

Regular Article

Development of Case-Based Rubrics to Assess the Achieved Competencies and Performance of Novice Research Ethics Consultant Trainees through Case-Scenario Discussions

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Abstract

Background: Recently, the need for research ethics consultation services has increased worldwide, but the number of experts who can provide those services (research ethics consultants: RECs) remains quite limited. We have been developing educational materials and training programs for novice REC trainees, aiming to help them acquire competency and appropriate performance skills as expert RECs. However, there was no tool to assess their achievements. This paper reports on our attempt to develop rubrics for novice REC training based on exercises with case-scenarios.

Methods: A case-scenario, developed according to an authentic consultation case, entitled “an observational research study with a conflict of interest (COI),” was used to make rubrics.

Results: A preliminary general scoring guide rubric, a task-specific scoring guide rubric, and a task-specific four-level scoring rubric were developed for the case-scenario. The general scoring guide rubric comprised seven preliminary dimensions for assessment, while the task-specific rubrics developed according to the general one comprised the six dimensions.

Conclusion: The developed task-specific scoring guide rubric and the four-level scoring rubric appear to be useful for assessment of educational achievement in terms of competencies and performance skills as an expert REC.

Keywords: Research ethics; Consultation; Training; Case-scenarios; Rubrics

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Introduction

In clinical research involving human subjects, researchers are required not only to collect scientific data, but to do so while protecting their research subjects appropriately [1]. Almost all ethical guidelines for medical research involving human research subjects require an ethics review board (ERB) to make the final “go/no-go” decision regarding scientific and ethical aspects of the research. As such, as defined in formal documents, the ERB plays a regulatory role. Notably, research ethics consultation services are, more or less, voluntary and non-regulatory activities, in which a research ethics consultant (REC) with expertise in clinical research ethics provides requesters or clients many of whom are clinical researchers with professional advice on ethical and to some extent, scientific aspects of a research project. For example, advice may be offered on how to protect research subjects appropriately, or how to plan the study to ensure better a reduced risk of the research; this insight is given from a perspective that is independent from that of the ERB. In addition to those brought up at the time of research planning, REC consultation covers a wide range of topics [2] that range from basic biomedical science at the bench through clinical experimental studies, and from giving advice on how to respond to comments by an ERB to an issue on publication ethics after research completion, to name just a few. Therefore, to a great extent, RECs are expected to support researchers and clinical research institutions in order to promote ethical conduct in research activities.

However, REC activities represent relatively new practices in medical ethics, and the number of expert RECs is still quite limited in many countries. Therefore, developing the human resources for those eligible

to provide REC services is necessary. Unfortunately, underdevelopment of educational curricula and effective training methods for RECs seems to be an issue across the globe. This begs the question of how potential RECs should be trained to become competent RECs, and how the acquisition of their expertise and performance should be evaluated.

In order to function professionally as a REC, REC trainees must acquire sufficient competencies. Matsui et al. have proposed a model list of core competencies required of RECs [3]; these core competencies for an expert REC include 61 items in three major domains: knowledge, skills, and personal characteristics. Of these, 35 competencies are minimal requirements for REC functioning at a basic level (**Appendix 1**), and trainees are expected to acquire at least those 35 competencies to become a competent “novice REC.” Our research project group (designated AMED Matsui Group in the present article), funded by the Japan Agency for Medical Research and Development (AMED), has been developing teaching materials/programs for research ethics education, and has been conducting novice REC training workshops since 2017 as part of the project [4]. The workshops aim to help participants acquire competencies that enable them to respond professionally to research ethics consultation requests; namely, to identify ethical issues inherent in the consulted medical research studies involving human subjects, to analyze the issues, to find solutions, and to advise or recommend appropriate/better/best courses of action by their own efforts. To this end, workshop participants perform training exercises with case-scenarios which were developed based on authentic prior research ethics consultations, and discuss in a small group, as reported elsewhere [4].

The basic structure of novice REC training programs for workshops is well established, although significant challenges remain with regard to assessment of both trainee acquisition of the required core competencies and their performance as competent RECs. Use of a rubric is one way to evaluate such items; as noted by Stevens and Levi, “At its most basic, a rubric is a scoring tool that lays out the specific expectations for an assignment [5].” Thus, we have developed rubrics to assess competencies and performance of our workshop participants as REC trainees through the workshop programs. The purpose of this article is to describe the rubric development process and provide example rubrics for use in novice REC training programs based on case studies, so that other institutions or groups of people engaged in REC education might be able to modify and implement them for their own REC training programs.

Methods

Underlying REC training workshop programs

As of 2019, when rubric development was initiated, the AMED Matsui Group consisted of 17 members, some of whom were RECs and/or ERB members, and whose areas of expertise included medicine, pharmacology, nursing, public health, law, philosophy, bioethics, research ethics, education, and medical education. During 2018-2019, those members led the novice REC training workshops, which consisted of a lecture (50

min sessions) and 2-4 case-scenario discussion sessions by small groups (90-180 min sessions, 150 min average), held over one or two days. We prepared two case-scenarios for the one-day workshop (an example agenda for the one-day workshop is reported elsewhere [4]) and three or four for the two-day workshop. Scenarios to be used vary for each workshop to ensure that attendance at multiple workshops will not result in redundant discussions. During case-scenario discussions, questions are posed based on the model of core competencies. However, not all core competencies are included in a single case-scenario.

Workshop participants (REC trainees)

Because the goal of the workshops was to train potential novice RECs with the minimum necessary (basic) abilities, regardless of their fields of specialization, our established conditions for participation were that one has some basic knowledge of and experience in bioethics and/or medical ethics, and that one is likely to or hopes to be in charge of research ethics consultation and education. Therefore, workshop participants had a variety of occupations, comprising medical doctors, nurses, clinical laboratory technicians, medical representatives at pharmaceutical companies, academic researchers/teachers, research ethics committee office staff, and so forth.

Table 1 Consultation case about “an observational research study with a conflict of interest (COI)”

