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Factors influencing IACUC decision making: Who leads the discussions?

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Abstract

Decisions about the appropriate use of animals in research are largely made by Institutional Animal Care and Use Committees (IACUCs). Several commentators claim that scientists exert excessive influence on IACUC decisions. We studied 87 protocol reviews from 10 IACUCs to assess if any group of participants appeared to dominate the protocol discussions. Audio recordings of the meetings were coded to capture the topics of the discussions. We found that animal research scientists made the largest total number of topic mentions while community members made the fewest. On a per person basis, chairpersons and attending veterinarians made the most mentions. Scientists presented the largest number of protocols and the subsequent discussions tended to contain the same topics mentioned in the presentations. The large number of protocols presented by scientists and their total number of comments made during protocol discussions suggest that scientists may significantly influence IACUC decision making.

Animal research plays a major role in medical progress. However, since animals cannot protect themselves, federal law has mandated that Institutional Animal Care and Use Committees (IACUCs) balance the need for animal research with protection of the animals in research, teaching, and testing activities. Using animals that are regulated under the Animal Welfare Act (as amended 2008 [AWA]) or the guidelines of the Health Research

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Extension Act (1985) requires IACUC review. The minimal composition of an institution's IACUC is specified in the AWA regulations (AWAR, 2012) and the Public Health Service's Policy on Humane Care and Use of Laboratory Animals (Public Health Service [PHS] 2002) but the composition of IACUCs often exceeds the minimum federal requirements. A typical academic IACUC is composed of a chairperson, an attending veterinarian, and one or more of each of the following types of people: an individual who represents community interests and is unaffiliated with the institution, a scientist experienced in research using animals and a member whose primary concerns are in a non-scientific area.

Much has been written about how the composition of IACUCs and similar ethics-based committees can impact the committee's discussions and subsequent decision making (Candilis et al., 2002; Graham, 2002; Greitemeyer, Schulz-Hardt, Brodbeck & Frey, 2006; Hagelin, Hau, & Carlsson, 2003; Hansen, Goodman, & Chandra, 2012; Hansen, 2013; Hawkins, 2002; Hayry, 1998; Hedgecoe, 2012; Houde, Dumas, & Leroux, 2003; Ideland, 2009; Orlans, 1997; Schuppli & Fraser, 2005; Schuppli & Fraser, 2007; Schuppli, 2011; Silverman, Baker, & Lidz, 2012; Tjarnström, 2013; Verweij, Brom & Huibers, 2000). Two related concerns are that scientists are either overrepresented or exert an unusually strong influence, based on their expertise, on the direction of committee discussions (Hansen et al., 2012; Hayry, 1998; Ideland, 2009; Schuppli & Fraser, 2007). In a recent study we reported that only 9% of the scientists serving on IACUCs believed that scientists like themselves dominated their IACUC whereas 20% of IACUC administrators saw their committees as being dominated by scientists (Silverman et al., 2012). To better understand the influence of the various participants on the dialog in IACUCs we had 3 goals for the present study. The first was to determine the topics that were discussed by IACUC meeting participants. Our second goal was to assess if any group of participants dominated protocol discussions at the meetings. The final goal was to evaluate the possible influence of the person presenting a protocol on the ensuing discussion of the protocol.

Materials and Methods

Eighteen academic biomedical research institutions, among the top 50 of National Institutes of Health grant and contract dollar recipients, volunteered to participate in this study. The details of the methods used to recruit those institutions have been published elsewhere (Silverman, et al., 2015). To help assure study site anonymity, only 10 of the 18 institutions were chosen for data acquisition. They represented the west (2 sites), east (3 sites), north (1 site), south (2 sites) and central U.S. (2 sites). The 10 institutions reviewed a total of 87 protocols which included 51 new applications, 14 amendments, 15 renewals, 6 resubmissions from an earlier review and 1 teaching protocol. All protocols underwent full committee review (FCR) and all protocols were classified by the institution as likely to result in more than momentary or mild pain or distress. The average number of IACUC members and nonmembers attending a meeting was 18.3 (+/- 5.8 SD) with a range of 13–31 people. This included 68 scientists with experience in research using animals, 10 IACUC chairs, 10 attending veterinarians, 8 community members, and 36 other voting members, as well as 37 staff and 14 non-voting veterinarians. Community members did not attend the meetings at 3 sites and no "other voting member" was in attendance at one site. The "other voting members" included biosafety officers, compliance officers, veterinarians other than the

attending veterinarian, and others. The procedures used to code the protocol discussions also were described previously (Silverman et al., 2015). Briefly, the 87 protocol discussions were audio-recorded and transcribed, and redacted as needed to ensure confidentiality. We then assigned topic codes (Table 1) to each speaking turn (that is, everything a speaker said until he or she stopped speaking and another person began speaking). The codes (e.g., animal numbers or animal death) captured the contents of all pertinent comments made during the discussions. Any specific topic code was assigned only once during a single speaking turn. This method greatly increased the reliability of the coding as the units to be coded were predefined.

