

Fundamental Study for Establishing Standardized e-IRB Computer System in Healthcare

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ABSTRACT

The Ministry of Health and Welfare in Korea has been obliged to establish the IRB. However, in many cases, items that should be included in the review process are omitted in the process of modification. Therefore, this study analyzes the IRB-related deliberations and evaluation forms of the institutional bioethics committee members of public and private universities that were announced for evaluation and certification of the institutional committee in 2016. The data were collected the new review documents and the review exemption documents that are open to the homepage. Then, we analyzed the items included in the paper form for new deliberation and exemption from each university, and analyzed for form standardization of the institutional bioethics committee based on the data. Most of the research proposal and bioethical compliance pledges were included in the new application form, but the manuals for the subjects, the consent form, and the consent form for the use of personal information were often omitted. The e-IRB standardized system should be developed which not only include the form, but also provide information about the contents for protection of research subject and personal information for the researcher or the deliberation committee member.

Keywords: Healthcare, IRB, e-IRB, Bioethics, Standardization

Introduction

The “Act on Bioethics and Safety”, which came into force on February 2, 2013, removed the term “life science technology” such as embryo research and genetic testing/research, and expanding the application scope of human subjects. Human-oriented research defined by the Ministry of Health and Welfare includes studies that physically intervene in people, research on interaction such as communication and interpersonal contact, and research that uses information to identify individuals. The Ministry of Health and Welfare has been obliged to establish the Institutional Review Board (IRB) as of February 2013, based on Article 10^[1] of the Act^[1].

For institutions violating IRB installation obligations, penalties of up to KRW 5 million are imposed in accordance with Article 70^[1] of the Act. As the IRB has to be expanded, mandated, and be installed in research institutes in the life sciences and medical sciences as well as the social sciences, the Ministry of Health and Welfare has established the Public Institutions Bioethics Committee. The Bioethics Committee for Public Organizations has commenced the first pilot project of the Korea Health Medical Center in 2010, held a deliberation committee meeting in 2013 as a member of the Bioethics Committee for Public Organizations, and introduced the e-IRB and has been holding four meetings of the committee each month to date ^[1,2].

Public institution bioethics committee can entrust work through the agreement if there are not more than 5 researchers engaged in the institution or less than 30 number of research reviews in the last three years even though the IRB is not installed in the institution itself^[3]. The IRB’s main responsibilities are to review the scientific and ethical feasibility of the study protocol,

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to confirm the safety of the subjects and to confirm the consent process of legitimate procedures, to protect personal information, and to investigate and supervise the process and result of research^[4]. In addition, it plays a role in education and operation such as education for researchers and employees, establishment of measures for protection of vulnerable research subjects, and preparation of ethics guidelines for researchers^[5,6]. As the countermeasures for the safety of the subjects have been strengthened, the Public Bioethics Committee of Public Institutions has introduced the institutional committee evaluation and certification system with the goal of an introduction of Korean version system for the quality control of institutions and committee of institutions, strengthening the institutional committee role as an ethical institution, improving of bioethical environment and enhance trust as an international standard, and establishing and managing the role of each institution committee type in accordance with the bioethics and safety law. It is mandatory to evaluate the institutional committee from year of 2016 to 2019 through implementation of the pilot evaluation from year of 2013 to 2015. In order to implement the current evaluation and certification system aiming at IRB quality management, preparations for IRB staff are essential. However, according to a study by^[7], the number of IRB staff in the institution of 1,000 to 1,500 beds has varied from 0.4 to 3.8. In addition, it appears that IRB has an excessive burden on the work itself. A comparison of the US IRB with the Korean IRB reveals a lack of supporting IRB work and administrative staff in Korea. The role of the IRB staff includes a wide range of roles to be undertaken, such as educating researchers and employees at the relevant institutions, establishing protective measures for vulnerable research subjects, and preparing ethical guidelines for researchers. In addition, the time required for the preparation of documents for evaluation and certification may be a cause for the lack of review of the ethical feasibility to protect the study subjects which is main work of IRB^[8-10].

It is necessary to construct a computerized support system that can faithfully fulfill the role of supervising the ethical feasibility of IRB’s main purpose. Therefore, this study analyzes the IRB-related deliberations and evaluation forms of the institutional bioethics committee members of public and private universities that were announced for evaluation and certification of the institutional committee in 2016. The results of this study will be helpful for the IRB staffs, researchers and review committee members

to review the ethical feasibility of the research. This study analyzes the IRB-related deliberation and evaluation forms of the institutional bioethics committee of public and private universities, which were announced for evaluation and certification of the institutional committee in 2016, and provides basic data on the establishment of standardized e-IRB system.

Materials and Method

Subjects: The subjects of this study were selected 30 institutions which provide IRB form among the 47 Institutional Bioethics Committees of public and private universities, which were announced for evaluation and certification of the institutional committee in 2016.

