

The role of nursing members in research ethics committees in Japan

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ABSTRACT

The International Council of Nurses (2012) and the Council for International Organizations of Medical Sciences (2016) determined and published ethical standards relevant to nursing researchers and practitioners; based on these standards, nurses are expected to participate in committees where decisions on ethical issues are made. While clinical practitioners and nursing educators actively serve on research ethics committees, their precise role in these platforms has yet to be elucidated. In this study, medical, humanities/social science, lay, and nursing members in research ethics committees across Japan were invited to participate in a semi-structured interview; data were analyzed through a qualitative analysis method. Specifically, we interviewed 23 research ethics committee members in Japan to clarify the role of nursing members in the committee. Our qualitative analysis yielded six themes: share perspectives and experiences in nursing, protect research participants, evaluate the research design, represent the voice of research participants, confirm the informed consent documents and ascertain research participants' free will. The analyses revealed a slight difference between what other committee members expected of the role of nursing members and nursing members' recognition of their own role. Nursing members make an important and independent contribution to ethics committees on deliberations and decision-making regarding research ethics. Within the context of research ethics committees, member selection and training are essential issues, and this study contributes to the literature by showing how these topics relate to the role of the research ethics committees and of their members.

Keywords: research ethics, ethics committee, nurse

Abbreviations:

REC: research ethics committee

MED: medical member

HAS: humanities/social science member

NRS: nursing member

LAY: lay member

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INTRODUCTION

To conduct medical research, researchers need ethical review and approval, which is provided to them by research ethics committees (RECs); hence, in order to ensure the effective review of medical research proposals, the selection of REC members needs to be conducted with care and excellence. Although RECs in the medical sciences originate as committees of colleagues (often comprising physicians and scientists) that provide peer reviews, the Council for International Organizations of Medical Sciences¹ guidelines require them to be composed of expert physicians and experts from various related professions.

In the case of Japan, the committee members are required to be experts in the natural sciences (eg, medicine and pharmaceuticals, namely medical members) and humanities/social science (eg, lawyers and ethicists).^{2,3} In this context, the World Health Organization⁴ published the *Standards and Operational Guidance for Ethics Review of Health-related Research with Human Participants*, and the Steering Committee on Bioethics⁵ published the *Guide for Research Ethics Committee Members*. Additionally, the International Council of Nurses⁶ and the Council for International Organizations of Medical Sciences¹ determined and published ethical standards relevant to nursing researchers and practitioners; they described that nurses are expected to participate in committees where decisions on ethical issues are made. However, research on the particular role of nursing members is scarce; and these members tend to be grouped under the category of “medical members;” and although clinical practitioners and nursing educators actively serve on RECs, their precise role in these platforms has yet to be elucidated. Therefore, in this study, we interviewed Japanese REC members about their expectations of the role of nursing members in RECs, and interviewed the latter on their recognition of these roles.

The role of REC members has been discussed in various countries. The Canadian researchers Cook et al⁷ argued that the role of REC members differed by a country’s health system and care provision. Hemminki⁸ who examined regulatory requirements for clinical research in Finland, England, Canada, and the United States, showed that research ethics, law, medicine, and nursing specialists were appointed to the general committee differently by country. Moreover, Janssens et al⁹ surveyed REC members in the Netherlands and found that their roles were those of protectors, facilitators, educators, advisors, and assessors. However, these roles apply to the committee as a whole, not to potential roles of nursing members. Considering this, our study reviewed the literature on nurses’ roles in RECs.

Cassidy and Oddi¹⁰ discovered that choosing female nurses to serve on these committees might help fulfill the requirements of gender balance. Further, Rothstein and Phuong¹¹ revealed that, of the various REC members, nurses were the most interested in ethics issues. However, the extent of nurses’ understanding of research ethics guidelines might be relatively low,¹²⁻¹⁵ suggesting that it is important to clarify the role of nurses in RECs.

The concept of roles includes role expectations and role recognition. Mead¹⁶ suggests that roles are tried, confirmed, and modified through the process of social interaction, which is the process by which we accept the expectations of others (society) into ourselves. For example, in a REC, members can improve the quality of the determinations of the committee by using their professional expertise to fulfill specified roles and respond to other REC members’ expectations. Therefore, we considered that Mead’s concept of roles could be useful to clarify the roles of nursing members in RECs.

