal, and social implications (ELSI) research. Our analysis finds that communication and consensus building between scientists and bioethics advocates in a broader sense is critical for improved governance. During the prolonged dispute over this legislation, the stakeholders advocating scientific advancements and those emphasizing the importance of ethics did not reach an agreement, which was reflected in the limitations of the act. The nascent ELSI research attempted to facilitate interdisciplinary communication and understanding between biotechnology scientists and those in humanities and social sciences, but was met with only limited success. Good governance of biotechnology requires scientists and other stakeholders to willingly comply with regulations and internalize certain norms. Based on our experience in ELSI research, a few suggestions are made to contribute to this end.

**Keywords** Biotechnology governance · ELSI research · Bioethics and biosafety act · Bioethics · Biotechnology in Korea

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## 1 Introduction

The National Bioethics Committee (NBC) in Korea came to a decision in April 2009 to approve a proposal to conduct human embryonic stem cell research which uses somatic cell nuclear transfer (SCNT). SCNT human embryonic research has continued to be a subject of heated controversy for the past decade. The Bioethics and Biosafety Act (BBA), effective as of January 2005, specifies that human embryonic stem cell research must be individually reviewed by the NBC and approved finally by the Minister of Health, Welfare and Family Affairs. This type of research was discontinued since the exposure of the Hwang Woo Suk scandal at the close of 2005. This research proposal had to wait for over a year after submission before passing the NBC review with four conditions added.<sup>1</sup> This decision indicates that the official regulations and regulatory institutions have come to play a critical role in the governance of biotechnology in Korea. The extensive press coverage of the decision reveals the politicized nature of the issue.

In June 2009, it was reported in the press that Hwang Woo Suk was chosen as the winner of an allegedly international competition for an award to commemorate Chang Young-Sil, a famous scientist in fifteenth-century Korea. Notwithstanding the legal charges against him, according to the organization sponsoring the award, he deserved to be recognized for his scientific accomplishment in the development of human embryonic stem cell research and the cloning of a dog. A number of dignitaries were involved, including a former minister of the Korean government, and current and former members of the National Assembly. Hwang could not be present at the ceremony in person as his court hearing coincided with the ceremony (*Donga Ilbo*, June 8, 2009). He, together with six colleagues, has been accused of scientific fraud, embezzlement of research funds, and illegal trading of human eggs, the indictment for which has been pending for over 3 years.<sup>2</sup> A series of events related to Hwang illustrate that there remains a substantial degree of confusion and conflict in the social perception and governance of biotechnology in Korea.

This paper explores the development of biotechnology governance and current challenges to its improvement in Korea. In recent years, the language of “governance”, rather than “policy”, has been widely used to describe the relationship between science, technology, and public decision-making. Conventionally, science and technology policy tended to focus on the narrowly defined activities of the government, that is, the collective measures taken for the development and exploitation of science and technology. The notion of governance, in contrast, is concerned with a wide range of actors and activities involved in public decision-making (Elzinga and Jamison 1995; Irwin 2008).

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<sup>1</sup> The four conditions are: (1) the revision of the title to avoid creating excessive expectations, (2) the reduction in the number of eggs to be used., (3) informed re-consent for the specific use of eggs, and (4) expansion of institutional bioethics review board members in order for the majority to consist of external members of diverse backgrounds including law, bioethics, and religion (National Bioethics Committee April 29, 2009).

<sup>2</sup> In late October, the court convicted Hwang of the illegal trading of human eggs in violation of BBA and embezzlement. Prior to the decision, his supporters had managed to file petitions with the court which included the signature of 55 National Assembly members.

Studies on the governance of biotechnology have shown that there exist significant variations across different countries and across different issues (Hedgecoe and Martin 2008; Jones and Salter 2003; Lassen 2004; Levidow and Carr 2007; Salter and Jones 2002). Based on the comparative analysis of Germany, Great Britain, and the United States, Jasanoff (2005) clearly illustrated this point with the concept of “civic epistemology”. In these three liberal democratic countries at “similar levels of social and economic development”, the same biotechnology has produced divergences in its governance. Civic epistemology is more likely to be “articulated through practice rather than in formal rules”. These findings suggest that “historically grounded and locally situated” analysis is required to better understand the governance of biotechnology in specific countries, which, in turn, is essential for the theoretical elaboration of biotechnology governance.

