

The Roles of an Ethical Review Committee as Perceived by Lay Members

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Abstract

The purpose of this study is to examine an approach to the composition and requisition of the Ethical Review Committee, focusing particularly on lay members.

We conducted a questionnaire survey with lay members of Ethical Review Committees. The questionnaire was structured around four themes, and the secretariats of 498 committees representing all areas of Japan took part in this survey between June and September 2016. We analyzed the data using SPSS Statistics Ver. 24. This study was approved by the Ethical Review Committee of Nagoya University's graduate school of medicine (Approval Number: 15-153).

We obtained responses from 133 lay members (response rate: 26.7%). Lay respondents indicated that the role of lay committee members "to make an informed consent document easily understandable for research subjects" must be prioritized above the members' roles from the social and natural sciences. Lay respondents also concurred that the role "to reserve research subjects' free will of participation in research" must be prioritized over those of the natural science members.

Improving Ethical Review Committees in Japan requires a deeper examination of the roles and functions of all committee members, not merely lay members.

Keywords: ethical review committee, ethical guidelines, lay members, roles

1. Introduction

Most medical research protocols in Japan are reviewed by the Ethical Review Committee (abbreviated as 'ERC'), as stipulated in the Ethical Guidelines for Medical and Health Research Involving Human Subjects (abbreviated as 'Ethical Guidelines') promulgated by the Ministry of Education, Culture, Sports, Science, and Technology, and the Ministry of Health, Labor, and Welfare, in 2014.¹ According to the Ethical Guidelines, it is necessary that any committee shall have a "lay member who can provide a viewpoint both of the general public and research participants (abbreviated as 'lay members')," "experts in natural science, such as medicine and health care professionals (abbreviated as 'medical members')," and "experts in humanities and social sciences, such as professionals in ethics and law (abbreviated

as 'non-medical members'). In other words, opinions are expected from the standpoint of the general public and experts other than medical professionals for ethical review.

Based on this background, we first extracted factors related to the important role of lay members in the ERC and reviewed the literature in accordance with the ethical framework of Emanuel et al.² We found some researchers who focused on lay members' roles in ethical review boards and how lay members' views affect the board dynamics and opinion, and we have summarized them here. Anderson reported that the views of non-scientists and lay members in Australia are important in protecting vulnerable populations.³ Likewise, Lidz reported that lay members, unlike the other members, play a major role in providing general perceptions to medical IRBs (Institutional Review Boards) in the US.⁴ Porter, a researcher of ethical review, showed that the most important role perceived

by the lay members themselves is “expressing opinions in the IRB.”⁵ Along those lines, Muto et al. argued that the minority committee members in Japan (such as lay members) should express their opinions without fear of repercussions, due to the committee’s internal dynamics.⁶ Allison et al. and Klitzman showed that it is particularly important for non-medical members to review informed consent forms in the IRBs in the US.^{7,8} Furthermore, Sengupta et al. reported that non-scientists and non-affiliated members are in the best positions to assess the benefits and risks of research from the patient’s point of view and that the role of lay members is to conduct a safety and risk assessment of proposed research.⁹ Solomon, in kind, suggested that lay members can contribute to the promotion and transparency of the IRB process to the public.¹⁰ Porter posited that unaffiliated and non-scientist members play a major role in publicly disclosing and promoting understanding of research.⁵ In addition, Brown et al. reported that non-scientists should develop their viewpoints of science-society interactions through training and experience, and non-scientists should participate in peer review to provide these viewpoints to scientists.¹¹ Meanwhile, in recent studies on ERCs in Japan, studies that clearly describe the role of lay members in ethical review are very limited, and there is no research that explores who a non-expert is and what is of importance in non-expert participation,

Based on this literature review, we found seven distinct roles lay members provide: (1) articulating “diverse viewpoints,” (2) “expressing their opinions on behalf of research participants,” (3) “developing an easy-to-understand informed consent document for the research participants,” (4) assessing “risk and benefit...of the research protocol,” (5) formulating “selection criteria of the research participants,” (6) maintaining “sufficient transparency of the ERC process,” and (7) supporting research. We selected these seven elements as the basic roles of lay members in ERCs.