<p>Case description:</p> <p>We received the following consultation request from a researcher at a university hospital.</p> <p><i>"I was thinking of doing research on a new image analysis method to help diagnose a particular disease using images obtained from past medical treatment," he said. "The research would use new image analysis software recently developed by a company and compare it with conventional image analysis software. The company was going to provide us with the necessary software and research funds. I have done many similar studies in the past, but an issue was raised for the first time by the ethics review board (ERB). In past similar studies, I was allowed to use an opt-out method without obtaining individual informed consent. However, when I underwent the ethical review this time, I was told by the ERB that this research was not an academic research study, and that they would not allow me to use an opt-out method. I was puzzled by this response from the ERB, as it was different from that in the past. I am now unable to conduct the research study as planned. What should I do?"</i></p>
<p>Q1: What are the laws, regulations, and guidelines that may be relevant to this consultation case? List the ones that come to mind, and research in advance the content of the written clauses and regulations that you think should be followed particularly in this case.</p>
<p>Q2: When we asked the researcher about the conflict of interest (COI) policy of his university hospital, he said:</p> <p><i>"When we do a joint research project with a company, we are supposed to submit a COI sheet to our hospital. I wrote down how much research funding I would receive for this research and which software I would receive. I completed the documentation for this the same way I have done in the past, and there should have been nothing special about this research. Also, there is a COI Management Committee in our hospital, where conflicts of interest in research are reviewed."</i></p> <p>As a research ethics consultant (REC), is there any additional information that you need to extract from the researcher?</p>
<p>Case description (cont.):</p> <p>The initial information that the client gave us was insufficient for us to give thoughtful advice. Accordingly, we asked the following questions:</p> <p><i>"Would you tell us a little more about the research plan? The way the research will be handled will depend on the content of the research plan and the research partnership, including the form of the contract with the company. Also, could you give us more specific details about the comments you received from the ERB?"</i></p> <p>In response to the consultant's question, the client replied as follows:</p> <p><i>"First of all, I plan to use the new software to reanalyze image data to look into the differences between the new software images and the conventional images. If this research is successful, the new software may improve disease diagnostics. Of course, the impact of clinical use of the software needs to be examined in another study, but I believe that it will help us to make more accurate diagnoses. Also, I will only ask the company to provide equipment and research funds at a basic level, and I will not let them have any input into the analysis or interpretation of the research results. Although I was going to sign a joint research agreement with a company, I was planning to obtain consent from the research subjects via an opt-out method, as all of the images I will be using were derived from previous diagnostics work."</i></p> <p>Regarding the comments received from the ERB, the client responded as follows:</p> <p><i>"Apparently, the review raised the issue of conflict of interest. I have conducted other joint research studies with the same company. If you add up all the research funds I have received from this company, it is indeed a considerable amount, but the oldest research was done 10 years ago, and I have been reporting conflicts of interest accordingly. Besides, the amount of the funding I will receive for this research is not very large. Even at a high estimate, it is expected to be around 500,000 yen (or 4,500 US dollars) per year."</i></p> <p>Additionally, he noted the following:</p> <p><i>"The other problems seemed to be the adjustment of the software and the preliminary conference for publication of the paper. Adjustment means that the company sets the parameters for the analysis software before the analysis. This is done by sending anonymized diagnostic images to the company using a correspondence table. According to the person in charge at the company, this work can be completed within a day. Nevertheless, because of this adjustment work, I was told that this research was joint research with a company. The preliminary conference for publication of the paper means that I will report the contents of the paper to the company once before publication and obtain their consent before publication if there is a possibility that the company will be disadvantaged. I believe that this is a common agreement in joint research studies like this one. According to the ERB, this study did not ultimately qualify as an academic research study overall, and they said that I needed to obtain individual informed consent, as the research study could not be conducted using the opt-out method among the research subjects. But I'm not convinced. I designed the research project myself, and I will conduct the image analysis and the comparative evaluation. If this is not considered an academic research study, then would they argue that every other study I have conducted in the past may not be considered academic research either? More importantly, this research will use imaging data from about 1,000 patients; it will be impossible to obtain informed consent from all 1,000 patients."</i></p>

Table 1 (cont.) Consultation case about “an observational research study with a conflict of interest (COI)”

<p>Q3: Considering the responses from the researcher, which part of Japan’s ethical guidelines for medical research is relevant to the conclusions of the ethics review?</p>
<p>Q4: Speculate why the ERB made this decision.</p>
<p>Case description (cont.): At the end of the consultation, the researcher said: <i>“In all honesty, I just want to do this research, regardless of whether it is considered academic research or not. I’ve already negotiated with the company on this research, and I can’t say that I can’t do it now at this stage. In the end, what do I need to do to be allowed to conduct this research?”</i></p>
<p>Q5-1: If, on the one hand, the goal is to conduct the research as “an academic research study,” how would you, as a REC, suggest modifying the research plan?</p>
<p>Q5-2: On the other hand, if the goal is to conduct the research as “a product development research,” how would you, as REC, suggest modifying the research plan?</p>
<p>Q6: Based on the above analysis, come up with your final advice to the researcher.</p>

A case-scenario

In this article, we created rubrics for the consultation case shown in **Table 1**, tentatively entitled “an observational research study with a conflict of interest (COI).” In research ethics consultation, issues of research integrity such as conflicts of interest may also be addressed in addition to issues of clinical research ethics centered on human subject protection [6]. We therefore chose this case as a good case that includes both of the above issues.

The scenario pertained to a research situation involving collaborative development of medical imaging analysis software by academic researchers and a company, and involved potential ethical issues related to a financial COI. As is evident in **Table 1**, this case-scenario was structured in multiple layers in the form of a dialogue: (1) the initial case description/explanation of the situation and ethical problems which a requesting researcher encounters in his/her research project, followed by several subsequent questions of concern (Q1, Q2); (2) dialogue on additional information between the requester and a REC; with time, the dialogue revealed further details of the situation, along with several

concerning questions (Q3, Q4); and (3) the last case description and relevant questions were offered by a REC to develop final advice for researchers (Q5, Q6). The goal of this case-scenario was to train participants to develop competency in understanding research design/protocol, to discover relevant regulations including institutional policies and seek necessary additional information through dialogue with the requester, to identify and analyze ethical issues pertaining to this case, and to create final advice that would be ethically better/best.

REC performance assessments and rubrics

With some exceptions, research ethics consultation is generally conducted as a team [7], because it deals with various ethical issues as well as areas of biomedical research projects involving human subjects whose characteristics inevitably require review and analysis at a multi-disciplinary level [8]. By functioning effectively and practically regardless of whether as individuals or as a team, RECs are expected to improve the overall ethical quality of a consulted research project, thus, maximizing social benefits and protecting research subjects – namely, minimizing risks to the research subjects who

must solely bear all of the risks pertaining to the research project [8]. Therefore, RECs need to be equipped not only with sufficient knowledge of research ethics but also research ethics reasoning skills and the ability to translate the consequences of this reasoning into practical advice or feasible recommendations for the requesters [9-12].

Rubrics are often used by teachers as a tool to evaluate student performance in terms of such higher-order thinking and its subsequent outputting (practical performance) skills; in the general context of bioethics education, the use of rubrics has recently increased in popularity [10, 12]. Rubrics can also be used as a tool for self-assessment. As stated by Stevens and Levi (2013), “By encouraging students to think critically about their own learning, rubrics can inspire precisely the pattern of ‘self-assessment and self-improvement’ intrinsic to creating the kind of motivated, creative students we all want in our classes.[13]” Usually, a rubric is presented in the form of a table with descriptions of the characteristics corresponding to each level of achievement, according to the multiple assessment levels of performance (e.g., four levels). A rubric that shows only the descriptions of the highest level of performance for each dimension is called a scoring guide rubric [14]. In many cases, the knowledge, understanding, and skills required by a performance task are divided into multiple, more detailed dimensions, and each dimension is then assessed. Thus, the dimensions of a rubric represent the components of a performance task.

Rubrics development processes

A scoring guide rubric and a four-level scoring rubric have advantages and disadvantages respectively.