This paper aims to identify what element would be crucial to foster an effectively working system of biotechnology governance in Korea. The analysis is focused on two cases: the legislation of BBA, and the development of ethical, legal and social implications (ELSI) research. The former is a milestone in the installation of a regulatory framework for biotechnology in Korea; the latter exemplifies an intellectual effort to facilitate the betterment of biotechnology governance. They represent, in a sense, the hardware and the software of biotechnology governance in Korea. Our analysis finds that communication and consensus building between scientists and bioethics advocates in a broader sense is critical for improved governance in Korea.

The next section briefly describes, as a backdrop for the development of biotechnology governance, the process by which biotechnology has emerged as a controversial “social” issue in Korea. The following two sections are devoted to examining the prolonged dispute over legislation and assessing the formation and impact of ELSI research, in that order. In the concluding part, we provide some suggestions for a new direction of ELSI research, with the goal of making a contribution to the betterment of biotechnology governance in Korea.

## **2 Biotechnology as a Social Issue in Korea: Promotion versus Ethics**

In Korea, as in other industrialized countries, recent controversies about biotechnology governance have been associated mostly with the concerns about risks and the social and ethical impact of advanced research, particularly in genomics. It is noteworthy that the discourse of biotechnology governance in Korea over the past decade has taken on a moral tone, highlighting the issue of so-called “bioethics”.

It was not until the 1980s that biotechnology started to draw attention in Korea. After two decades of spectacular economic growth based on cheap labor and imported technology, it came to be widely recognized that international competitiveness in science and technology would be critical to continued economic development. In line with the new “technology drive” strategy, the government initiated intensive investment in research and development for key technologies. “Genetic engineering” was on the list of the key technologies promoted by the Ministry of Science and Technology (MOST). With the legislation of the Genetic Engineering Promotion Law in 1983 (later changed to the Biotechnology Promotion

Law), government-funded research and development in biotechnology was launched in earnest.

The commitment to biotechnology on the part of the government was further strengthened in the 1990s, and the long-term R&D plan entitled *Biotech 2000: 1994–2006* was established. It was succeeded by *Biovision 2016: 2007–2016*, a more aggressive plan involving eight ministries under the coordination of MOST. As shown in Fig. 1, the government investment in biotechnology research, which has increased from 54 billion Korean won (KRW) to 1,021 billion KRW and from 3.45% to 9.41% in the proportion of the total government research budget between 1994 and 2006, betokens the commitment to promote biotechnology in Korea (Ministry of Science and Technology (MOST) et al. 2006; MOST 2008, 90–96 and 552–555).

Science and technology in Korea have been conceived as a means to economic development since the 1960s. The government has promoted science and technology primarily with the view of enhancing the industrial infrastructure and competitiveness required for accelerated economic growth. As described in the government report for the establishment of a separate ministry of science and technology, the fundamental principle of the government policy has been to “obtain the economic effect at its maximum within a minimum period of time”. Scientists, as well as the general public, have been inundated with this conception of science and technology. Science and technology, on the other hand, have not been viewed as a matter of great social concern. Science and technology have been regarded as a “technical” matter to be relegated to a small group of interested experts (Yoon 2000, 17–37).

Under the authoritarian rule of the “development” state until the late 1980s in Korea, democratic processes and public engagement had been severely restricted, and important public decisions had been made predominantly in a technocratic manner. Science and technology was regarded as unlikely to be entangled with social controversies and political struggles. Biotechnology, its latecomer status notwithstanding, was no exception, and the concern for it was confined to a limited group of scientific, government, and industrial communities.