Our study aimed to find out how lay members perceive their own roles in ERCs, in contrast to how other members view their respective roles, while also outlining the general composition of an ERC in Japan and the contents of opinions expressed in ERCs.

2. Method

This study was conducted from June to September 2016, using questionnaires distributed by postal mail to the ERC secretariats of 498 committees. The participants were lay members of the ERCs. The questionnaire consisted of four themes: (1) attributes regarding the members and the committees (establishment body, number of lay members, number of reviews per month, delivery date of review documents to members, years of experience as members, gender, age, residential area, and experience as research subjects); (2) recent experiences in the ERC; (3) attitudes toward degree of participation in the ethics review process; and (4) questions about “interests,” “attitudes,” “considerations” as a lay member, as well as questions on role recognition as a lay member.

Questions about role perception of lay members involved 11 items based on the seven role elements derived from the literature review. Moreover, we asked lay members to rate how important they perceived each item to be for each of the three member types: medical, non-medical, and lay members. Participants were identified from the latest member list from the “Clinical Research Ethics Committee Report System” (the Ministry of Education, Culture, Sports, Science, and Technology, and the Ministry of Health, Labor, and Welfare). The committees that had received a “warning” or “caution” that they may violate ethical guidelines were excluded.

Respondents used a 3-point Likert scale from 1 (not particularly important) to 3 (very important) to rate the importance of each role for medical, non-medical, and lay members.

We analyzed the data using SPSS Statistics Ver.24. We conducted a chi-square test to examine the differences in response trends by attributes and a t-test and chi-square test to examine the differences in the role perceptions of lay members.

This questionnaire was conducted anonymously. Consent from the participants was assumed when the completed questionnaire was returned by mail. This research was conducted after receiving approval from the Nagoya University Graduate School of Medical Sciences Bioethics Committee (approval date: April 27, 2016; approval number: 15-153).

3. Results

3.1 Basic characteristics of lay members and committees

We asked a total of 498 ERCs nationwide to distribute the questionnaire to lay members and obtained 133 answers (response rate=26.7%). Table 1 shows the characteristics of the participants and organizations. Regarding the process of appointment as a lay member, we found that 44.4% of the respondents were nominated by other members of the committees to which they belonged, and 33.0% were nominated based on recommendations from friends, acquaintances, and the secretariat of the committee. In addition, 15.0% of the respondents answered, "Because I am an ex officio member, I accepted the position as a committee member." In many ERCs, officers who are in certain positions tend to be assigned as lay members. On the other hand, only one respondent answered, "I applied for membership by myself." The breakdown of the current occupations of the committee members was 47 (42.0%) in clerical positions at hospitals and universities, followed by 20 (17.9%) employed as civil servants and company employees, 15 (13.4%) corresponding to other professions, and 9 (8.0%) in medical/health/welfare professions.

3.2 Experience in ERC

In the questionnaire concerning ethical review items, some lay members reported that they "often look through review items" and that the ethical review items represented a "...burden on participants and expected risks and benefits" (79.7%). Other statements mentioned the ethical review items included "summary and abstract of research protocol" (77.4%), "handling of personal information, etc." (69.2%), and "procedures to obtain informed consent" (63.2%). Less than half of the respondents reported "economic burden and rewards of participants" (42.1%), "selection criteria of participants" (39.8%), and "scientific rationality of research" (24.1%) for the same question.

Table 1: Characteristics of participants and research ethics committees (N=133)

Item	n	(%)
Establishment body		
Educational institution (including university hospital)	30	(22.6)
General medical institution	101	(75.9)
NA	2	(1.50)
Review document type		
Including clinical trials (registration trials)	66	(49.6)
Not including clinical trials (registration trials)	65	(48.9)
NA	2	(1.50)
Number of lay members in committee		
One	27	(20.3)
Multiple	106	(79.7)
Member careers		
Less than 3 years	75	(56.4)
3 years or more	58	(43.6)
Number of reviews per month		
5 or less	71	(53.4)
6 or more	62	(46.6)
Delivery date of review document		
More than 2 weeks before	39	(29.3)
One week before	88	(66.2)
Same day (no advance distribution)	6	(4.5)
Gender		
Male	76	(57.1)
Female	57	(42.9)
Age group		
Under 59 years old	95	(71.4)
60 years old and over	38	(28.6)
Residential area		
Neighborhood of site	119	(89.5)
Other	14	(10.5)
Research subject experience		
Yes	9	(6.8)
No	124	(93.2)