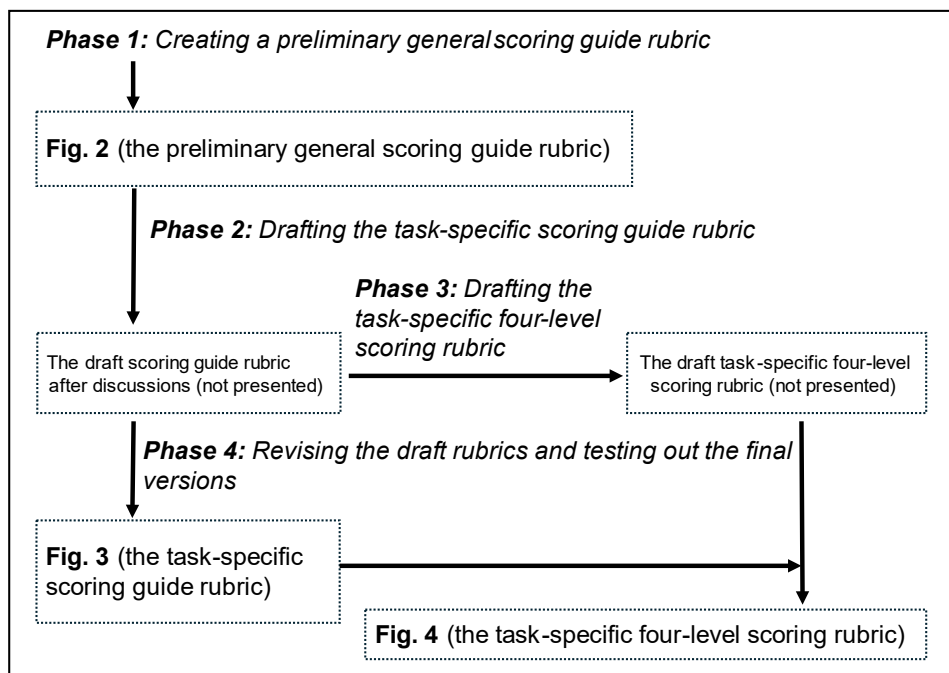
For instance, according to Stevens and Levi (2013), while a scoring guide rubric requires extra time for scoring and giving narrative feedback, it takes a relatively short amount of time to create, and has the advantage of allowing flexible, individualized assessment for each learner. A four-level rubric allows for quick scoring and detailed formative feedback by simply checking and circling [15]. Therefore, we thought that creating a four-level rubric would compensate for the downside of the scoring guide rubric, which requires extra time for scoring and giving feedback. From these reasons, we created not only a scoring guide rubric, but also a four-level rubric, with the goal of increasing the efficiency of the evaluation in the workshop.

Two experts experienced in research ethics consultation (KM, KY), two researchers of education (KK, AY), and one medical education/ethics expert (AN) in the AMED Matsui Group joined the other Group members in the meetings to lead the rubric development process for the above-mentioned consultation case. The author of the case-scenario (US) in the Group also participated in some of the team meetings to explain and confirm key ethical issues pertaining to this case. The rubric team discussed how to create and draft rubric prototypes, and made several revisions to them via group e-mails, which followed the face-to-face discussions in which a consensus was reached about the rubrics.

Following these discussions, the team and the Group decided to create a scoring guide rubric and a four-level scoring rubric for REC trainee performance self-assessment. In summary, the rubric creation processes comprised the following four phases (**Fig. 1**): 1) create a preliminary general scoring guide rubric; 2) develop the draft task-specific scoring guide rubric;

3) develop the draft task-specific four-level scoring rubric; 4) revise the draft rubrics and test out the final versions in actual REC training workshops.

Fig. 1 The rubrics development processes



1) Creating a preliminary general scoring guide rubric

To create a preliminary general scoring guide rubric, the rubric team utilized as performance examples the reports on three different consultation case-scenarios including the present case, which were submitted by eight participants of one of our workshops held in 2018. As the very first step, these reports were used for consideration of the dimensions of the performance tasks (a breakdown of the core competencies involved in the performance tasks). Members also referred to explanations and model answers for each consultation case provided by the case-scenario authors, using these as resources to think about the dimensions of the preliminary general scoring guide rubric. Following careful

examination of the reports submitted by the participants and the explanations and model answers of the case-scenarios, and having discussed the dimensions involved in the tasks, the team created a preliminary general scoring guide rubric for novice RECs (**Fig. 2**). This preliminary rubric was not a task-specific rubric for assessment of performances specific to a particular task, but a general one that can be applied to many different tasks [16]. Accordingly, the task description became very general, i.e., “Analyze ethical issues involved in the assigned consultation case and prepare your own final advice to the client.” As a scoring guide rubric, the preliminary rubric contained only the descriptions of the highest level of performance in each dimension.

Fig. 2 The preliminary general scoring guide rubric for novice research ethics consultants

Preliminary Dimensions		Descriptions of the highest level of performance	Assessment Highest (4) <=> Lowest (1)
I	<i>Identifying issues (points of interest)</i>	<ul style="list-style-type: none"> Identifies all points that contain ethical issues. Sufficiently understands the correlations among the points of interest. 	4 3 2 1
II	<i>Understanding and knowledge of relevant laws, regulations, guidelines, and other rules (by governments, academic societies, etc.)</i>	<ul style="list-style-type: none"> Points out the relevant laws, guidelines, regulations, and other rules. Sufficiently understands the contents of the relevant laws, guidelines, regulations, and other rules. Understands the normative nature (existence, strength, etc. of the binding force) of the relevant laws, guidelines, regulations, and other rules. 	4 3 2 1
III	<i>Understanding and knowledge of relevant research ethics principles, concepts, discussions, etc.</i>	<ul style="list-style-type: none"> Correctly points out relevant research ethics principles, concepts, discussions, etc. Sufficiently grasps the contents of the relevant principles, concepts, discussions, etc. 	4 3 2 1
IV	<i>Hearing additional information</i>	<ul style="list-style-type: none"> Correctly determines whether or not obtaining additional information is necessary. Sufficiently hears additional information needed to analyze ethical issues. Comprehends the client's policies and thoughts, research conditions, and limitations in practice. 	4 3 2 1
V	<i>Analyzing ethical issues</i>	<ul style="list-style-type: none"> Adequately analyzes all ethical issues. Provides sufficient justification for each issue and reasons why it cannot be justified. 	4 3 2 1
VI	<i>Devising and presenting best recommendations and alternatives (second best recommendations, etc.)</i>	<ul style="list-style-type: none"> Devises the best solution as an ideal one. Adequately devises alternative solutions (e.g., second best one). Presents the best practical solution based on the client's policy and thoughts in accordance with the conditions and feasibility of the research. 	4 3 2 1
VII	<i>Appropriateness as advice</i>	<ul style="list-style-type: none"> Appropriately selects the analysis results that should be disclosed (or not) to the client. Uses appropriate expressions in Japanese. Expressions are easily understood. Clearly indicates that the answers from the research ethics consultant constitute only advice or recommendations, and not instructions or orders. 	4 3 2 1
Overall evaluation: <input type="checkbox"/> Expert level (4) <input type="checkbox"/> Advanced level (3) <input type="checkbox"/> Basic level (2) <input type="checkbox"/> Below basic level (1)			
Comments :			

2) Drafting the task-specific scoring guide rubric

The rubric team provided the created preliminary general scoring-guide rubric for assessment to the members of the AMED Matsui Group, including the author of the case-scenario in question (US). We then attempted to evaluate the original reports with the general scoring guide rubric and discussed where there might be variation in performance of workshop participants, and areas in which evaluation using the general rubric might have been difficult for members. Thus, we examined its suitability as a tool to assess case-based performance.