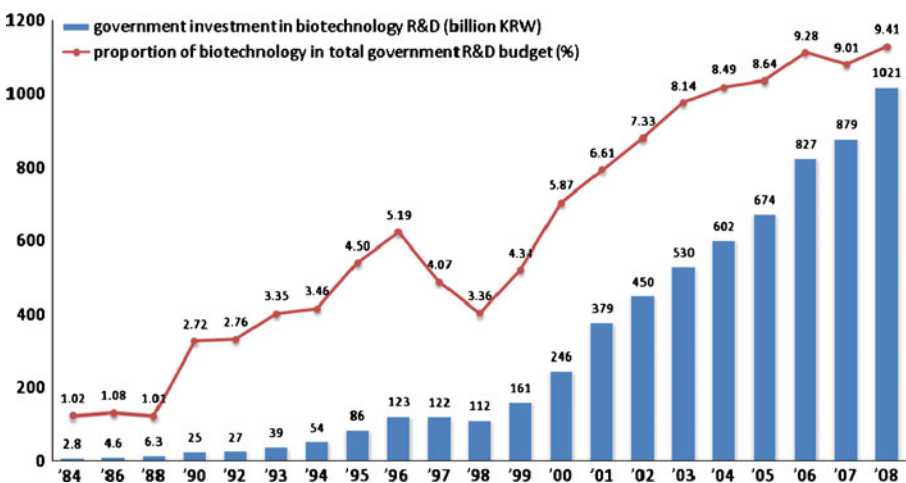


Fig. 1 Government investment in biotechnology research and development. Source: MOST et al. 2006, 8; National Science and Technology Information Service

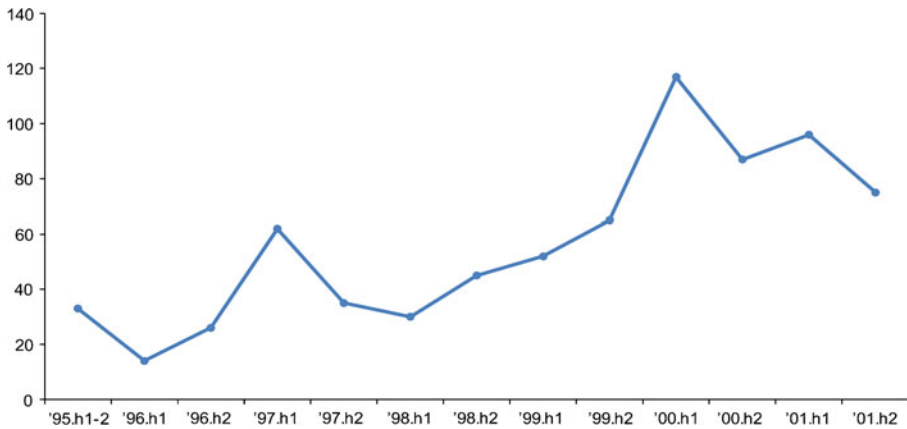


Fig. 2 Newspaper articles on biotechnology, 1995–2001. Source: Cho 2004, 36

The birth of Dolly in 1997, however, brought a profound change in the conception of biotechnology in Korea. As shown in Fig. 2, the mass media paid enormous attention to the news. It was an extremely rare case in which news about a scientific issue made headlines in the mass media. While astonished by the scientific advancement, the news coverage was more directed to the potential for human cloning as its consequence. The media became aware of the tremendous ethical and social implications of scientific advancement (Cho 2004; Song et al. 1998). Concurrent with the concern about human cloning, the intersection between science and society, which had been perceived to be discrete and unrelated, became dramatically enlarged. In a word, biotechnology emerged as a serious “social” issue.

The impact of Dolly in Korea was bifurcated. First, critical perspectives and social controversies over biotechnology became activated. The religious, academic, and non-governmental organization (NGO) communities played the leading role in the criticism. The religious community responded immediately against the birth of Dolly. The council of Catholic bishops petitioned the government and National Assembly for legislation prohibiting experimentation that could lead to human cloning. Christian and Confucian leaders issued public statements against human cloning. The critical stance of the academic community resulted in the founding of the Korean Association for Medical Ethics Education in late 1997 and the Korean Bioethics Association in early 1998. NGOs involved in the environment, consumer issues, and women’s issues were in alliance to organize the public demonstration and open forum to oppose cloning experimentation.<sup>3</sup> The NGOs’ actions led to the establishment of the Center for Democracy in Science and Technology in November 1997 which was affiliated with the Alliance for Participation, an active and prominent NGO in Korea. The center aimed at “constructing an alternative science and technology, humanitarian and eco-friendly, through the participation of citizens”. Biotechnology naturally became the focal point of the center’s activities. The center