MATERIALS AND METHODS

Medical, humanities/social science, lay, and nursing members in RECs across Japan were invited to participate in a semi-structured interview. We analyzed the interview data through a qualitative analysis method. The Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist¹⁷ and the Standards for Reporting Qualitative Research (SRQR) criteria¹⁸ were referenced to ensure qualitative analysis validity.

Participants and data collection

In Japan, there are Certified Review Boards (CRBs) approved by the Ministry of Health, Labour and Welfare based on the Clinical Research Act (2017).³ A purposive sampling method was used to obtain a sample of participants under the following criteria. First, organizations with an established CRB were selected. Second, organizations that conducted more than 10 review meetings every month on various medical research were selected. Third, organizations that did not include expert members with more than two years of experience in CRBs and lay members were excluded. We then examined the list of committee members and, based on specific criteria, strategically selected the participants to avoid overrepresenting any gender or committee type. In this study, 26 committee members from 10 CRBs were approached; 23 members belonging to 10 organizations participated. The participants were categorized into four committee types: medical members, humanities/social science members, lay members, and nursing members.

An interview guide was developed for this study that included the following content. First, each interviewee provided personal information regarding committee type, the number of years as a member, age, and academic and professional background. Next, the medical, humanities/social science, and lay members were asked about their expectations regarding nursing members' roles and functions in the committees, and nursing members were asked about their recognition of their own role. The interviews were conducted between May 2018 and April 2019; the average interview time was approximately 58 minutes.

Data analysis

All interviews were transcribed verbatim from audio recordings. The transcripts were then read verbatim multiple times and explored using free coding to include the smallest unit spoken.¹⁹ The coding focused on extracting the participants' thoughts regarding role expectations for nursing members, nurses' recognition of their REC role, and the characteristics of members other than nurses. The extracted codes were categorized and organized into themes according to the similarity of the semantic content. The analysis employed content²⁰ and comparative analysis²¹ methods. To ensure quality, nine research participants performed data checks (including three researchers who had published academic papers on qualitative research), and the transcripts, analytical processes, and results were evaluated, confirming the rigor of the study's results.²² This content analysis was performed by a team with experience in qualitative research, one of whom has experience as a REC chairperson and the other in REC monitoring.

Ethical considerations

The Bioethics Review Committee of Nagoya University (approval number 17-170) approved this study. The study was carried out in accordance with the 1964 Declaration of Helsinki and its later amendments. Written informed consent was obtained from all participants, and all participants agreed to be audio-recorded before the interview. All personal information, such as institution names and individual identifiers, were deleted from the data when the verbatim records were created. Instead of original committee types, anonymization was performed using "MED"

number codes for medical, “HAS” number codes for humanities/social science, “NRS” number codes for nursing, and “LAY” number codes for lay members.

RESULTS

In total, 23 REC members were interviewed, including six MED members, five HAS members, five LAY members, and seven NRS members (Table 1). In this study, one code was counted only once throughout the transcription data of each research participant. The analysis extracted 187 codes that were organized into six themes: share perspectives and experiences in nursing, protect research participants, evaluate the research design, represent the voice of research participants, confirm the informed consent documents and ascertain research participants’ free will. Table 2 presents the themes and subthemes of nurses’ REC roles by committee member type. The following describes, by theme and subtheme, the role expectations outlined by non-nursing members (medical, humanities/social science, lay members) and the role recognition of nursing members.

Table 1 Participant characteristics (*N* = 23)

Characteristic		<i>n</i>
Gender	Male	12
	Female	11
Committee member type	Medical (MED)	6
	Humanities/social science (HAS)	5
	Layperson (LAY)	5
	Nurse (NRS)	7
Number of years as a member	3 or less	7
	4–6	6
	7 or more	10
Age	40–49	5
	50–59	12
	60 or older	5
	Missing	1
Specialization^a	Medical science	5
	Pharmacy	1
	Ethics	3
	Sociology	1
	Law	1
	Nursing	7
Affiliation	University	15
	Medical Research Center	8

^a The lay members were omitted.