However, after hours of discussion, we concluded that the general scoring guide rubric developed through three different case-scenarios was too abstract to fit each specific ethical issue raised by each case-scenario. Consequently, we decided to develop task-specific scoring rubrics based on the general scoring guide rubric, rather than revising the general rubric and continuing to use it.

The case-scenario author was asked to draft a prototype of a task-specific scoring guide rubric in accordance with the specific case-scenario. Once a task-specific scoring guide rubric was drafted by the author, we re-examined its dimensions and the suitability of the dimension descriptions.

3) Drafting the task-specific four-level scoring rubric

We set a matrix of four scale levels for a task-specific scoring rubric. The case-scenario author was also asked to draft a prototype of a four-level scoring rubric in accordance with the specific case-scenario. In parallel with the revision of the task-specific scoring guide rubric, the dimensions of the four-level scoring rubric prepared by the author were also examined, along with descriptions of what constitutes each level of performance

in each dimension. Specifically, we set the dimensions according to the task-specific scoring guide rubric that had been developed. Then, after deciding on the labels for each scale level, we wrote down the content for each description of performance used in the matrix.

4) Revising the draft rubrics and testing out the final versions

Following the examinations described above, we asked the author to revise the task-specific scoring guide rubric and the task-specific four-level scoring rubric. We also asked him to reexamine whether or not there was any discrepancy with the aim of the case-scenario or the points for evaluation with regard to the rubrics, and whether or not the expressions were suitable from his own perspective. After the author made minor revisions to the descriptions of each level of performance of each rubric, we completed the tentative final versions of both rubrics, which comprised six dimensions.

At a separate venue in which we were given another opportunity to conduct a REC training workshop using the relevant case-scenario, “an observational research study with a conflict of interest (COI),” we presented the tentatively finalized task-specific scoring guide rubric to workshop participants and asked them to self-assess their performance using the rubric. Because the workshop could provide only 15 minutes to the attendees for an opinion-and-evaluation survey, we used a task-specific scoring guide rubric which enables them to read through in a shorter amount of time. Twenty-two workshop participants completed this self-evaluation.

Results

1) Creating a preliminary general scoring guide rubric

Fig. 2 shows the preliminary general scoring guide rubric. The seven preliminary dimensions developed for this rubric were basically ordered according to the flow of consultations common to research ethics consultation services described elsewhere. Briefly, when a consultation request comes from a client, the REC will first listen to the client and identify points that involve or potentially raise ethical issues. During the conversation, s/he will identify relevant regulations, ethical principles and/or, if any, global discussions in the field of research ethics concerning the case. If s/he thinks that more information is necessary for analysis, s/he will ask the client for the detailed and/or additional information. Then, s/he will analyze ethical issues identified in the case, and develop and recommend several better/best options of optimal countermeasures, in consideration of practical conditions and feasibility of the research project.

Accordingly, preliminary dimensions were arranged as follows: Dimension I: “Identifying issues (points of interest)”; Dimension II: “Understanding and knowledge of relevant laws, regulations, guidelines, and other rules (by governments, academic societies, etc.)”; Dimension III: “Understanding and knowledge of relevant research ethics principles, concepts, discussions, etc.”; Dimension IV: “Hearing additional information”; Dimension V: “Analysis of ethical issues”; Dimension VI: “Devising and presenting best recommendations and alternatives (second best recommendations, etc.)”; and Dimension VII: “Appropriateness as advice.”

2) Drafting the task-specific scoring guide rubric

Fig. 3 shows the finalized version of the task-specific scoring guide rubric prepared for the consultation case, entitled “an observational research study with a conflict of interest (COI).” At the top of the table, the task description reads, “Analyze ethical issues involved in the assigned consultation case and prepare your own final advice to the client. You, as a research ethics consultant, are expected to be able to provide advice on an observational research study with a conflict of interest, taking into consideration both the opinions of an ethics review board and the intentions of the client/researcher.” The underlined words are specific to this consultation case, and the rest are common statements used in task description of other cases. This rubric adopts a scale of four levels of performance corresponding to each dimension, with levels ranging from 1 to 4 (lowest to highest); notably, while the preliminary scoring guide rubric presented these in descending order, we inverted this in this rubric.

To represent the components of the performance task (i.e., knowledge, understanding, and ethical reasoning skills), our rubric assesses the following six dimensions: I: Understanding of the contents of a requested consultation; II: Understanding and knowledge of relevant laws, regulations, guidelines, and other rules (by governments, academic societies, etc.); III: Recognition of additional information to be collected from the client; IV: Understanding and knowledge of relevant research ethics principles, concepts, discussion, etc.; V: Analysis of ethical issues; and VI: Devising and providing countermeasures. Appended to each of those dimensions are corresponding question numbers in the concerned case-scenario, and corresponding dimension-specific

descriptions of the performance task are presented. Because this is a scoring guide rubric, those descriptions exemplify the highest level of performance and are therefore often allowed to contain ‘judgmental’ terms, such as “appropriately” or “properly.”

Fig. 3 The task-specific scoring guide rubric on “an observational research study with a conflict of interest (COI)”