<sup>3</sup> NGO activities have been remarkably activated since the democratization of the political system in the late 1980 s. NGOs engaged in different issues tended to make a partnership for common cause, since many NGO leaders then shared their involvement in the anti-government democratization movement.

took the initiative in biotechnology-related NGO activities, which included the establishment of the Coalition for Biosafety and Bioethics. The banner of “bioethics” represented the critical views of diverse groups interested in and critical of the ethical and social repercussions of the astonishing advancement in biotechnology (Lee 1999; Song et al. 1998, 9–20).

On the other hand, the birth of Dolly provided a momentum to accelerate research and development in biotechnology, and cloning research specifically, in Korea. In those days, the spotlight was given to genetically modified animal research, which transplanted genes into fertilized eggs, as the most advanced biotechnology. The examples included making cows produce an ingredient in human milk, and making goats produce an ingredient of medicine for treating leukemia. The ingredient for treating leukemia, according to mass media reports, was valued at 1.1 billion KRW per gram, and the “golden cow” would be able to secure a significant share of the three-billion-dollar global market.<sup>4</sup> Faced with the severe financial crisis in Korea from late 1997, the anticipated economic value of successful biotechnology research was likely exaggerated, which, in turn, reinforced the motivation to promote research and development in biotechnology.

Given these circumstances, Hwang Woo Suk emerged as a rising star in cloning research. He announced in the press from 1998 a series of successful animal cloning attempts using the somatic cell nuclear transfer *exactly like* Dolly, such as milk cow *Yongnongi* and super Korean cow *Jini*.<sup>5</sup> The alleged accomplishments of Hwang, no doubt, significantly boosted the social support of biotechnology. The mass media, politicians, and industrial community rushed in promoting biotechnology, to say nothing of the government.

An incident in December 1998 brought the bioethics issue to the fore. It was the news that a medical research team in Korea succeeded in making a four-cell human embryo through SCNT. It was the first case of applying the SCNT, which had been restricted to animal cloning, to human beings. Whether successful or not, the attempt itself was alarming. It bore witness to the argument of the slippery slope which claims that animal cloning would very likely lead to human cloning. In addition, Hwang Woo Suk announced the launch of SCNT human embryo research in early 1999. It was reported extensively by the mass media in August 2000 that Hwang succeeded, *for the first time in the world*, in making human blastocysts, and that he would apply for patents in fifteen countries. Hwang continued to announce shocking research accomplishments until the scandal was exposed in 2005. As a consequence, the controversies surrounding ethical issues became more and more heated (Kim 2007).

### 3 Legislation of Bioethics and Biosafety Act

As cloning research progressed from animals to humans, social controversies heated up and emphasized the need for regulation and bioethics. The controversies focused

<sup>4</sup> The names of those animals, *Boram* (meaning reward in Korean) for the cow and *Medi* (abbreviation of medical) for the goat, indicated the expectations at the time.

<sup>5</sup> *Yongnongi* means brilliance in Korean. The name of *Jini* was given by then President Kim Dae-Jung personally, which reveals the heightened public attention. Hwang *Jini* is the name of a famous woman poet and geisha in sixteenth-century Korea.

on how to legally regulate biotechnology. Those NGOs, academic and religious communities who took a critical stance on biotechnology strongly demanded a law to guarantee “bioethics” with adequate regulation and sanctions. Faced with the rising social concerns and global trends toward greater regulation, the government became aware of the need for regulations, though paradoxical, in order to further promote biotechnology. The process of forming a legal framework for the regulation, however, was complicated by the need to prioritize either the development of biotechnology or the prescription of needed bioethics.