3.3 Participation in ethical review

In this survey, 106 (79.7%) respondents reported "expressing opinions at least once" during a meeting of the ERC. The most frequent lay members' comments were regarding "how to obtain consent from the research participants" (69.8%), followed by "research safety" (42.5%). Meanwhile, the item with the lowest frequency of

comments was “medical terms” (19.8%), followed by “how to select study participants” (21.7%).

A significant association was found between years of experience and comments in the review process ($p < .01$). Members with 3 years of experience or more tended to comment more about medical terms and research safety than members with less than 3 years of experience (Table 2). Regarding basic characteristics of members and committees (type of establishment, number of lay members, number of committee members, number of reviews per month, date of acquisition, member years of experience, gender, age, residential area, and subject experience), we found a significant association only between years of experience and comments.

3.4 Lay members’ “interests,” “attitudes,” “considerations,” and role perception

We asked the lay members about their “interests,” “attitudes,” and “considerations,” and asked them to rate items on a 4-point Likert scale from 1 (absolutely not applicable) to 4 (very applicable) (Table 3). Among the results were statements such as “I am always interested in society’s movements such as politics, economics, and international issues” had the highest average score of 3.28, followed by “I am conscious of being an ‘ordinary citizen’ in the ethical review process” with 3.24, and “I am always interested in medical news” with 3.23. On the other hand, “I think that the conclusion does not change even if I speak during the ethical review process” had an average score of 2.27, and “I sometimes feel there is insufficient deliberation time per case” was 1.98.

Table 4 shows lay members’ perceived importance of each role as played by lay members themselves, non-medical members, and medical members. Among the roles of lay members, the highest average score was 2.85 for “To review the informed consent form with easy-to-understand words for research participants,” followed by 2.77 for “To investigate whether research risks and benefits are clearly conveyed to the participants in an easy-to-understand manner,” and 2.75 for “To confirm whether the protection of the personal information of research participants is properly explained.” Regarding the importance of roles of non-medical members as perceived

Table 2: Content of lay members’ comments according to years of experience

	Expressing opinions	Years of experience		χ^2	p
		<3	≥3		
Medical terminology	Yes	5	16	10.765	.001**
	No	70	42		
Selection policy of study participants	Yes	9	14	3.369	.066
	No	66	44		
Informed consent	Yes	39	35	.923	.337
	No	36	23		
Safety	Yes	17	28	9.582	.002**
	No	58	30		
Other	Yes	10	14	2.582	.108
	No	65	44		

** $p < .01$

Table 3: Lay members’ “interests,” “attitudes,” and “considerations”(N=133)

	Mean*	SD
I am interested in politics, economics, and international issues, from a generalist point of view.	3.28	0.542
I am interested in medical news from mainstream media sources for the public.	3.23	0.611
I regularly study medical terms and the medical system.	2.26	0.765
I usually consider legal terms.	2.14	0.750
I ask questions if in doubt.	2.96	0.722
I actively participate in local events (local residents’ associations, festivals, school events, etc.).	2.60	0.852
I am conscious of “grasping the viewpoint of the research subject” when reading ethics review materials and during meetings.	3.02	0.853
I think that the determination of a case does not change, even if I speak during the ethics review process.	2.27	0.789
I am conscious of being a “patient representative” in the ethics review process.	2.96	0.848
I am conscious of being an “ordinary citizen” in the ethics review process.	3.24	0.750
I sometimes feel there is insufficient deliberation time per case.	1.98	0.657

*Average score for each item; scores range from 1 (absolutely do not apply) to 4 (very true).