Table 2 Themes and subthemes with the number of codes referring the role of nursing members in research ethics committees

Theme	Subtheme	MED ^a	HAS ^b	LAY ^c	NRS ^d
Share perspectives and experiences in nursing	Use specific nursing knowledge and clinical expertise	2	3	2	1
	Share expertise and the nursing perspective	4	3	3	0
	Clarify the differences between nursing and other professional healthcare perspectives	1	3	2	1
	Support advisory committees regarding nursing research proposals	3	3	0	5
	Provide medical and research information to non-medical members	1	1	3	0
	Express opinions	1	2	3	0
Protect research participants	Predict the possible burden of participation on research participants	5	3	4	4
	Evaluate their risks and benefits	5	1	1	0
	Propose ways to lessen the burden on the participants	2	2	1	0
	Support research participants' interests	4	0	1	2
	Assess the protection of research participants' rights	0	1	1	5
Evaluate the research design	Evaluate the research design	2	1	0	4
	Consider whether the research can be conducted	1	1	2	2
	Inspect the research proposal for contradictions and flaws	5	2	0	1
	Clarify the distinctions between medical practice and the research protocol	4	0	1	1
	Assess the work burden of clinical nurses	2	0	0	2
Represent the voice of research participants	Speak on behalf of research participants	3	4	3	2
	Assume research participants' thoughts	2	1	2	0
	Act as bridge between research participants and healthcare professionals	2	1	1	3
Confirm the informed consent documents	Confirm that research participants can understand the informed consent documents	4	2	2	5
	Examine the appropriateness of the informed consent documents for participants	0	3	0	1
	Ensure that participants receive all necessary information	2	0	0	5
Ascertain research participants' free will	Ascertain research participants' free will to participate in research	1	1	2	6
	Assess research participants' ability to consent	3	2	0	4

^a Number of codes answered by medical members

^b Number of codes answered by humanities/social science members

^c Number of codes answered by lay members

^d Number of codes answered by nursing members

Share perspectives and experiences in nursing

This theme has six subthemes. Nurses were expected to use their nursing experience in multiple clinical departments and talk about this experience to help the review committee and fulfill their role of using nursing expertise (MED16, LAY20, MED03, HAS02, HAS04). A HAS member stated, “Nursing care covered patients’ families, healthy people, and communities; therefore, nurses would have unique perspectives that are not observed in other healthcare fields” (HAS22). Therefore, nurses were expected to share their broad perspectives to help in discussions. Moreover, many LAY members expected NRS members to provide information (eg, explaining medical terms and patients’ feelings and requests) to the non-medical members during research ethics discussions (LAY14, LAY05, LAY10) and share this information in response to other members’ requests. A LAY member stated, “I prefer the nurse to explain how the patient feels and requests. Providing such information is helpful” (LAY10).

Regarding the subtheme, “support advisory committees regarding nursing research proposals,” NRS members recognized that their role included explaining nursing research methods and interpreting nursing researchers’ explanations to other committee members (NRS01, NRS06, NRS18). MED and HAS members confirmed that they expected nurses to explain nursing research methods to other committee members and provide a perspective when nursing research was discussed (MED08, HAS23).

The subthemes, “share expertise and the nursing perspective,” “provide medical and research information to non-medical members,” and “express opinions” were expectations that only other committee members placed on nurses’ roles, as the nurses themselves did not recognize them. Regarding these themes, several NRS members said, “When I was appointed as a member of the committee for the first time, I did not have the opportunity to receive education and training by specialty or type of committee member.”

Protect research participants

This theme has five subthemes. The MED and HAS members were particularly interested in nursing members’ prediction of the burden of participation, or the physical burden associated with clinical research, or even on the daily life of research participants and their families and caregivers (MED07, HAS23). One HAS member stated, “Regarding nursing, nurses receive a lot of nursing education, not only for patient care but also the family member and caregiver support. Therefore, I think it is useful that they point out possible burdens from that point of view (HAS23).” Regarding the subtheme “predict the possible burden of participation on research participants,” NRS members recognized that their role included considering the overall influences on the research participants and predicting the physical and mental burden associated with the research procedure (NRS01, NRS18).

Further, in the subtheme, “evaluate their risks and benefits,” the nurses’ role was to evaluate the risks and benefits of research participation, particularly those specified by the MED members. This role required the nurses to infer the research participants’ physical and mental condition and examine whether the clinical trial problems are acceptable (MED07, MED11, MED12). Nonetheless, this expectation that nurses had to “evaluate their risks and benefits” was exclusive to committee members other than nurses, as nurses did not recognize this role. Moreover, nurses were expected to propose ways to reduce the disadvantages of research from a nursing perspective (MED12, HAS15). However, the subtheme “propose ways to lessen the burden on participants” was not expressed in the role recognition of the nurses. Regarding the subtheme, “support research participants’ interests,” the MED members were mostly interested in nurses’ communicating opinions that are easy for laypersons to understand instead of healthcare professionals’ opinions (MED08). Regarding this subtheme, NRS members recognized that their role included taking the

side and considering the perspective of research participants (NRS09, NRS21). Finally, regarding the subtheme, “assess the protection of research participants’ rights,” NRS members recognized that their role included investigating the violation of rights and ensuring the protection of research participants (NRS06, NRS17).