The legalization was exposed to a power struggle between governmental agencies involved. First, the MOST attempted to preempt the jurisdiction of bioethics by including a section on bioethical issues in the amendment of the pre-existing Biotechnology Promotion Law and contacted the National Assembly members. After the birth of Dolly, the lawmakers at the assembly became aware of, and interested in, bioethical matters. Conflict between the ruling party and the opposition, however, resulted in disagreement on the content of the law, and each party presented its own draft of an amendment; neither was approved. The Ministry of Health and Welfare (MOHW), on the other hand, strongly opposed the position the MOST was taking. They argued that bioethics is a human issue, and as such, a health and medical responsibility. In 2000, the MOHW submitted a new bill, the Biotechnology Safety Act. This in turn was opposed by the MOST, but was supported by some NGOs (Kim 2001, 2005; Song et al. 2001, 43–59). The jurisdiction of bioethics was deemed to be consequential for their voice regarding biotechnology issues in the years to come.

Due to the conflict between the two ministries, the Office for Policy Coordination, under the Prime Minister, became involved and tried to settle the conflict. This office suggested that, from September 2000, for 1 year, the MOST would run the National Bioethics Advisory Committee and come up with a framework for laws on bioethics.<sup>6</sup> The MOST suggested five names each from four distinct groups: professionals in humanities and social sciences, NGOs and religion, biotechnology scientists, and medical professionals. These names included Hwang Woo Suk and other scientists who were already engaged in human embryonic research. The most hotly disputed issue at that point was whether to allow for human embryonic research or not.

The NGOs opposed the composition, arguing that a committee with those appointees may end up “helplessly endorsing the stance of the scientific community which lopsidedly advocated the development of biotechnology”. For this reason, the MOST then changed the composition, retaining seven scientists in biotechnology and medicine as members with the rest of the people changed. The new composition resulted in the NGOs and religious groups, traditionally against biotechnology, now being in the majority. Those members against human embryonic research played a leading role in the major subcommittees such as steering, agenda setting, and report writing. It was determined, based on a detailed analysis of the entire proceedings, that “the National Bioethics Advisory Committee was open to ideas generated within, but not to ideas from the outside” (Kim 2007, 280).

<sup>6</sup> It was scheduled to submit the bill in consultation with the MOHW to the National Assembly in the fall of 2001.

The committee set the goal of formulating a fundamental law on bioethics. The bill proposed on May 2001 addressed the following issues: a national bioethics committee, cloning, hybridization, human embryonic research, gene therapy, genetically modified animal research, utilization and protection of human genetic information, and patents. Controversial issues such as human individual cloning, animal–human nuclear transplantation, human embryonic cloning, and xeno-gamete gene therapy were totally banned. Stem cell research performed on abandoned frozen embryonic cells and miscarried embryonic tissues as well as human somatic cell therapy were allowed with limitations (National Bioethics Advisory Committee 2001).<sup>7</sup>

The network for promotion was made in alliance between the National Assembly (Science, Technology and Communications Committee), the MOST, the scientists, and the industry. The statement that “the advisory committee was not representative from the beginning and lacked the ability to collect a wide range of public opinions or to settle the controversies” bespoke the position of the scientific and industrial communities against the proposed bill. The NGOs and religious groups, to the contrary, stated that “this is a bioethics law, not a biotechnology promotion law. As far as ethics is concerned, I am not sure if biotechnology scientists are qualified to be heard and I am not sure if they even take ethics issues into sincere considerations” (Kim 2001, 100–119; Kim 2007, 277–283).<sup>8</sup>

After the completion of the advisory committee’s work, the MOST attempted to promote the law favoring science and technology, and ignoring the positions of the NGOs and religious groups. The MOST submitted a bill in May 2002. In that bill, only human individual cloning was prohibited. Human embryonic cloning and animal–human nuclear transplantation research were to be allowed with the approval of a national committee. The MOHW opposed the MOST bill, discontent that they were to be left out of the process.