Task Description: Analyze ethical issues involved in the assigned consultation case and prepare your own final advice to the client. You, as a research ethics consultant, are expected to <i>be able to provide advice on an observational research study with a conflict of interest, taking into consideration both the opinions of an ethics review board and the intentions of the client/researcher.</i>		
Dimensions	Descriptions of the highest level of performance	Assessment Lowest (1) <=> Highest (4)
I <i>Understanding of the contents of a requested consultation</i> (All questions)	<ul style="list-style-type: none"> Properly understands the contents and circumstances of a consultation case. 	1 2 3 4
II <i>Understanding and knowledge of relevant laws, regulations, guidelines, and other rules (by governments, academic societies, etc.)</i> (Q1)	<ul style="list-style-type: none"> Knowledgeable about the <i>Ethical Guidelines for Medical and Health Research Involving Human Subjects</i> (“The Guidelines”), and the <i>Guidance</i> of the Guidelines. Knowledgeable about the Act on the Protection of Personal Information (Act No. 57 of May 30, 2003/Article 76(1)(iii): Exclusion of academic studies from application). Understands “clinical research” and “specific clinical research” as defined by the Clinical Trials Act (Act No. 16 of Apr 14, 2017). Knowledgeable of some of the official guidelines and rules regarding COI (e.g., “<i>The Guidelines for Formulation of Conflicts of Interest Policy for Clinical Research</i>,” “<i>The Report of the Working Group on the Conflicts of Interest</i>,” “<i>The Guidelines for Managing Conflicts of Interest (COI) in Health, Labour and Welfare Science Research by the Ministry of Health, Labour and Welfare</i>,” “<i>The Japanese Association of Medical Sciences COI management guidelines</i>,” etc.). 	1 2 3 4
III <i>Recognition of additional information to be collected from the client</i> (Q2)	<ul style="list-style-type: none"> Recognizes that additional detailed information should be collected with regard to the research plan, including the contents of the research, the research team, and the contract with a collaborating company. Recognizes that additional detailed information on the comments by the Ethics Review Board should be collected. 	1 2 3 4
IV <i>Understanding and knowledge of relevant research ethics principles, concepts, discussions, etc.</i> (Q3, Q4)	<ul style="list-style-type: none"> Understands “collaborative research” and “collaborative research implementing entity” as defined in the Guidelines (Guideline 2(9), (10); Guidance p.14, Explanation 5). Understands the concept of “existing information” and the requirements when providing existing information to other research implementing entities (defined in Guideline 12-1(2), (3)). Understands the concept of “conflicts of interest.” Understands the difference between academic and non-academic research (e.g., commercial/for-profit research). 	1 2 3 4
V <i>Analysis of ethical issues</i> (Q3 to Q5)	<ul style="list-style-type: none"> Appropriately analyzes the rationale behind the decisions by the Ethics Review Board in relation to the relevant laws, regulations, guidelines, and/or other rules. Appropriately analyzes the justification for conducting the research as “academic research,” and understands its merits and demerits. Appropriately analyzes the justification for conducting the research as a “commercial/for-profit research,” and the merits and demerits therein. Appropriately focuses analysis on the important ethical issues, in addition to listing issues involved in the consultation case. The issues being analyzed are properly reflected in the proposals/recommendations. 	1 2 3 4
VI <i>Devising and providing countermeasures</i> (Q5, Q6)	<ul style="list-style-type: none"> Appropriately considers the ideal research plan. Appropriately considers a feasible research plan. Respects the client’s intentions, and appropriately devises how the research plan should be modified or revised in accordance with the conditions and feasibility of the research. Appropriately selects which analysis results should be told to the client (or not). 	1 2 3 4
Below, a column for comments is prepared, in which evaluators can list the good points of the workshop participant responses and explain the grounds for the evaluations of each dimension of their performance.		
Comments:		

Dimension I represents a participant's ability to grasp the contents and circumstances of the consultation case from a bird's-eye view. Dimension II represents whether the participants of the workshop have sufficient knowledge of laws, guidelines, regulations, and other rules related to the particular case. For instance, *The Ethical Guidelines for Medical and Health Research Involving Human Subjects*, the then-effective non-binding ethics guidelines jointly issued by the Ministry of Education, Culture, Sports, Science and Technology and the Ministry of Health, Labour and Welfare (2014), were one of the then-most important governmental research regulations on medical research (and relevant for most cases). Equally important and relevant was the then-Act on the Protection of Personal Information, which deals with the handling of personal information in Japan and thus relates to most consultation cases. At the very least, anyone who wants to be a REC is commonly expected to have a good understanding of these basic regulations, and of any specific regulation such as an institutional COI policy. Dimension III represents a participant's ability to seek and find additional necessary information to be collected from the client in order to develop good advice or recommendations. Dimension IV represents the understanding of the principles and concepts of research ethics relevant to the case, such as COIs and the difference between academic research and product development. Dimension V represents the assessment and analysis skills of the participant on ethical issues involved in the particular case, such as critical thinking about ethical concerns relevant to the research project raised by the ERB. It also represents their ability to identify or appreciate any rationale for and behind a particular case brought for consultation. Dimension VI

represents whether the participants can develop appropriate and practically feasible advice or recommended courses of action for the client.

3) Drafting the task-specific four-level scoring rubric

Based on the finalized task-specific scoring guide rubric, we have developed a task-specific four-level scoring rubric (**Fig. 4**). As was done to develop a preliminary general scoring guide rubric, we completed the description of each dimension of the four-level rubric by referring to the model answers in the relevant case-scenario and the sample answers from workshop participants. The task-specific rubric adopts a scale of four levels of performance. The terms used to describe the four levels are unacceptable (1), not yet competent (2), competent (3), and exemplary (4). As the Scale Level 4 (Exemplary) is the highest level of performance, the description of the Level 4 corresponds to that of the task-specific scoring guide rubric.

Fig. 4 The task-specific four-level scoring rubric developed for the consultation case

Task Description: Analyze ethical issues involved in the assigned consultation case and prepare your own final advice to the client. You, as a research ethics consultant, are expected to <i>be able to provide advice on an observational research study with a conflict of interest, taking into consideration both the opinions of an ethics review board and the intentions of the client/researcher.</i>				
Dimensions	Unacceptable (1)	Not yet competent (2)	Competent (3)	Exemplary (4)
I Understanding of the contents of a requested consultation (All questions)	Has many misunderstandings about the contents and circumstances of a consulted case.	Has slightly misunderstood the contents and/or circumstances of a consulted case. Alternatively, does not have a concrete understanding of the contents and circumstances of a consulted case.	Has some concrete understanding of the contents and circumstances of a consulted case without any misunderstanding.	Fully understands the contents and circumstances of a consulted case in a correct and concrete manner.
II Understanding and knowledge of relevant laws, regulations, guidelines, and other rules (by governments, academic societies, etc.) (Q1)	Lists only one of the following: (1) <i>The Ethical Guidelines for Medical and Health Research Involving Human Subjects, and their Guidance</i> (2) <i>The Act on the Protection of Personal Information (Article 76)</i> (3) <i>The Clinical Trials Act</i> (4) <i>The official guidelines and rules regarding COI</i>	Lists two of the following:	Lists three of the following:	Lists all of the following:
III Recognition of additional information to be collected from the client (Q2)	Recognizes none of the following: (1) <i>the necessity of additional detailed information regarding the research plan (the contents of the research, the research team, the contract with a collaborating company, etc.)</i> (2) <i>the necessity of additional detailed information on the comments by the Ethics Review Board</i>	Recognizes only one of the following:	Recognizes to some extent both of the following:	Recognizes fully both of the following:
IV Understanding and knowledge of relevant research ethics principles, concepts, discussions, etc. (Q3, Q4)	Understands none or only one of the following: (1) <i>“collaborative research” and “collaborative research implementing entity” in the Guidelines</i> (2) <i>“existing information” and the requirements when providing existing information to other research implementing entities</i> (3) <i>the concept of “conflicts of interest”</i> (4) <i>the difference between academic research and non-academic research</i>	Understands two of the following:	Understands three of the following:	Understands all of the following:
V Analysis of ethical issues (Q3 to Q5)	Analyzes none or only the second of the following: (1) the rationale behind the decisions by the Ethics Review Board in relation to the relevant laws, regulations, guidelines, and other rules; or (2) the justification both for conducting the research as “academic research,” and for conducting the research as a “commercial/for-profit research,” and their respective merits and demerits.	Analyzes to some extent the following: (1) the rationale behind the decisions by the Ethics Review Board in relation to the relevant laws, regulations, guidelines, and other rules, while focusing analysis on the important ethical issues; (2) the justification both for conducting the research as “academic research,” and for conducting the research as a “commercial/for-profit research,” and their respective merits and demerits.	Appropriately analyzes the following: (1) the rationale behind the decisions by the Ethics Review Board in relation to the relevant laws, regulations, guidelines, and other rules, while focusing analysis on the important ethical issues; but appropriately analyzes only one of the following: (2a) the justification for conducting the research as “academic research” and its merits and demerits, and (2b) the justification for conducting the research as a “commercial/for-profit research” and its merits and demerits.	Appropriately analyzes both of the following: (1) the rationale behind the decisions by the Ethics Review Board in relation to the relevant laws, regulations, guidelines, and other rules; and (2) the justification both for conducting the research as “academic research,” and for conducting the research as a “commercial/for-profit research,” and their respective merits and demerits, while focusing their analysis on the particularly important ethical issues, and appropriately relating the issues to the proposals / recommendations.
VI Devising and providing countermeasures (Q5, Q6)	Considers none or only one of the following: (1) the ideal research plan, and (2) a feasible research plan.	Devises some modifications toward a feasible research plan that is as close to the ideal as possible, but does not respect the client’s intentions fully.	Fully respects the client’s intentions, and devises modifications toward a feasible research plan that is as close to the ideal as possible, but excessively emphasizes issues that are not important in this consulted case, and/or insufficiently points out important issues.	Fully respects the client’s intentions, devises modifications toward a feasible research plan that is as close to the ideal as possible, providing adequate countermeasures without excess or deficiency.
Below, a column for comments is prepared, in which evaluators can list the good points of the workshop participant responses and explain the grounds for their evaluations of each dimension of their performance.				
Comments:				