Table 4: Roles of lay, non-medical, and medical members as perceived by lay members

Roles	Member type	Very	Somewhat	Not	Mean	SD	<i>t</i> Lay vs. Non-M	<i>t</i> Lay vs. Medical
1) Safety and validity of research	Lay	53	62	14	2.30	0.66	-4.08**	-11.54**
	Non-M	46	53	4	2.41	0.57		
	Medical	103	3	0	2.97	0.17		
2) Communication of risks and benefits	Lay	101	31	0	2.77	0.43	1.04	0.95
	Non-M	78	26	0	2.75	0.44		
	Medical	77	28	0	2.73	0.44		
3) Ethical problems	Lay	87	41	2	2.65	0.51	-5.92**	0.19
	Non-M	100	7	0	2.93	0.25		
	Medical	67	36	1	2.63	0.50		
4) Legal matters concerning research	Lay	24	78	24	2.00	0.62	-17.41**	-6.13**
	Non-M	100	7	0	2.93	0.25		
	Medical	38	62	3	2.34	0.53		
5) Appropriateness of protection of personal information	Lay	98	31	1	2.75	0.45	-3.75**	2.23
	Non-M	99	8	0	2.93	0.26		
	Medical	63	39	2	2.59	0.53		
6) Informed consent form provision	Lay	112	18	1	2.85	0.38	6.23**	4.11**
	Non-M	61	42	2	2.56	0.54		
	Medical	68	36	1	2.64	0.50		
7) Compensation for adverse events	Lay	67	55	8	2.45	0.61	-6.71**	-1.24
	Non-M	93	12	1	2.87	0.37		
	Medical	63	38	4	2.56	0.57		
8) Social significance of research	Lay	39	72	17	2.17	0.64	-5.44**	-6.55**
	Non-M	61	41	4	2.54	0.57		
	Medical	74	31	1	2.69	0.49		
9) Fair selection of participants	Lay	56	58	13	2.34	0.66	-3.55**	-3.55**
	Non-M	66	33	4	2.60	0.57		
	Medical	67	33	2	2.64	0.52		
10) Respect for free will	Lay	88	35	6	2.64	0.57	-1.00	2.69*
	Non-M	79	26	0	2.75	0.43		
	Medical	57	47	0	2.55	0.50		
11) Contribution to further development of research	Lay	23	75	29	1.95	0.64	-2.95**	-16.55**
	Non-M	21	63	19	2.02	0.63		
	Medical	100	5	0	2.95	0.21		

p: Bonferroni correction value. **p*<.05, ***p*<.01

Each role is a shortened version corresponding to the following 11 forms of concrete roles: 1) To examine the safety and validity of research; 2) To investigate whether research risks and benefits are clearly conveyed to the participants in an easy-to-understand manner; 3) To confirm whether there is an ethical problem; 4) To focus on the legal matters concerning research; 5) To confirm whether the protection of the personal information of the research participants is properly explained; 6) To ensure the informed consent form has easy-to-understand words for research participants; 7) To review whether appropriate compensation for adverse events is provided; 8) To review the social significance of the research; 9) To judge whether participants are selected fairly; 10) To examine whether free will in research is protected; 11) To confirm contributions to further research development.

List of abbreviations used in this figure: Lay: lay member; Non-M: non-medical member; Medical: medical member; Very: Very important; Somewhat: Somewhat important; Not: Not particularly important.

by lay members, “To confirm whether there is an ethical problem” had the highest score with 2.93, followed by “To focus on the legal matters concerning research” with 2.93, and “To confirm whether the protection of personal information of research participants is properly explained” with 2.93. As to the importance of roles of medical members as perceived by lay members, “To examine the safety and validity of research” had the highest score with 2.97, followed by “To confirm contribution to further research development” with 2.95, and “To investigate whether research risks and benefits are clearly conveyed to the participants in an easy-to-understand manner” with 2.73.

We compared the perceived importance of the roles of lay members and non-medical members. As shown in the right column of Table 4, “To confirm whether there is an ethical problem,” “To focus on the legal matters concerning research,” “To review whether appropriate compensation for adverse events is provided,” and “To review the social significance of research” were the roles perceived as more important for non-medical members than for lay members ($p < .01$). On the contrary, “To review the informed consent form with easy-to-understand words for research participants” was regarded as a more important role for lay members than for non-medical members ($p < .01$).

Further, comparing the roles of lay members and medical members, respondents perceived the following roles as more important for medical members than for lay members: “to examine the safety and validity of research,” “to focus on the legal matters concerning research,” and “to review the social significance of research” ($p < .01$). The items “to review the informed consent form with easy-to-understand words for research participants” and “to examine whether voluntariness in research is protected” were more strongly perceived as being their roles rather than those of the medical members ($p < .01$, $p < .05$).