Research Method: The research data were collected by downloading the new review documents and the review exemption documents that are open to the homepage of the institution ‘s bioethics committee of the selected university. Then, we analyzed the items included in the paper form for new deliberation and exemption from each university, and analyzed for form standardization of the institutional bioethics committee based on the data.

Statistical Analysis: The statistical program R was used for the analysis of this study. The independent variables were national and public universities and the study conducted chi-square test.

Method

Characteristics of the Subject: Table 1 shows the characteristics of the study subjects. The survey subjects were 30 public and private universities. Seoul was the highest with 33.3%, followed by Busan 13.3%, Gangwon 10.0%, and Gyeonggi 10.0%. Gwangju, Daegu, Jeonnam, and Chungnam were 6.7%, and Gyeongnam and Daejeon were 3.3%.

Table 1: The General Characteristics of Research Subjects

Region	Public	Private	Total
Gangwon	2 (25.0)	1 (4.5)	3 (10.0)
Gyeonggi	-	3 (13.6)	3 (10.0)
Gyeongnam	-	1(4.5)	1 (3.3)
Gyeongbuk	-	-	-
Gwangju	-	2 (9.1)	2 (6.7)

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Daegu	1 (12.5)	1 (4.5)	2 (6.7)
Daejeon	-	1 (4.5)	1 (3.3)
Busan	2 (25.0)	2 (9.1)	4 (13.3)
Seoul	1 (12.5)	9 (40.9)	10 (33.3)
Sejong	-	-	-
Ulsan	-	-	-
Incheon	-	-	-
Jeonnam	1 (12.5)	1 (4.5)	2 (6.7)
Jeonbuk	-	-	-
Jeju	-	-	-
Chungnam	1 (12.5)	1 (4.5)	2 (6.7)
Chungbuk	-	-	-
Total	8(100.0)	22(100.0)	30(100.0)

Application form for new examination by university based on Public Institution Bioethics Committee: Table 2 shows the results of the analysis of application forms of public and private universities based on the new application forms provided by the Public Institution

Bioethics Committee. Most of the universities selected in this study included the research plan (100% public and 90.9% private) and the Pledge of Bioethics Compliance (62.5% public and 90.5% private). There were many cases in which the explanatory manual and the consent form for research subjects were not included (37.5% public and 13.6% private). In addition, most of the universities were missing the form of consent to use personal information.

Main items of required documents for new review application: Table 3 shows the major items of the documents submitted by each university. Most of the new application forms include the names of the research subjects, research supervisors, co-researchers, information of main researchers, study period, the types of research in the research methodology. It also included information on research commissioned agencies. In addition, there were many cases in which plans for the study budget, research types, references, and anonymization were not included.

Table 2: The new review application forms

Contents	Public	Private	Total	p-value	Contents	Public	Private	Total	p-value
Documents to be submitted for new deliberation				1.000 ^a	Resume				0.666 ^a
Yes	8(100.0)	20(90.9)	28(93.3)		Yes	5(62.5)	11(50.0)	16(53.3)	
No	-	2(9.1)	2(6.7)		No	3(37.5)	11(50.0)	14(46.7)	
Application for deliberation exemption				0.407 ^a	Research Expense Plan				0.300 ^a
Yes	44(50.0)	11(50.0)	15(50.0)		Yes	3(37.5)	6(27.3)	9(30.0)	
No	44(50.0)	11(50.0)	15(50.0)		No	5(62.5)	16(72.7)	21(70.0)	
Research plan				1.000 ^a	Personal Information Agreement				0.112 ^a
Yes	5(62.5)	13(59.1)	18(60.0)		Yes	1(12.5)	-	1(3.3)	
No	3(37.5)	9(40.9)	12(40.0)		No	7(87.5)	22(100.0)	29(96.7)	
Instructions and agreement for the subject				0.689 ^a	Abstract of research plan				1.000 ^a
Yes	3(37.5)	3(13.6)	6(20.0)		Yes	2(25.0)	11(50.0)	13(43.3)	
No	5(62.5)	19(86.4)	24(80.0)		No	6(75.0)	11(50.0)	17(56.7)	
Checklist for deliberation exemption				1.000 ^a	New project evaluation checklist				0.267 ^a
Yes	2(25.0)	6(27.3)	8(26.7)		Yes	2(25.0)	2(9.1)	4(13.3)	
No	6(75.0)	16(72.7)	22(73.3)		No	6(75.0)	20(90.9)	26(86.7)	
Change table				0.678 ^a	Pledge of Bioethics Compliance				0.284 ^a
Yes	4(50.0)	8(36.4)	12(40.0)		Yes	5(62.5)	19(90.5)	24(82.8)	
No	4(50.0)	14(63.6)	18(60.0)		No	3(37.5)	2(9.5)	5(17.2)	
Total	8(100.0)	22(100.0)	30(100.0)		Total	8(100.0)	22(100.0)	30(100.0)	

^a Using the exact test of a fisher

Main items of the documents for exemption from deliberation: Table 4 summarizes the main items of the documents submitted for the exemption of deliberation in this study. The most commonly used item was cause of exemption (50.0%). In the item of the exemption of deliberation documents, research subjects were 46.7%, the information of the research supervisor was 46.7%, and IRB education was 3.3%.