Evaluate the research design

This theme has five subthemes. The MED and HAS members expected the nursing members to “evaluate the research design” (MED12, HAS23). Regarding this subtheme, NRS members recognized that their role included evaluating the validity of research methods and confirming the appropriateness of research data management (NRS01, NRS06). The subtheme, “consider whether the research can be conducted,” was based on the feasibility of the research participants (HAS23, MED16). Regarding this subtheme, NRS members recognized that their role included confirming that the clinical research implementation procedure was a plan that could be implemented smoothly and pointing out problems in the actual research implementation scenario (NRS17, NRS18). Further, MED members considered that nurses had to “inspect the research proposal for contradictions and flaws,” deeming this as a significant role of nurses in the REC; it included pointing out discrepancies in the proposals’ explanations and flaws in the research design (MED08, MED11). The NRS members recognized that their role included seeking discrepancies between descriptions in research protocols and informed consent documents, as well as unusual things buried in the standard procedures (NRS06).

MED members also expected nurses to “clarify the distinctions between medical practice and the research protocol,” deeming this a significant role of nurses in the REC (MED12, MED07); specifically, these MED members described that they expected nurses to ask researchers to explain the standard treatment of participants, invasive trials, and determine, from the participants’ standpoint, whether there was a burden above that of normal medical practice. A MED member stated, “Invasive trials inevitably burden the participants. I always think that it is the nurse who can assess patients’ best interests based on whether the burden is very different from the normal medical practice” (MED07). Regarding this subtheme, NRS members recognized that their role included verifying that differences between normal medical practice and research are explained and the number of visits to the research program (NRS09). In practice, clinical nurses sometimes participate in research studies as collaborators. The next subtheme was the nurses’ role to “assess the work burden of clinical nurses” based on feasibility for the research participants. The MED members indicated that nurses should “assess the work burden of clinical nurses” to determine whether they could perform research responsibilities along with their nursing care duties (MED03), and NRS members recognized that their role included confirming that there was no overload on nurses in clinical research practice (NRS09, NRS17).

Represent the voice of research participants

This theme has three subthemes. Regarding the subtheme, “speak on behalf of research participants,” HAS members said they expected nurses to explain patients’ pain, suffering, and personal characteristics from a nursing perspective (HAS02). Additionally, NRS members recognized that their role included speaking on behalf of the participants and communicating the latter’s feelings (NRS06, NRS18). Moreover, the role “assume research participants’ thoughts” pertained to nurses being expected to understand the research participants’ anxiety, concerns, and thoughts from an intimate nursing perspective (LAY14, MED16). However, this subtheme was not expressed in the role recognition of the nurses. Finally, the role “act as a bridge between research participants and healthcare professionals” pertained to bridging the common differences between laypersons and healthcare professionals by interpreting both their perspectives (MED07, LAY10).

Confirm the informed consent documents

When conducting research in Japan, the following items should be included in the informed consent documents: information on research purpose, significance, methods, predicted results (including both risks and benefits of the results), the potential burdens on the participants, among others.^{2,3} Therefore, this theme with three subthemes were extracted. In the subtheme, “confirm that research participants can understand the informed consent documents,” both the MED and LAY members expected nursing members to paraphrase the terminology in the explanatory document appropriately for participants. Concerning the informed consent document, a MED member stated, “We want to simplify descriptions that are difficult to understand. They tend to be written in medical terms” (MED03). NRS members recognized the meaning of this role in the same way as non-nursing members (NRS06, NRS17).