Every site had non-voting attendees at the meetings and one site had researchers whose studies were being reviewed attend and participate at its meeting. The latter's comments were not included in our analysis as inclusion would bias the results more than their exclusion. One committee member declined to be audio-recorded and that person's 11 speaking turns were redacted from the transcript. All coded mentions were entered into a commercial online software program (Dedoose, Hermosa Beach, CA) for ease of qualitative analysis. Additional analyses of transcripts were conducted using the SAS statistical package, version 9.3 (SAS Institute, Cary, NC) or SPSS statistical package, version 22.0 (IBM, Armonk N.Y). We performed a multivariate logistic regression to determine if our control group (scientists) was more likely than each of the other participant groups to mention a particular topic code. The 95% confidence intervals for the odds ratios are shown, as is the p-value when $p < 0.05$. A statistically significant odds ratio of >1 indicated a greater likelihood of a participant group (such as community members) mentioning a topic code as compared to the scientists. A statistically significant odds ratio of <1 indicated a greater likelihood that the scientists were more likely than the participant group to mention a topic code.

At all study sites, prior to a general discussion about a protocol, one or two committee members summarized the protocol for the other committee members. In order to determine whether a scientist presenting a protocol would be more likely than a veterinarian presenting a protocol to influence subsequent discussion of that protocol, we fitted another set of logistic equations. We combined the attending veterinarians and non-voting veterinarians into a single group, "veterinarians." We excluded any additional comments that were made by the presenter after the summary presentation was made. We then estimated the adjusted odds ratios to detect possible associations between the group the participants belonged to and their probability of mentioning a given topic.

All study sites were advised that this study was initial exploratory research. It was approved by the University of Massachusetts Medical School Institutional Review Board.

Results

Within the 17 coded topics shown in Table 1 there were 5632 topic mentions within the 87 protocol discussions. The most frequently coded topic was pain or distress ($n=816$ mentions) followed by mentions about the specific procedures to be performed ($n=770$) and then the study design ($n=659$). Among the topics receiving the fewest number of mentions were

preliminary data, alternatives to animal use or to painful or distressful procedures, and the scientific or clinical benefit of the research.

Table 1 shows the number of mentions by the participant group. The 2 participant groups having the largest total representation on the 10 IACUC (scientists and other voting members) also made the largest total number of mentions (n=1825 and 1202, respectively). Community members, the group with the smallest total representation, provided the fewest total mentions (n=196). However, the picture changes when viewed on a per person basis. As Table 1 shows, the 10 chairpersons made the most mentions per person (119.6 mentions per chairperson) followed by the attending veterinarians (59.1 per attending veterinarian), the “other voting members” and then the scientists. The community members and the scientists had a similar number of mentions per person while the non-voting IACUC staff members made the fewest mentions per person.

In almost every instance the first five topic codes shown in Table 1 included the greatest number of mentions from each group of meeting participants. Pain or distress generated the most mentions among scientists, chairpersons, attending veterinarians and non-voting veterinarians, and was among the top five mentions made by all groups. As can be seen from the odds ratios, all participant groups except for the community members and non-voting veterinarians were significantly less likely than the scientists to discuss pain or distress. The community members and non-voting veterinarians were approximately 1.7 and 1.5 times (respectively) more likely than the scientists to discuss pain or distress.

One important topic is the skill and experience of the research team. However, there was a relatively small total number of mentions of this topic. The odds ratio analysis indicated that community members and chairpersons were significantly less likely than scientists to discuss a research team’s skill and experience (Table 1). The likelihood of the non-voting IACUC staff commenting on skill and experience did not differ significantly from the scientists.

The odds ratio analysis for the justification of animal numbers indicated that all groups were less likely than the scientists to discuss animal numbers, except for the community members who were 1.8 times more likely than the scientists to discuss animal numbers.

The justification of the species to be used was ranked thirteenth among the total number of topic code mentions and was most often mentioned by the non-voting veterinarians. The odds ratio analysis revealed that the chairpersons and non-voting IACUC staff were the only two groups for which a discussion about the species being proposed for use was significantly less likely to occur, as compared to the scientists. We also looked at the broad topic of alternatives to animal use, which had among the fewest mentions for all groups; there was insufficient data to perform an odds ratio analysis. Other comparisons are shown in Table 1.

Table 2 shows that on average at least one scientist participated in the discussion of 88% of the protocols. The chairpersons made at least one mention on 84% of the protocols. The eight community members participated in the discussion of only 24% of the protocols, although no community members were present for 27 protocol discussions, so they participated in 35% of those for which they were present.

The IACUC roles of the presenters of protocols at the FCR meetings are also shown in Table 2. A total of 119 people presented one or more protocols to their IACUC colleagues. In some instances there was more than one presenter of a protocol. Thus, although there were only 68 scientists on the 10 IACUCs, 77 of the presenters of the 87 protocols (88.5%) were scientists. The group with the second highest representation on the IACUCs (other voting members) participated in the presentation of only 10 protocols. Chairpersons presented very few protocols with the exception of one site where the Chair presented all of the protocols. One site had a nonvoting IACUC staff member present a protocol.