4. Discussion

4.1 Experience of lay members

As shown in Table 1, many of the participants had 3 years or more of experience in ethical reviews. The terms of committee membership are not clearly specified in any ethical guidelines, but

according to the report by Lidz et al., the longer community members participate in an IRB, the more their activities begin to look similar to those members with scientific backgrounds. If so, this raises the possibility that the term of office for community membership in an IRB should be limited to preserve that perspective.⁴ Kuyare et al. also suggested that experience is sometimes counterproductive to their roles as representatives of research participants and the community, and their capacity to represent the community will be lost when they gain more experience and knowledge.¹²

In our survey, the lay members with more experience tended to provide more opinions concerning medical terminology and safety of research (Table 2). This suggests that with more experience in research ethics reviews, lay members’ opportunities to hear and learn from the opinions of other members in medicine, law, ethics, etc. would increase, and this might influence their perceptions and behaviors concerning their role as representatives of research participants. This result suggests that it is necessary to reconsider, for the foreseeable future, the role of lay members from many viewpoints.

4.2 Reasons to be appointed as lay members and independence from the ERC

Regarding the question about reasons for becoming a member of the ERC, we found that almost all lay members answered, “Because I was appointed from an institution by a request from the committee/chairperson, friends/acquaintance/secretariat” or “Because I am an ex officio member; I accepted the position as a committee member.” According to Klitzman, committee members in America are often selected in unsystematic ways.⁸ In Kuyare’s research as well, for about one third of the respondents, there was no reason (or motivation) on their part, and they were appointed by the institution based on the opinion of the chairperson or the heads of institutions.¹² Setoyama also stated that such a situation is inevitable in Japan.¹³ Under the present circumstances, the systems and methods for appointing ERC members are based on public recruitment of lay members or resulting from

ERC applicants' free will. We agree that such a way of appointing a committee is unavoidable to some extent. Lemmens et al., on the other hand, asserted that the independent IRB structure is an important component of a reliable review system.¹⁴ The compositional requirement of the committee according to the ethical guidelines clearly distinguishes lay members from members of medicine, the humanities, and the social sciences; thus, further discussion is necessary to examine the adequacy of the current situation.

In addition, the results of this survey show that although their number was small, there were some lay members who were currently working as medical/health/welfare professionals and others who had retired from positions as medical professionals, legal/religious experts, and hospitals and university clerks. As mentioned above, given the ethical guidelines' requirements to clearly distinguish lay members from non-medical and medical committee members, we think further discussion is necessary. Therefore, defining the recruitment process for lay members is an important challenge.

4.3 Role of lay members in the ERC

The Ethical Guidelines state that the position of lay members as advocates of research participants must be occupied by those who can objectively speak out and inquire. This includes, for instance, questions of whether documents such as informed consent forms, which include research content, are generally understandable to research participants with little knowledge of medical research.

Klitzman suggested that the roles lay members would take vary widely, from reading the informed consent form to reviewing the whole research plan.⁸ Similarly, Sengupta et al. stated that the role of lay members should be extended beyond the review and editing of the informed consent form.⁹ In research in Japan as well, Suzuki et al. stated that it is necessary to educate lay members about their roles, the function of the ERC, the justification of the research, and its risks and benefits.¹⁵

In the next section, we discuss the seven elements of the roles lay members extracted from the literature review: "diverse viewpoints," "expressing their opinions for the research

participants," "developing an easy-to-understand informed consent document for the research participants," "risk and benefit assessment of the research protocol," "selection criteria of the research participants," "sufficient transparency of the ERC process," and "support research."

4.3.1 Diverse viewpoints

According to the Ethical Guidelines, lay members are required to adopt "viewpoints of research participants" and to act accordingly.¹ In addition, Shirai and Gamo in Japan, as well as Staley, have shown that diversity and representation are important aspects of the role of lay members.^{16,17,18} However, each research subject is selected according to the specific selection criteria for participation in the research. Therefore, research participants have various backgrounds and values. Consequently, how can lay members adopt the viewpoints of research participants? In this study, we examined the lay members' daily "interests," "attitudes," and "considerations."