Coincidentally, and shockingly, the American company Clonaid announced in July 2002 that in 6 months, a cloned human would be born in Korea.<sup>9</sup> At that time, there was no law prohibiting human cloning in Korea. Alarmed by the news from abroad, the Office for Policy Coordination decided that the MOHW, seemingly more attentive of bioethical issues, would be in charge of drawing up the bioethics bill. In spite of the opposition of NGOs and religious groups, human embryonic cloning and animal–human nuclear transplantation came to be allowed after committee review in the newly proposed MOHW bill (Kim 2005).

In February 2003, simultaneous with coming into power, the new government partially accepted the demands of both the NGOs and the scientists. The NGOs demanded that the National Bioethics Committee be entitled to voting rights, not an

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<sup>7</sup> The NGOs in coalition opposed human embryonic cloning as well as human individual cloning. This view was reaffirmed at the consensus conference in September 1999 organized by the Center for Democracy in Science and Technology with the financial support of the UNESCO Korea.

<sup>8</sup> In an effort to advocate their views, fifteen professional organizations in biotechnology collaborated to establish a working committee to cope with the legislation issues; the NGOs and religious groups undertook collective campaigns for the legislation as soon as possible. The Korean Federation of Science and Technology Societies strongly opposed the proposed bill and organized public debates in collaboration with the science and technology study group of National Assembly members (KFSTS 2001).

<sup>9</sup> The company Clonaid was affiliated with a religious group called the Raelian Movement (Kim, S. 2004)



advisory committee, and the scientists demanded that the ratio of scientists in the committee be increased. This bill became the BBA effective from January 2005.

The BBA, however, has many limitations. Two are particularly worth noting. The first issue concerns its comprehensiveness. Although the act is the fundamental law for regulating biotechnology research, it does not regulate all categories of biotechnology research. In the case of embryonic cloning research by means of SCNT, the act has quite detailed regulations. Yet other areas of stem cell research, including adult stem cell research, are not adequately regulated. In addition, the regulation itself is vaguely defined. Concerning xeno-transplantation for which guidelines are almost nonexistent, the act falls short of adequate regulation. The amendment in 2008 remained focused on human embryonic stem cell research.

Secondly, there is the problem of efficiency. The act prescribes that every research institute must have a separate institutional bioethics review board for each different type of research. As a consequence, one single institution may have to operate up to seven different review boards. This problem was addressed in the 2008 amendment.

To summarize, the two lines of promotion versus ethics have continued to be parallel to each other, with no reconciliations made and no consensus reached in between. The advisory committee which was meant to serve as an intermediary for consensus ended up as a locus where the disagreement and conflict became open. The ethics advocates greatly contributed to the legislation of the BBA. The act, however, was the imposition of state power, not that of voluntary and autonomous consensus between stakeholders advocating the two different positions. Highlighted in the legislative process was the fact that there was neither communication nor agreement between scientists and bioethics advocates and the consequent limitations in the substance of the act. In the next section, we will look at the role of ELSI research in the development of biotechnology governance.

#### 4 ELSI Research

For the past decade, ELSI research in Korea has been introduced as an intellectual undertaking to encourage good governance of biotechnology through interdisciplinary research led by the humanities and social sciences. From the late 1960s, there were sporadic discussions about medical ethics, specifically regarding brain death and organ transplants, within a small group of medical professionals and academicians. But it was not until the birth of Dolly in 1997 that the ethical aspects of biotechnology became hot issues in Korea (Song et al. 1998: 3–16). Korea has supported research on the ethical and social implications of biotechnology since 2000. The MOST, inspired by the Human Genome Project in the USA which allocated 3–5% of its budget to ELSI, initiated this support for interdisciplinary studies in the humanities and social sciences by providing grants as part of large scale national research and development projects in biotechnology.<sup>10</sup>

<sup>10</sup> Since 2000, the MOST has started new kinds of long-term projects, under the name 'Frontier Projects', to secure original technologies by providing ten billion KRW per annum (approximately ten million US dollars) over a 10-year period. These projects are different from other projects in that they are given more discretion in conducting research. Seven projects out of a total of 22 are in the area of biotechnology, which shows the importance of biotechnology in Korea.