Regarding the subtheme, “examine the appropriateness of the informed consent document for participants,” nurses were expected to confirm that the provided information matches the disability characteristics and understanding of research participants (eg, visual disturbance, personal characteristics, and intelligence of research participants). Regarding this subtheme, an NRS member stated, “This includes checking that an appropriate informed consent is provided according to the participants’ cognitive function and providing opinions about the format of an appropriate informed consent document according to the disability characteristics, such as layout and character” (NRS18). Finally, regarding the subtheme, “ensure that participants receive all necessary information,” nurses were expected to confirm that the information provided to the research participants was sufficient when there were potential side effects or risks (MED03). NRS members recognized that their role included verifying that the informed consent documents indicated when and what would be occurring and ensuring that the expected benefits were not exaggerated (NRS01, NRS17).

Ascertain research participants’ free will

This theme has two subthemes. All the non-nursing members indicated that the nurse’s role should include the subtheme, “ascertain research participants’ free will to participate in research.” This role entails protecting research participants by confirming that the physician-patient relationship in regular medical practice will not induce research participation and that consideration is given to eliminating paternalism when consenting to participate (LAY05, MED11). NRS members recognized that their role included verifying that the participants did not feel compelled to participate and that the physician-patient relationship in regular medical practice does not influence participants’ free will (NRS01, NRS06). MED and HAS members emphasized the importance of the subtheme, “assess research participants’ ability to consent.” Regarding this subtheme, NRS members recognized that their role included estimating research participants’ ability to consent and considering patients’ characteristics, including changes in physical function during the developmental stage (NRS01, NRS18).

DISCUSSION

We performed this interview investigation to determine the perceived role of nursing members from the viewpoints of various and different REC members. The survey revealed a slight difference between the role expected of nursing members and their recognition of their own role.

Recognition and expectations regarding nursing members’ role

Regarding the nursing members’ role of supporting advisory committees regarding nursing

research proposals, several previous studies focused on and revealed issues regarding nurses' reviews of qualitative research ethics.²³⁻²⁶ In research ethics deliberations, nursing members might need to call the attention of other members to the risks (eg, non-disclosure of information, invasion of privacy posed) of qualitative research.²⁷

Some previous studies indicate that nurses advocate for clinical research participants.^{14,28,29} Similar to these results, this study's findings imply that an advocacy role (ascertain research participants' free will, protect research participants, and represent the voice of research participants) is expected of nursing members in RECs. In clinical nursing, nurses must hear and communicate patients' thoughts and interests. However, the role of nurses as advocates in RECs includes more than putting patients first because they need to consider possible futures regarding the proposed research; this includes inferring the reactions of prospective research participants and their families to research participation from the nursing perspective. In this context, Abbasinia et al³⁰ stated that advocacy in nursing encompasses five attributes, including safeguarding, appraising, valuing, mediating, and championing social justice in the provision of healthcare. This study also demonstrated the role of nursing members in helping study participants make independent decisions. The advocacy role is highly ethical, and more research should be conducted on this aspect of nursing as nurses provide direct intimate care. Furthermore, nurses are trained to maintain professional boundaries³¹ and use clinical reasoning based on their nursing practices. Therefore, nursing members might be the most likely to communicate patients' thoughts and worries (eg, their concerns about new treatments or family support).

Besides this, the MED members particularly emphasized the themes related to scientific evaluations of proposals (eg, evaluate the research design) as part of the nurses' role in RECs. For example, nurses working closely with patients might perceive a difference between intervention and invasiveness by noticing a difference in the volume or frequency of blood samples between usual and unusual treatment. Previous researchers have pointed out that distinguishing between research and treatment is useful to avoid unnecessary burden and risk to research participants, and that it is an essential criterion for protecting research participants.³²⁻³⁵ Nurses might also notice that research procedures, such as hospitalizations and increased visits associated with the clinical trials, can influence research participants' performance and social burden. Therefore, nursing members were expected to understand each research participant as a whole³⁶ and broadly consider the burden of participation in research. Additionally, nursing members effectively communicate and collaborate on diverse medical teams.³⁷ Therefore, nurses, who work with physicians in clinical practice and research, were expected to take responsibility for upholding scientific and ethical research practices by reviewing the research plans from a perspective different from that of the physicians conducting the research.

An Egyptian study³⁸ indicated concerns about the presence of technical terms in informed consent documents. Furthermore, Silaigwana and Wassenaar³⁹ who identified the types of ethical issues raised in two RECs in South Africa, found that the most common ethical issues were related to informed consent. Furthermore, one previous study revealed that lay members verified whether the language of informed consent documents was understandable.⁴⁰ After physicians provide explanations for patients, patients often ask nurses to provide them a supplementary explanation. Therefore, nurses might be able to use those experiences to help research participants make informed decisions about consent.⁴¹

The results of this study indicated six themes for the role of nursing members in RECs. These seem to overlap in some areas with the principles of research ethics.⁴² In addition, nursing members are also nursing professionals, so they are given unique roles that can contribute to the development of nursing science, such as that of reviewing nursing research and supporting nursing researchers as committee members.