4) Revising the draft rubrics and testing out the final versions

There are several differences in the dimensions and the evaluation forms between the preliminary general scoring guide rubric and the task-specific scoring guide rubric. First, the task-specific rubric for the case-scenario, “an observational research study with a conflict of interest (COI),” lacks the dimension labeled “Identifying issues (points of interest),” which appears in the preliminary general rubric as its preliminary Dimension I. That is because, in contrast to many other case-scenarios, this particular one is not structured to ask workshop participants to identify issues (points of interest) for examination; as such, the dimension of “Identifying issues (points of interest)” is retained in those other task-specific rubrics.

Second, Dimension I of the task-specific rubric (“Understanding of the contents of a requested consultation”) does not appear in the general rubric. We have added this dimension not only to the case of concern, but also to all other rubrics, regardless of the scenario, because several reports on three consultation cases submitted by our workshop participants revealed a lack of understanding about the contents and circumstances of consultation cases which cannot be reduced to poor performance in other dimensions.

Third, we omitted “Overall evaluation” of performance from the task-specific scoring guide rubric, which is prepared for the preliminary general scoring guide rubric. The reasoning behind this was that, although REC trainees are expected to achieve the minimum standard on each dimension in order to develop good advice for a specific consultation case, giving an overall evaluation score, or grade, for a particular

scenario may lead them to misunderstand their true overall competency as a REC. A comprehension test is often given at the end of the training session, for the purpose of measuring the level of achievement in knowledge and is graded as correct or incorrect; in contrast, a rubric evaluates the performance qualitatively, not as correct/incorrect. However, this comprehensive evaluation may lead to incorrect perceptions. Therefore, we concluded that the task-specific rubric should simply function for REC trainees as a tool for self-assessment and self-awareness of their current competency, but not as a pass/fail judgement.

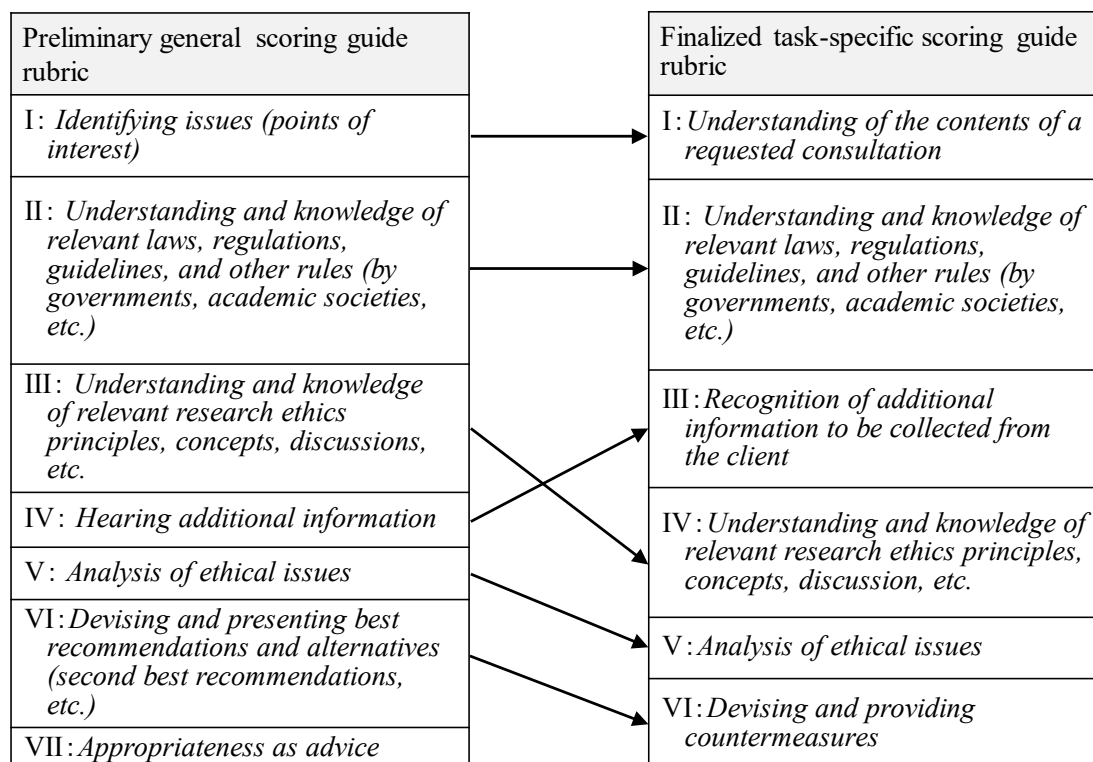
Fourth, the title of Dimension III (“Recognition of additional information to be collected from the client”), equivalent to the preliminary Dimension IV in the preliminary rubric, was renamed from “Hearing additional information,” because the ability to recognize what additional information needs to be collected from a consultation requester is more essential than the mere ability to hear this from the requester.