Human genome, stem cell and xeno-transplantation are among the major research areas that supported these interdisciplinary studies of the humanities and social sciences. The Center for Functional Analysis of Human Genome, launched in 2000 as the first Frontier Project and the largest biotechnology project at that time, included studies in the humanities and social sciences named ELSI Korea after ELSI in the USA.<sup>11</sup> The Stem Cell Research Center, which started in September 2002, also supported this kind of interdisciplinary study of the humanities and social sciences. It created an ethics committee and supported its activities. The Xeno-transplantation Research Center has supported the study of ethics and industrial application since 2003.

The ELSI studies groups in these three research centers all attempted to formulate ethical guidelines for the scientists in each field, even though each study had its own areas of emphasis. The ELSI team of the human genome project in Korea made it a core goal to develop guidelines and an informed consent form. The resulting guidelines and its companion on the ethical and legal background of the guidelines used plain language and were structured according to the actual research process in an effort to enhance the accessibility for scientists. Experts from diverse areas such as law, communications, sociology, education, bioethics, and biology took part in this work.<sup>12</sup> The ethics committee of the Stem Cell Research Center ran an institutional review board (IRB) and an additional working group for the development of ethics guidelines. The interdisciplinary study supported by the xeno-transplantation center focused on patent issues, as well as ethical issues (Kwon 2007; Jung 2006; Yoon 2001; Yoon et al. 2003).

It is because there had been no relevant regulations in Korea regarding biotechnology research before 2005 when the BBA became effective that all three research groups devoted effort to the development of ethical guidelines. Most ELSI researchers in Korea felt that ethical guidelines were urgent in order for scientists to regulate themselves. But there are doubts as to how much these ethical guidelines have actually affected the research practice of scientists. ELSI researchers who worked for the Stem Cell Research Center admitted that the ethics committee activities were disregarded by the scientists of that center, even though the center had stated in its research proposal that it would conduct ethical reviews of its research and provide ethics education to its researchers. During 2002, the first year, 36 research proposals were approved conditionally, but no documents discussing modifications to the proposals based on the recommendations or instructions of the ethics committee were submitted. The director of the center, who was also a member of the ethics committee, did not take strong enough actions to compel the researchers to comply with the instructions of the ethics committee. No decisions of the ethics committee resulted in the stoppage of a grant.<sup>13</sup> Most scientists regarded the review of the ethics committee as an administrative nuisance (Kwon 2007, 21–23; Kim and Choi 2007, 90–93). Neither human genome project researchers nor xeno-

<sup>11</sup> The ELSI project began in June of 2001, 1 year after the main project started. All the three authors of this paper have participated in the project, with Yoon as its principal investigator.

<sup>12</sup> As to the detailed discussion on this guideline, refer to Jung (2004).

<sup>13</sup> Before 2005, there had been few IRBs in Korea, except in hospitals conducting clinical research. Research proposals were submitted without the approval of an IRB even in institutions with an IRB. Only the Stem Cell Research Center had required the IRB review before the BBA became effective in 2005.

transplantation researchers had shown any earnest efforts at the organizational level to adopt the ethical guidelines made by ELSI researchers before legally required to in 2005.

Sheltered in the technocratic environment, scientists in Korea are not yet accustomed to being responsive to social concerns and demands relating to their research practice. Their priority has remained to concentrate on accomplishing technical advancement. Therefore, the findings and suggestions of ELSI research, with no binding power, were incapable of bringing significant changes in the outlook and practice of scientists. The ELSI researchers, on the other hand, also share some of the responsibility in creating a communication problem. ELSI studies tend to address more general and abstract issues, rather than focusing on specific and concrete issues at stake.

The reluctance of scientists in responding to social requests regarding ethics is also shown in the *modus operandi* of professional organizations. The Korean Society for Molecular and Cellular Biology established its ethics committee in 2001 in response to increasing social controversies over bioethics (KSMCB 2005). But the committee did not include any members from outside the organization, and did not endeavor to actively communicate with the outside either. Sometimes the person concerned, such as Hwang Woo Suk, even took the role of a chairperson. The charter of ethics for the members was issued only after Hwang's scandal.