We found that relatively high scores were shown for the items "I am always interested in society's movements, such as politics, economics, and international issues," and "I am always interested in medical news" (Table 3). There was only one lay member who had experience as a participant of clinical research among the 133 respondents. On the other hand, the items "I am conscious 'of grasping the viewpoint of the research subject' when reading ethical review documents and during meetings," "I am conscious of being a 'patient representative' in the ethical review process," and "I am conscious of being an 'ordinary citizen' in the ethical review process" showed relatively high scores (Table 3). In relation to this result, in a study by Allison et al., 60% of non-scientist members and 81% of medical members answered "yes" to the question "Do non-scientist members represent community viewpoints, values, and standards?"⁷ Although the results of this survey also showed that there was only one lay member who had experience as a participant in clinical research, the members were aware of being a "representative of patients" in ethical reviews, as well as "citizens." This is in accordance with the results of Allison et al.⁷ It was shown that the lay members were trying to maintain "the viewpoint of the research subject" as much as possible. Hung et al. also stated

that if bonding and bridging relationships are established among lay members, staff members of the IRB, other committee members, and research participants, a more careful examination process will be enhanced.¹⁹ It was expected that lay members, who can more easily relate to research participants than other committee members, would mediate with other committee members wanting to promote research by providing the viewpoints of patients/citizens in the ethical review process and considering ethical values and a sense of value necessary to maintain a balance.

4.3.2 Expressing opinions

In this survey, many lay members reported “Expressing opinions” in ethical reviews. Respondents showed high scores on the item “I ask questions positively if in doubt” (Table 3). Meanwhile, the score for the item “I think that the conclusion does not change even if I speak during the ethics review process” was low (Table 3). From these results, it seems that the lay members were able to express their doubts and make comments in a positive manner, while also feeling their opinions were respected.

The Council for Science and Technology Bioethics and Safety Committee report stated that it is not easy for lay members to express opinions and discuss things on the same level as members belonging to universities and research institutions.²⁰ There is also a report from Setoyama showing that lay members in Japan feel that their role in the committee should be “to meet the quorum of the committee.”¹³ On the other hand, it was reported that lay members felt their opinions were respected when the chairperson understood them well.²¹ Therefore, it is expected that lay members will participate more if there is an atmosphere that facilitates and respects their opinions.

4.3.3 Review of the informed consent form

In the ethical review of clinical research documents, the informed consent form is kept at hand by the research participants and is an important research program document to which they can refer at any time. In previous studies, the main responsibility of the lay members was found to be reviewing the informed consent forms.^{5,7} In this survey, more than half of the respondents said they made comments on

informed consent in the deliberations. Therefore, discussion of informed consent forms and related comments would be the main role of lay members. In addition, it was shown that the review of informed consent forms among the other roles in the ethical review was perceived as more important for lay members than for other members (Table 4).

Gamo identifies “plain language” and “sincerity” as necessary, while showing that uniform criteria regarding the information that should be provided in the informed consent form are difficult to construct.¹⁷ According to the results of this survey, the technical knowledge and ability of lay members was not clear. Lay members considered the following questions, “What kind of words do you not understand?” and “What kind of expressions would make it a more descriptive explanatory document?” The survey results revealed the fact that lay members considered the standpoints of research participants, tried to help them understand the research, and sincerely tried to respect their free will.

Meanwhile, Speers et al. stated that it is unacceptable to limit the duties of members who represent the perspectives of participants to reviewing consent documents.²² Based on the results of this survey, it is necessary to discuss the role of other committee members, since many lay members perceive it is their role, rather than that of other members, to review informed consent forms.

4.3.4 Risk and benefit evaluation

As shown in Table 4, the lay members perceived that “To investigate whether research risks and benefits were clearly conveyed to the participants in an easy-to-understand manner” was a role equally important for lay, non-scientist, and medical members. On the other hand, reviewing documents regarding the “outline and summary of research protocol” and “burdens on research participants and the expected risks and benefits” was perceived as primarily the role of lay members.