Finally, the preliminary Dimension VII (“Appropriateness as advice”) in the preliminary rubric was ultimately excluded from the task-specific rubric, because it was considered similar to and likely to be absorbed into the preliminary Dimension VI (“Devising and presenting best recommendations and alternatives (second best recommendations, etc.)”). Accordingly, the description, “Appropriately selects the analysis results that should be disclosed (or not) to the client,” which appeared in the preliminary rubric, was transferred into the preliminary Dimension VI so as to form Dimension VI, “Devising and providing countermeasures,” of the task-specific rubric. The remaining descriptions in the preliminary Dimension VII were eliminated, as we decided

to focus more on the quality of the final advice itself, rather than the external formality of the language or

expressions. Those changes of dimensions are illustrated in **Fig. 5**.

Fig. 5 Dimension changes



Next, we asked our twenty-two workshop participants of the five groups to self-assess their individual performance in each group using the finalized task-specific scoring guide rubric (**Table 2**). We found that three groups marked several scores with a high standard deviation (SD) of 0.8 or higher, and that such high

standard deviations were observed mainly in Dimensions III and IV. The high standard deviations suggested the possibility of a wide range in participant self-assessment skills in some groups, and/or that the descriptions of Dimensions III and IV might have been inappropriately developed.

Table 2 Self-assessed scores (mean ± SD) of the workshop participants by the task-specific scoring-guide rubric

	Dimension I	Dimension II	Dimension III	Dimension IV	Dimension V	Dimension VI
Group 1	2.5±0.6	2.5±0.6	2.3±1.0	2.8±1.0	2.5±0.6	2.5±0.6
Group 2	3.0±0.8	2.7±0.5	3.0	2.8±1.0	2.5±0.6	2.5±0.6
Group 3	3.2±0.4	2.8±0.4	3.2±0.4	2.8±0.4	2.6±0.5	2.6±0.5
Group 4	3.0±0.7	3.0	2.6±0.5	2.8±0.4	2.6±0.5	2.6±0.5
Group 5	2.8±0.5	2.8±0.5	3.0±0.8	2.8±0.5	2.0±0.8	2.5±0.6
All members (n=22)	2.9±0.6	2.8±0.4	2.8±0.7	2.8±0.6	2.5±0.6	2.6±0.5

Assessment score: from the lowest (1) to the highest (4)
SD: a standard deviation

At the draft development stage, when considering the descriptions of four levels of performance in the Dimension II (“Understanding and knowledge of relevant laws, regulations, guidelines, and other rules (by governments, academic societies, etc.”), we had set “Can refer to an institutional COI policy” as Scale Level 3 (Competent). However, most of our workshop participants were rated as Level 1 (Unacceptable) because they did not think of it at all. This could have been due to the complicated regulatory circumstances in Japan regarding COI, wherein medical and healthcare researchers must refer to several relevant official regulations in addition to the COI policy at their own institutions; these include The Clinical Trials Act (2017), *Ethical Guidelines for Medical and Health Research Involving Human Subjects* (2014), *Guidelines for Managing Conflicts of Interest in Health, Labour and Welfare Science Research by the Ministry of Health, Labour and Welfare* (2008), and *The Japanese Association of Medical Sciences COI Management Guideline* (2017). When practicing research ethics consultation, the REC is expected to be knowledgeable of at least those complicated sets of regulations. Because of such a flood of relevant regulations, our participants seemed to be ill-prepared for appropriate referencing to their own institution’s policies. Accordingly, although we discussed whether or not to set the description of “Can refer to an institutional COI policy” as one of the descriptions in Dimension II, we ultimately decided not to use it as a description because some people noted that some facilities have not created such institutional COI policies.

Discussion

We have developed the task-specific scoring guide

rubric and the four-level scoring rubric to be used in self-assessment of higher-order thinking acquisition and practical performance skills as a competent REC through an educational training workshop with exercises by case-scenarios. As mentioned above, although we began by creating a preliminary general scoring guide rubric, our end products became task-specific rubrics for the particular case-scenario, entitled “an observational research study with a conflict of interest (COI).”

Our goal with rubric development changed following the workshop, as we realized that consultation cases used for discussion will differ by workshop and that relevant ethical issues will also be case-dependent. One advantage of a task-specific rubric is that it can provide clear and concrete matters as focal points through the specific case-scenario discussion, allowing for easier (self-)assessment of performance. As Brookhart notes [16], it is easier for evaluators to apply task-specific rubrics because appropriate application of general rubrics takes longer to learn. On the other hand, one of the advantages of a general rubric is that it can be distributed to workshop participants *before* any case-scenario discussion, because it simply provides what should be achieved in an abstract way in an assignment in general, without giving away answers to questions. In addition to this merit, Brookhart also raises four other advantages of a general rubric: it can be used with many different tasks with the same learning outcome, focusing participants on the knowledge and skills they are developing over time; it describes participant performance in terms that allow for many different paths to success; it focuses the instructor on developing participants’ learning of skills instead of task completion; and it does not need to be rewritten for every assignment [16].

In contrast, one—and probably the most prominent—disadvantages of a task-specific rubric is that we cannot provide workshop participants with it before the case-scenario discussion, as it would reveal all the answers to the workshop participants. Therefore, it is important to acknowledge the advantages and disadvantages of each kind of rubric and prepare accordingly, keeping in mind the purpose of each project. For the purposes of our workshop, which were to train and assess achievements of novice RECs, we consider a task-specific rubric to be more appropriate than a general one.

Our task-specific rubrics developed for the consultation case, entitled “an observational research study with a conflict of interest (COI),” cover many of the required core competencies for novice RECs listed in Appendix 1 [See Additional File 1]: (1), (4), (5), (7) through (10), (12), (15), (17) through (19), (22), (28),

(30), (34), (37) through (39), (48), (51) through (53), (56), and (57). Although it is generally considered difficult to assess competencies directly, especially when we consider personal characteristics such as open-mindedness (51) and empathy (52), they can be assessed indirectly through participant performance during the workshop. Our rubrics have been developed through repeat expert reviews; as such, they may have sufficient content validity and are reasonable, even though there is certainly room for further improvement. One of the primary difficulties in creating the rubrics was translating one’s expertise as a REC into words and sharing these with others. In other words, this rubric development process required us to spell out what goes through the mind of an experienced REC during an actual consultation service.