Discussion and Conclusion

The purpose of this study was to identify the items and contents of each form in order to standardize the application forms for the new deliberation and the exemption application form for the 30 public and private universities which have institutional bioethics committee in Korea. As a result, most of the research proposal and bioethical compliance pledges were included in the new application form, but the manuals for the subjects, the consent form, and the consent form for the use of personal information were often omitted. In addition, the exemption form for deliberation was supposed to prepare the content of exemption reasons, but the contents of the complete IRB education were not included. It is meaningful that this study first analyzed the items and contents of the application forms for new deliberation and exemptions from the Institutional Bioethics Committee in Korea. In addition, it is meaningful to provide basic data for developing standardized e-IRB format through analysis result. Currently, the Institutional Bioethics Committee of each university has changed the format provided by the Public Institution Bioethics Committee according to the research environment of each university. However, in many cases, items that should be included in the review process are omitted in the process of modification. In the future, it will be necessary to have a standardized application form to protect the research

subjects participating in the study in accordance with the purpose of establishing the Institutional Bioethics Committee with the introduction of e-IRB. Based on the analysis of this study, future e-IRB forms should include the pledge of compliance with bioethics which is the most important to protect the current research subjects, the manual and agreement for research subjects, and the consent to use personal information. The review committee members of the Institutional Bioethics Committee should make sure that this study accurately assesses whether there is any damage to the research subject. In addition, according to the analysis of the results of this study, many universities did not include the content of complete IRB education in the application. However, both the researcher and the co-researchers will need to complete the study of bioethics in order to carry out the research, so this part should also be included in the e-IRB form. As institutional bioethics committees are mandated for each institution that conducts recent research, researchers also face many confusion and difficulties in completing the application form for IRB deliberation. Standardized form provision and education is considered to be a way for researchers to easily participate in mandatory IRB deliberation. Therefore, the e-IRB standardized system should be developed which not only include the form, but also provide information about the contents for protection of research subject and personal information for the researcher or the deliberation committee member. By providing education with application through e-IRB, the researcher will consider how to protect the research subject, and this will be in line with the purpose of establishing the Institutional Bioethics Committee. Finally, we propose that the e-IRB system quickly educates researchers on questions. For example, it is to allow researchers to look up terminology quickly, via the pop-up system of IRB term. This system help researchers faithfully write IRB.

Table 3: Main items of required documents for new review application

Contents	Public	Private	Total	p-value	Contents	Public	Private	Total	p-value
Research subjects				1.000 ^a	Research type				0.166 ^a
Yes	8(100.0)	20(90.9)	28(93.3)		Yes	2(25.0)	1 (4.5)	3(10.0)	
No	-	2(9.1)	2(6.7)		No	6(75.0)	21(95.5)	27(90.0)	
Information of supervisors				0.545 ^a	Research approval number				0.148 ^a
Yes	8(100.0)	19(86.4)	27(90.0)		Yes	8(100.0)	15(71.4)	23(79.3)	
No	-	3(13.6)	3(10.0)		No	-	6(28.6)	6(20.7)	