Non-nurses' expectations compared to nurses' recognitions of the role of nurses in RECs

This study revealed that nursing members did not recognize their roles to “evaluate their risks and benefits,” “propose ways to lessen the burden on the participants,” “assume research participants’ thoughts,” “share expertise and the nursing perspective,” “provide medical and research information to non-medical members,” and “express opinions.” Particularly, regarding the subtheme, “share expertise and the nursing perspective,” the fact is that nursing members hardly mentioned any roles based on their expertise and experience; hence, they might have taken that role for granted. Alternatively, they might not have perceived the above as an aspect of their role. Regardless of the reasons as to why nursing members did not recognize these roles, the other members seem think that nurses need to carefully consider their professional identities and take on the perspective of a nursing professional when discussing the research-related topics. During the interviews, several nursing members pointed out a “lack of education and training for the type of expertise and committee members.” Matar and Silverman,³⁸ who investigated the current state of RECs in Egypt, stated that many REC chairs are concerned that their members lack research ethics training. As shown in a previous survey-based study,⁴³ there is a need for educational and training opportunities according to the expertise and attributes of REC members.

CONCLUSIONS

In this study, we have identified the roles of nursing members in RECs. Nursing members make important and independent contributions to ethics committees on deliberations and decision-making regarding research ethics. Therefore, the results of the present study may be useful in many countries.

However, this study has limitations that should be considered when interpreting the findings. The results might disproportionately reflect the opinions of individuals with relatively strong knowledge of research ethics. Therefore, future research might inquire about the feasibility of the expected role of nurses among nursing members to further assess their recognition of the nurses’ role and fulfillment abilities.

This study also has implications for nursing research. Many nursing education studies collect data from students, educators, and administrators, and it has been concluded that educational research involving human subjects must be reviewed by a REC, such as an institutional review board, before it is conducted.⁴⁴ Hence, all researchers, educators, and clinical nurses who conduct nursing research need to be fully aware of the realities of RECs, which are designed to protect research participants. Then, upon coupling the results of two studies on research ethics education for nurses^{12,45} and the results of the current paper, one may imply the need to consider and prioritize research ethics education for nurses owing to its importance. Within the context of RECs, member selection and the training of members are two essential topics, and the current paper contributes to the literature by showing how they relate to the role of the RECs and their members.

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DISCLOSURE STATEMENT

There are no conflicts of interest to declare.