ELSI research may be criticized as simply providing justification for scientists. There is a possibility that ELSI research, closely teamed up with biotechnology research, might cease to be critical and serve as the mouthpiece for biotechnology promotion. But ELSI researchers do not have a close relationship with scientists in Korea. ELSI researchers are, in fact, rather isolated from scientists, which has contributed negatively to the development of ELSI research in Korea. Also the fact that the number of ELSI researchers in Korea has not increased much over the past 10 years has limited the scope and depth of ELSI research. ELSI research in Korea attempted to encourage communications between biotechnology and humanities and social sciences and thereby to contribute to the improvement of governance. But the results are not satisfactory as yet.

## 5 Conclusion

Currently, research and development in biotechnology is legally regulated in Korea. The enforcement of the BBA since 2005 has brought significant improvement in biotechnology governance. The law requires that research involving human subjects pass the review of an institutional bioethics review board (IBRB), and, for some cases, the National Bioethics Committee as well. IBRBs had been established at 252 institutions by 2008, while only medical institutions engaged in clinical trials had IBRBs before the legislation came into effect. The total number of reviews increased by 30%, and the number of reviews per institution increased by 22% per annum between 2005 and 2008. More than 30% of institutions, on the other hand, had not yet reviewed a case by 2008 (National Bioethics Committee February 5, 2009). This implies that there remains much to be improved in the operation of IBRBs. The quality of the review needs to be improved as well.

Legal regulation of biotechnology, however, is limited in its scope and efficacy. Biotechnology has been rapidly advancing and thus it is not easy to predict the direction of research and development in biotechnology. Legislation, particularly in the legal system of Korea, which relies on written statutes, cannot be flexible or change quickly enough to adequately regulate newly emerging areas of biotechnology. Legislation, in addition, does not guarantee good governance in biotechnology. Legal compliance is only one necessary condition of good governance; it is not sufficient by itself.

Good governance of biotechnology requires scientists and other stakeholders to willingly comply with regulations and internalize certain norms. A consensus on the substance and mode of regulations based on communication and reconciliation between diverse stakeholders, including the general public, is indispensable for the realization of good governance. The BBA did not succeed in attaining a consensus in its legislation process in Korea. With the divide between interested parties remaining wide, state power was exercised to institute regulations. It is no wonder that compliance with the enforced regulations is accompanied by grudges and resistance to internalizing the norms desired.

In order to accelerate voluntary legal compliance and the internalization of norms, a new mode of communication and consensus building needs to be implemented. The divide between scientists and bioethics advocates including NGOs ought to be bridged. ELSI research ought to contribute to this end. Our experience in ELSI research has led us to several suggestions.

First, we need to reorient the direction of ELSI research. Until now, ELSI research in Korea has mainly tried to identify potential problems which might result from the advancement of biotechnology. Even though these efforts are important, finding solutions to current conflicts and controversies deserves more immediate attention from ELSI researchers.

Second, ELSI research has attempted to enhance the public understanding of science. But it is not enough for the lay citizens to be knowledgeable and informed of biotechnology. For good governance of biotechnology, the scientists need to understand the public and accordingly, the ethical, legal, and social implications of biotechnology. Therefore, education of and communication with students and young scientists should be regarded as important.

Third, a new communication program needs to be designed which will contribute to social consensus on biotechnology issues. Various attempts have been made such as public hearings, consensus conferences, etc. but with unsatisfactory results. A wide opinion gap among social groups persists. For good governance, we also need alternative channels and modes of communication for the reconciliation of conflicting opinions. Bioethicists, social scientists, lawyers, and NGO groups, for example, need to be encouraged to participate in the scientific conferences and share their ideas with scientists. Joint sessions between scientists and non-scientific groups, nominally available at the moment, need to be promoted to a much greater extent.

Last but not least, the academic community needs to pay more attention to ELSI. Despite financial support over the past 10 years, the number of researchers committed to ELSI has not increased significantly. The current number of ELSI researchers is far below the minimum needed to complete the missions demanded by

society. An innovative method for encouraging and inspiring researchers to move out of their own established research field into the interdisciplinary research area of ELSI is urgently needed.

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