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Information of co-researcher				1.000 ^a	Research goal and importance				1.000 ^a
Yes	7(87.5)	18(81.8)	25(83.3)		Yes	-	2(9.1)	2(6.7)	
No	1(12.5)	4(18.2)	5(16.7)		No	8(100.0)	20(90.9)	28(93.3)	
Information of main researcher				1.000 ^a	Research contents				0.287 ^a
Yes	4(50.0)	10(45.5)	14(46.7)		Yes	-	5(22.7)	5(16.7)	
No	4(50.0)	12(54.5)	16(53.3)		No	8(100.0)	17(77.3)	25(83.3)	
Pharmacist				0.267 ^a	Target review contents				1.000 ^a
Yes	1(12.5)	-	1(3.3)		Yes	1(12.5)	2(9.1)	3(10.0)	
No	7(87.5)	22(100.0)	29(96.7)		No	7(87.5)	20(90.9)	27(90.0)	
Research period				0.155 ^a	Reference				0.550 ^a
Yes	8(100.0)	16(72.7)	24(80.0)		Yes	-	4(18.2)	4(13.3)	
No	-	6(27.3)	6(20.0)		No	8(100.0)	18(81.8)	26(86.7)	
Research type				0.545 ^a	Number of subject				0.143 ^a
Yes	8(100.0)	19(86.4)	27(90.0)		Yes	8(100.0)	15(68.2)	23(76.7)	
No	-	3(13.6)	3(10.0)		No	-	7(31.8)	7(23.3)	
Multilateral Cooperative Research				0.682 ^a	Consent of subject				0.391 ^a
Yes	5(62.5)	10(45.5)	15(50.0)		Yes	7(87.5)	15(68.2)	22(73.3)	
No	3(37.5)	12(54.5)	15(50.0)		No	1(12.5)	7(31.8)	8(26.7)	
Subject-related information				0.374 ^a	Characteristics of research				0.226 ^a
Yes	7(87.5)	14(63.6)	21(70.0)		Yes	6(75.0)	10(45.5)	16(53.3)	
No	1(12.5)	8(36.4)	9(30.0)		No	2(25.0)	12(54.5)	14(46.7)	
Size of budget				0.210 ^a	IRB approval of other institutions				0.384 ^a
Yes	1(12.5)	9(40.9)	10(33.3)		Yes	4(50.0)	6(27.3)	10(33.3)	
No	7(87.5)	13(59.1)	20(66.7)		No	4(50.0)	16(72.7)	20(66.7)	
Information of research commissioned agencies				0.345 ^a	Anonymization				0.638 ^a
Yes	5(62.5)	18(81.8)	23(76.7)		Yes	1(12.5)	6(27.3)	7(23.3)	
No	3(37.5)	4(18.2)	7(23.3)		No	7(87.5)	16(72.7)	23(76.7)	
Data submission to research provider				0.638 ^a	Presence of Human Derivatives				1.000 ^a
Yes	1(12.5)	6(27.3)	7(23.3)		Yes	1(12.5)	3(13.6)	4(13.3)	
No	7(87.5)	16(72.7)	23(76.7)		No	7(87.5)	19(86.4)	26(86.7)	
Type of review				0.682 ^a	Risk of research				0.545 ^a
Yes	3(37.5)	12(54.5)	15(50.0)		Yes	-	3(13.6)	3(10.0)	
No	5(62.5)	10(45.5)	15(50.0)		No	8(100.0)	19(86.4)	27(90.0)	
Total	8(100.0)	22(100.0)	30(100.0)		Total	8(100.0)	22(100.0)	30(100.0)	

^a Using the exact test of a fisher**Table 4: Main items of the documents for exemption from deliberation**

Contents	Public	Private	Total	p-value	Contents	Public	Private	Total	p-value
Research subject				1.000 ^a	Consent of subject				0.545 ^a
Yes	4 (50.0)	10 (45.5)	14 (46.7)		Yes	-	3 (13.6)	3 (10.0)	
No	4 (50.0)	12 (54.5)	16 (53.3)		No	8(100.0)	19 (86.4)	27 (90.0)	

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Information of the research supervisor				0.545 ^a	Research grant institution				0.550 ^a
Yes	4 (50.0)	10 (45.5)	14 (46.7)		Yes	-	4 (18.2)	4 (13.3)	
No	4 (50.0)	12 (54.5)	16 (53.3)		No	8(100.0)	18 (81.8)	26 (86.7)	
Route of submission				1.000 ^a	Period of research				0.545 ^a
Yes	-	2 (9.1)	2 (6.7)		Yes	-	3 (13.6)	3 (10.0)	
No	8(100.0)	20 (90.9)	28 (93.3)		No	8(100.0)	19 (86.4)	27 (90.0)	
Co-researcher				1.000 ^a	IRB approval of other institutions				1.000 ^a
Yes	-	3 (13.6)	3 (10.0)		Yes	-	2 (9.1)	2 (6.7)	
No	8(100.0)	19 (86.4)	27 (90.0)		No	8(100.0)	20 (90.9)	28 (93.3)	
Type of research				0.267 ^a	Completed IRB training				1.000 ^a
Yes	1 (12.5)	3 (13.6)	4 (13.3)		Yes	-	1(4.5)	1 (3.3)	
No	7 (87.5)	19 (86.4)	26 (86.7)		No	8(100.0)	21(95.5)	29 (96.7)	
Number of subject				0.155 ^a	Cause of exemption				1.000 ^a
Yes	-	4 (18.2)	4 (13.3)		Yes	4 (50.0)	11(50.0)	15 (50.0)	
No	8(100.0)	18 (81.8)	26 (86.7)		No	4 (50.0)	11(50.0)	15 (50.0)	
Total	8(100.0)	22(100.0)	30(100.0)		Total	8(100.0)	22(100.0)	30(100.0)	
^a Using the exact test of a fisher									

Ethical Clearance: The study was approved by the Institutional Review Board (IRB No. KYU-2019-166-01) of Konyang University.

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Conflict of Interest: Nil

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