However, of the lay members who directly made comments about “research safety,” less than half of them confirmed “expressing opinions” during an ERC meeting. Because many lay members in this study perceived reviewing the

safety and validity of research to be a role of medical members, we believe that it is necessary to help facilitate the expression of opinions in these matters by lay members.

4.3.5 Appropriateness of ethical review

In this research, “Selection of participants” in terms of selection criteria was investigated as an item related to the appropriateness of the ethical review. Fair selection of research participants from the population is stated in the Belmont Report’s “Justice” principle²³ and the ethical framework of Emanuel et al.’s principle “Fair subject selection.”² However, when we asked lay members to what extent they were in charge of the ethical review of fair subject selection, the score was low.

In addition, the number of respondents who made comments in ethical reviews regarding “how to select research participants” was low. However, the selection policy for research participants in the research protocol, that is, the setting of inclusion/exclusion criteria, and the feasibility of conducting research including recruitment is designed for consideration of scientific evidence for the research. Therefore, it may be difficult to seek the opinions of lay members.

4.3.6 Transparency of the review process

Publishing the social value of research derived from the process of ethics examination and research results to society is related to the principle of “social or scientific value” in Emanuel et al.’s study.² In the present study, we investigated the importance of reviewing the social significance of research by lay members. In the perception of the lay members, this role was more appropriate for non-medical and medical members than for lay members (Table 4).

As mentioned by Porter, lay members also have the role of disclosing the process of the ethical review and promoting the understanding of public citizens and research candidates.⁵ From this, it is considered that lay members, as well as non-medical and medical members, should play a role in publicizing the research results. In this survey, it was found that lay members perceived that their role was limited; therefore, as indicated in previous studies, it is important to enhance the perception of their role.

4.3.7 Support research

Among the roles of lay members, “Contributing to the further development of research” had significantly lower scores than other roles (Table 4). The reason for this is that lay members perceived this role to be more appropriate for medical members, who are specialists in medicine and occupy the majority of positions in the ERCs. Similar to the discussion for the item “Transparency of the review process” regarding how medical research is performed, it was shown that it is important for lay members to actively review how the medical research is performed, with what kind of target group, how it is implemented, and how the results are made accessible to the public.

4.4 Limitations

In this survey, the sample size was small (response rate=26.7%), though participants were identified from the latest member list from the “Clinical Research Ethics Review Committee Report System” (Ministry of Education, Culture, Sports, Science, and Technology, and the Ministry of Health, Labor, and Welfare). Therefore, our results cannot be generalized to Japan as a whole.

5. Conclusion

The results of this survey suggest that, among all the roles in the ethical review process, according to respondents, the review of informed consent forms was more appropriately performed by lay members than by non-medical and medical members. Moreover, according to the lay members, the roles of non-medical members included “To confirm whether there is an ethical problem,” “To focus on the legal matters concerning research,” “To review that appropriate compensation for adverse events is provided,” and “To review the social significance of research.” Medical members, for their part, were “to examine the safety and validity of research,” “to focus on the legal matters concerning research,” and “to review the social significance of research.” However, the lay members were fully conscious of their roles of providing “diverse viewpoints,” “expressing opinions,” and performing “risk and benefit assessment,” and it

was shown that this contributes to the protection of the research participants.

In addition, the results of this survey suggest that the years of experience of lay members and their positions in organizations would affect their performance as representatives of the research participants. It was also revealed that a small number of lay members were, or had been, medical/health/welfare professionals, experts in law and religion, and clerks of hospitals and universities. Although the Ethical Guidelines do not clearly state what kind of individuals should become lay members, they are expected to have different roles from those of non-medical and medical members. From now on, it is necessary to clarify what kind of roles lay members have and what actions are appropriate so that they can fulfill their duties as adequate representatives of research subjects with diverse viewpoints.

Conflict of interest

There are no entities or relationships, etc., presenting a potential conflict of interest requiring disclosure in relation to this paper.

Notes

- This article is an English version of a Japanese article published in the academic journal of the *Japanese Association for Philosophical and Ethical Research in Medicine's Medical Philosophy/ Medical Ethics*. The editorial chairperson has authorized this journal to publish it.
- This paper is part of a master's thesis submitted to Nagoya University Graduate School of Medical Sciences Categories.

Endnotes

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