Appendix 1 Core competencies required for novice research ethics consultants (RECs) [3] (excerpted)

Competency domains and intermediate categories		REC level <i>Basic</i>
Domain 1:	Knowledge	
(1)	History of research ethics, historical cases	•
(2)	Three principles of research ethics/basic theory	•
(4)	Medical research—basic design and methods	•
(5)	Domestic laws related to medical research (e.g., personal information law, clinical research law, regenerative medicine law, next-generation medical infrastructure law)	•
(7)	Japanese administrative (ethical) guidelines for medical research (e.g., medical guidelines, genome guidelines)	•
(8)	Institution policies/regulations on medical research and in-facility REC/IRB, related departments (e.g., REC/ IRB, clinical research support center, medical information, medical safety)	•
(9)	Basic terms and concepts related to medical research and medical care	•
(10)	Japan’s medical insurance system, medical/biomedical policy	•
(11)	Basic matters related to research expenses (public and private)	•
(12)	Basic matters of research integrity (e.g., research misconduct, authorship)	•

Appendix 1 (cont.) Core competencies required for novice research ethics consultants (RECs) [3] (excerpted)

Competency domains and intermediate categories		REC level
		<i>Basic</i>
Domain 2-1:	Ethics assessment skills	
(15)	Research protocol reading skills	•
(16)	Skill of distinguishing between medical care and research	•
(17)	Skill of distinguishing legal matters from non-legal matters governed by ethical norms	•
(18)	Logical thinking/analytical skills	•
(19)	Eliciting (or understanding) the true intentions of consultees/researchers	•
(20)	Identification of ethical, legal, and social issues (ELSI) related to the consultation case: (1) Identification of problems related to the fair selection of subjects	•
(21)	Identification of ethical, legal, and social issues (ELSI) related to the consultation case: (2) Identification of problems related to risks and benefits	•
(22)	Identification of ethical, legal, and social issues (ELSI) related to the consultation case: (3) Identification of problems related to consent	•
(28)	Search and collect necessary information, supplementary information, and materials relevant to domestic situation	•
Domain 2-2:	Management and procedural skills	
(30)	Dividing roles and purposes between REC/IRB review and consultation	•
(34)	Issuing appropriate warnings to terminate, abandon, or modify issues, matters, or practices that cannot be legally or ethically permitted/justified	•
(35)	Appropriately connecting and consulting with related departments (e.g., REC/IRB, medical information, medical safety, research integrity audit office) in facility as necessary	•
Domain 2-3:	Interpersonal skills	
(37)	General communication skills (e.g., listening, clarity, non-verbal communication)	•
(38)	Accurate and clear expression skills in Japanese language	•
(39)	Ability to first answer required questions	•
Domain 2-4:	Educational skills	
(48)	Ability to explain in plain language	•
Domain 3:	Personal characteristics	
(50)	Self-discipline skills	•
(51)	Open-minded attitude	•
(52)	Empathic attitude	•
(53)	Neutral/independent-minded attitude, fair mindedness	•
(54)	Honesty, integrity	•
(55)	Reflective/self-knowledge attitude	•
(56)	Perseverance, diligence	•
(57)	Coherence, logicalness	•
(58)	Calmness, prudence	•

Some of the dimensions of the task-specific scoring guide rubric are more easily applied than others. For example, for Dimension II (“Understanding and knowledge of relevant laws, regulations, guidelines, and other rules (by governments, academic societies, etc.)”), its descriptions of the highest level of performance refer to four items, the understanding of which is required of RECs. As is the case with the four-level rubric, it is natural to apply Dimension II mathematically in accordance with the grades assigned in the workshop: when participants enumerate all of four items, then it is rated as 4; when they enumerate three out of four items, then it is rated as 3, and so forth. However, our participants’ self-assessment results revealed two groups with an SD of 0.8 or higher for both Dimensions III and IV. These two dimensions are more difficult to apply, as their descriptions cannot be used in a simple mathematical way to assess participant answers. It is premature to conclude, therefore, whether or not the high SDs resulted from the unavoidable nature of these dimensions, inadequate assessment abilities among our workshop participants, and/or the inappropriateness of our developed descriptions of performance. Further examination of the reliability and validity of our developed rubrics is needed, through repeated use and, if necessary, repeated revision at actual training workshops.

The highest level of performance for the case of interest is illustrated by the model answers to the case-scenario questions. Through repeated collection and assessment of workshop participant answers to the questions pertaining to this case, we can expect to identify “anchors” for other lower levels of performance, defined as “[s]amples of work or performance used to set the specific performance standard for each level of a

rubric [17].” The identified anchors for lower levels would contribute to scoring reliability. Anchor identification may also lead to revision of the task-specific rubrics which we have developed this time. Generally speaking, as rubrics need continuous refinement, we are ready not only to modify the descriptions of performance, but also to continue with identification of better anchors.

No single consultation case used in our training workshop covers all the core competencies required of a novice REC. Therefore, it is necessary to consider the optimal combinations of consultation cases so that the widest possible range of core competencies can be assessed throughout the workshop.

The general scoring guide rubric created this time remains in a preliminary stage and further revisions based on the task-specific scoring guide rubric, developed here for the case of interest, are needed. However, as it stands now, it will serve as a model for the development of task-specific scoring guide rubrics for other consultation cases. Providing participants with the revised general rubric before the workshop would make self-assessment easier because the general rubric helps workshop participants to conceptualize a high level of performance for a novice REC.

On the other hand, providing participants with the task-specific scoring guide rubric after the case study can serve as a form of feedback. Ideally, task-specific four-level scoring rubrics would allow us to provide detailed feedback and point out relevant descriptions of performance. Unfortunately, development of four-level rubrics requires more time and effort than that required for scoring guide ones. Since our training workshops do not utilize the same consultation cases repeatedly, the

burden of developing task-specific four-level rubrics becomes greater with every additional case that is used. Currently, we have 20 consultation case-scenarios created for the REC training and will need to develop similar rubrics for other cases in the future. Realistically, feedback could be provided by assigning grades for each dimension of the task-specific scoring guide rubrics and circling the relevant descriptions of performance.

Conclusions

We have developed a task-specific scoring guide rubric and a task-specific four-level scoring rubric for an authentic ethics consultation case as tools that can be used to assess the achieved competencies and performance skills of novice RECs at REC training workshops. Our goal in writing this paper was to share our experience and insight with others who are, or will be, engaged in REC training activities, which will inevitably require good educational materials, methods, and tools to assess participant competencies.

Looking to the future, we hope to find ways to further the growth of intermediate RECs as well, as they are expected to teach novice RECs, medical researchers, and ERB members. Knowledge and skills required of intermediate RECs are much broader in scope, deeper in content, and more challenging than those required of a novice REC. The know-how and model procedures obtained through the process of developing rubrics for a novice REC will likely be useful in creating rubrics for self-assessment of competencies and instructional performance skills among intermediate REC trainees.

Abbreviations

AMED: The Japan Agency for Medical Research and Development

COI: A conflict of interest

ERB: An ethics review board

REC: A research ethics consultant

SD: A standard deviation

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Authors' contributions

A.N.: analysis, developing the rubrics, prepared **Table 2**, and writing the first draft manuscript with K.K.. K.K.: analysis, leading the development of the rubrics,

and writing the first draft manuscript with A.N.. K.Y.: analysis, developing the rubrics, and giving critical intellectual inputs to the first draft manuscript. A.Y.: analysis, helping the rubrics development, and revising the first draft manuscript. K.M.: study conceptualization, analysis, developing the rubrics, and revising the draft manuscripts, tables, and figures. All authors read and approved the final manuscript.

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