REFERENCES

- 1 Council for International Organizations of Medical Sciences in collaboration with the World Health Organization. *International ethical guidelines for health-related research involving humans*. Council for International Organizations of Medical Sciences. <https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf>. Published 2016. Accessed October 26, 2021.
- 2 Japanese Ministry of Education, Culture, Sports, Science and Technology, the Ministry of Health, Labour and Welfare & the Ministry of Economy, Trade, and Industry. *Ethical guidelines for medical and biological research involving human subjects*. Japanese Ministry of Health, Labour and Welfare. <https://www.mhlw.go.jp/content/000757566.pdf>. Published 2021. Accessed October 26, 2021.
- 3 Japanese Ministry of Health, Labour and Welfare. *Rinshokenkyuuhou* [Clinical Trials Act]. Japanese Ministry of Health, Labour and Welfare. <https://www.mhlw.go.jp/file/06-Seisakujouhou-10800000-Iseikyoku/0000213334.pdf>. Published 2017. Accessed October 26, 2021.
- 4 World Health Organization. *Standards and operational guidance for ethics review of health-related research with human participants*. World Health Organization. <https://www.who.int/publications/i/item/9789241502948>. Published September 2011. Accessed October 26, 2021.
- 5 Steering Committee on Bioethics. *Guide for research ethics committee members*. Council of Europe. https://www.coe.int/t/dg3/healthbioethic/activities/02_biomedical_research_en/Guide/Guide_EN.pdf. Published April 2012. Accessed October 26, 2021.
- 6 International Council of Nurses. *The ICN code of ethics for nurses*. International Council of Nurses. https://www.icn.ch/sites/default/files/inline-files/2012_ICN_Codeofethicsfornurses_%20eng.pdf. Published 2012. Accessed October 26, 2021.
- 7 Cook K, Snyder J, Calvert J. Canadian research ethics board members' attitudes toward benefits from clinical trials. *BMC Med Ethics*. 2015;16(1):84. doi:10.1186/s12910-015-0079-8.
- 8 Hemminki E. Research ethics committees in the regulation of clinical research: comparison of Finland to England, Canada, and the United States. *Health Res Policy Syst*. 2016;14:5. doi:10.1186/s12961-016-0078-3.
- 9 Janssens RMJPA, van der Borg WE, Ridder M, Diepeveen M, Drukarch B, Widdershoven GAM. A qualitative study on experiences and perspectives of members of a Dutch medical research ethics committee. *HEC Forum*. 2020;32(1):63–75. doi:10.1007/s10730-019-09394-4.
- 10 Cassidy VR, Oddi LF. Nurses on hospital IRBs: a critical voice in protecting human subjects. *Nursingconnections*. 1993;6(1):31–38.
- 11 Rothstein WG, Phuong LH. Ethical attitudes of nurse, physician, and unaffiliated members of institutional review boards. *J Nurs Scholarsh*. 2007;39(1):75–81. doi:10.1111/j.1547-5069.2007.00147.x.
- 12 Cho KC, Shin G. Operational effectiveness of blended e-learning program for nursing research ethics. *Nurs Ethics*. 2014;21(4):484–495. doi:10.1177/0969733013505310.
- 13 Gu C, Ye M, Wang X, Yang M, Wang H, Khoshnood K. Nurse researchers' perspectives on research ethics in China. *Nurs Ethics*. 2019;26(3):798–808. doi:10.1177/0969733017720848.
- 14 Karjalainen H, Halkoaho A, Pietilä AM, Bendel S, Keränen T. Intensive care nurses' perceptions of various ethics concerns affecting clinical research. *Scand J Caring Sci*. 2019;33(2):371–379. doi:10.1111/scs.12632.
- 15 Yanagawa H, Takai S, Yoshimaru M, Miyamoto T, Katashima R, Kida K. Nurse awareness of clinical research: a survey in a Japanese University Hospital. *BMC Med Res Methodol*. 2014;14:85. doi:10.1186/1471-2288-14-85.
- 16 Mead GH. *Mind, Self, and Society*. Chicago: University of Chicago Press; 1934.
- 17 Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *Int J Qual Health Care*. 2007;19(6):349–357. doi:10.1093/intqhc/mzm042.
- 18 O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. *Acad Med*. 2014;89(9):1245–1251. doi:10.1097/ACM.0000000000000388.
- 19 Connolly M. Qualitative analysis: A teaching tool for social work research. *Qual Soc Work*. 2003;2(1):103–112. doi:10.1177/1473325003002001282.
- 20 Mayring P. Qualitative content analysis. *Forum Qual Soc Res*. 2000;1(2):Art.20. doi:10.17169/fqs-1.2.1089.
- 21 Gibbs GR. *Qualitative Data Analysis: Explorations with NVivo*. Buckingham: Open University Press; 2002.

- 22 Birt L, Scott S, Cavers D, Campbell C, Walter F. Member Checking: a tool to enhance trustworthiness or merely a nod to validation? *Qual Health Res.* 2016;26(13):1802–1811. doi:10.1177/1049732316654870.
- 23 Caelli K. Engaging with phenomenology: is it more of a challenge than it needs to be? *Qual Health Res.* 2001;11(2):273–281. doi:10.1177/104973201129118993.
- 24 Holloway I, Wheeler S. Ethical issues in qualitative nursing research. *Nurs Ethics.* 1995;2(3):223–232. doi:10.1177/096973309500200305.
- 25 McCormack D, Carr T, McCloskey R, Keeping-Burke L, Furlong KE, Doucet S. Getting through ethics: the fit between research ethics board assessments and qualitative research. *J Empir Res Hum Res Ethics.* 2012;7(5):30–36. doi:10.1525/jer.2012.7.5.30.
- 26 Olsen DP, Mahrenholz D. IRB-identified ethical issues in nursing research. *J Prof Nurs.* 2000;16(3):140–148. doi:10.1053/PN.2000.5918.
- 27 Polit DF, Beck CT. *Nursing Research: Generating and Assessing Evidence for Nursing Practice.* 10th ed. Philadelphia: Lippincott Williams & Wilkins; 2016.
- 28 Browning B, Page KE, Kuhn RL, et al. Nurses' attitudes toward clinical research: Experience of the therapeutic hypothermia after pediatric cardiac arrest trials. *Pediatr Crit Care Med.* 2016;17(3):e121–e129. doi:10.1097/PCC.0000000000000609.
- 29 Vaartio H, Leino-Kilpi H. Nursing advocacy—a review of the empirical research 1990–2003. *Int J Nurs Stud.* 2005;42(6):705–714. doi:10.1016/j.ijnurstu.2004.10.005.
- 30 Abbasinia M, Ahmadi F, Kazemnejad A. Patient advocacy in nursing: A concept analysis. *Nurs Ethics.* 2020;27(1):141–151. doi:10.1177/0969733019832950.
- 31 National Council of State Boards of Nursing. *A nurse's guide to professional boundaries.* National Council of State Boards of Nursing. https://www.ncsbn.org/ProfessionalBoundaries_Complete.pdf. Published August 2018. Accessed April 20, 2021.
- 32 Appelbaum PS, Roth LH, Lidz C. The therapeutic misconception: informed consent in psychiatric research. *Int J Law Psychiatry.* 1982;5(3-4):319–329. doi:10.1016/0160-2527(82)90026-7.
- 33 Levine RJ. Clarifying the concepts of research ethics. *Hastings Cent Rep.* 1979;9(3):21–26. doi:10.2307/3560793.
- 34 Levine RJ. Reflections on 'Rethinking research ethics'. *Am J Bioeth.* 2005;5(1):1–3;author reply W15–W18. doi:10.1080/15265160590944076.
- 35 Lidz CW. The therapeutic misconception and our models of competency and informed consent. *Behav Sci Law.* 2006;24(4):535–546. doi:10.1002/bsl.700.
- 36 Bishop AH, Scudder JR. *Nursing Ethics: Holistic Caring Practice.* 2nd ed. Sudbury, Massachusetts: Jones & Bartlett Learning; 2001.
- 37 Shivnan JC, Kennedy MM. The Nurse in the Modern Hospital. In: Latifi R, ed. *The Modern Hospital: Patients Centered, Disease Based, Research Oriented, Technology Driven.* Cham, Switzerland: Springer International Publishing; 2019:341–356. doi:10.1007/978-3-030-01394-3.
- 38 Matar A, Silverman H. Perspectives of Egyptian research ethics committees regarding their effective functioning. *J Empir Res Hum Res Ethics.* 2013;8(1):32–44. doi:10.1525/jer.2013.8.1.32.
- 39 Silaigwana B, Wassenaar D. Research ethics committees' oversight of biomedical research in South Africa: A thematic analysis of ethical issues raised during ethics review of non-expedited protocols. *J Empir Res Hum Res Ethics.* 2019;14(2):107–116. doi:10.1177/1556264618824921.
- 40 Sakaida Y, Ota K. The roles of an ethical review committee as perceived by lay members. *J Philos Ethics Health Care Med.* 2018;12:24–34.
- 41 Karigan M. Ethics in clinical research: the nursing perspective. *Am J Nurs.* 2001;101(9):26–31. doi:10.1097/00000446-200109000-00017.
- 42 Emanuel EJ, Wendler D, Grady C. What makes clinical research ethical? *JAMA.* 2000;283(20):2701–2711. doi:10.1001/jama.283.20.2701.
- 43 Al Omari O, Khalaf A, Al Delaimy W, Al Qadire M, Khatatbeh MM, Thultheen I. Perceptions of challenges affecting research ethics committees' members at medical and health science colleges in Omani and Jordanian universities. *J Acad Ethics.* 2021. doi:10.1007/s10805-021-09410-8.
- 44 Oermann MH, Barton A, Yoder-Wise PS, Morton PG. Research in nursing education and the institutional review board/ethics committee. *J Prof Nurs.* 2021;37(2):342–347. doi:10.1016/j.profnurs.2021.01.003.
- 45 Ahn S, Jeong GH, Shin HS, et al. Nursing faculties' knowledge of and attitudes toward research ethics according to demographic characteristics and institutional environment in Korea. *SAGE Open.* 2020;10(1):215824402091454. doi:10.1177/2158244020914543.