One of our goals was to examine the influence of the person presenting a protocol on the subsequent discussion of the same protocol. In Table 3 we compared the impact of a scientist as the initial presenter to the impact of a veterinarian as the initial presenter. These people constituted the two largest groups of protocol presenters. The odds ratio analyses indicated that, in general, whatever topics the presenter mentioned, the subsequent discussion would likely include the same topics. For example, the odds ratio for pain or distress was 2.56 when the presenter was a scientist, indicating that pain or distress was 2.56 times as likely to be discussed in the subsequent discussion if a scientist mentioned pain or distress in the initial summarization of the protocol. The same pattern was true when a veterinarian was the presenter. Thus, there appears to be very little difference between the impact of scientists or veterinarians as initial presenters. However, the presenters had a very large influence on whether a topic was subsequently discussed.

Discussion

In this study of 10 IACUCs, 5632 total mentions were made during the discussions of 87 IACUC protocols. Nearly one of every three mentions was made by scientists, about one of every five mentions was made by the chairpersons and also about one in five mentions was made by the “other voting members.” Only one of every 10 mentions was made by the attending veterinarians and about one in 30 mentions came from the community members. Even though the chairpersons made more mentions than did the scientists when evaluated on a per person basis, these were primarily administrative or facilitating comments. The scientists made the most total mentions as a consequence of their sheer numbers on the IACUCs we studied and their propensity to voice their opinions.

The topics discussed during the initial presentation of a protocol were likely to be the same topics discussed during subsequent discussion of that protocol. This was true whether the summary presentation was made by a scientist or veterinarian. A scientist had no more influence over the direction of the subsequent discussion than a veterinarian when summarizing a study but scientists presented almost twice as many protocols as all other participants combined. Based on this fact, in conjunction with the finding that scientists were the majority of voting members on most of the IACUCs we studied and that scientists made the most total mentions, we believe it is reasonable to conclude that scientists wield a very strong influence on the topics that other members of their IACUC discuss.

The large number of total mentions made by scientists on the IACUCs reflects that 50% of the voting members were scientists with experience in research using animals. Chairpersons

who were scientists were not included in those numbers, but if they had been, the percentages would have been even greater. In a study of the composition of IACUCs at 21 research universities in the United States, it was found that approximately 67% of IACUC members (including chairpersons) were scientists with experience in research using animals (Hansen et al., 2012; Hansen, 2013). Others also have documented the heavy representation of scientists on IACUCs (Houde, Dumas, & Leroux, 2003; Ideland, 2009; Schuppli & Fraser, 2005). Although this was a study of only 10 IACUCs and it is possible that others would be different, our data show that scientists were not only highly represented on the IACUCs but they were the large majority of reviewers.

Scientists do, and should, play a key role on IACUCs as they provide critical expertise about their fields of study, including important methodological issues. However, their experience gives them a particular perspective on the use of animals in research. They are accustomed to the use of animals in research and may be less likely to find a particular animal use problematic. The community members who serve on IACUCs are charged with representing the less specialized, non-scientific concerns of an institution's surrounding community. The present study was not designed to determine if community members actively promoted community interests or values or raised concerns about ethical uncertainty (Dyer, 2004) during full committee reviews. However, it is of interest that they were the only group of participants giving the topic of animal death the most mentions, the only group that included the number of animals being used among its top five mentions, and in comparison to scientists, community members were more likely to discuss pain or distress and less likely to discuss specific research procedures. All of this suggests that whether or not their perspective reflects the interests of the surrounding community, the community members provide a valuable perspective that differs from that of many other IACUC members.

Best Practices

Several steps can be taken to provide a more balanced review process. One important step would be to decrease the percentage of IACUC voting members who are scientists and increase the percentage of nonscientists, including veterinarians and community members. The addition of a veterinarian who is not affiliated with the research institution could be a balancing influence.

Our findings have demonstrated the influence of the reviewers who present the protocol. This is a key role and more balanced review would be greatly facilitated by having two reviewers for every protocol, one of which should be a scientist and the other a non-scientist. Having a defined rotation of protocol presenters based on their role on the IACUC, not based on their numbers, would assure an important voice for non-scientists even if the committee membership continues to be dominated by scientists (Greitemeyer, Schulz-Hardt, Brodbeck, & Frey, 2006). This is, however, definitely a less desirable approach than a more balanced membership since it would mean that the non-scientists would be burdened with presenting more protocols than the scientists.

Research Agenda

The critical role of the presenters in determining the topics discussed may not be unique to IACUCs. It would be important to see to what degree this is a general pattern. For example, is the same thing true in IRBs, in NIH review panels, in committees reviewing bids for various different types of contracts? To what degree does this depend on the specialized expertise of the reviewer? If this effect is limited to reviewers who are perceived as experts, community members may not be appropriate reviewers to balance scientists. Our sample of community members as reviewers was too small to answer this question.

Our data show that some topics, including those for which there are more standardized approaches (e.g., pain alleviation) were the most frequent topics of discussion. Other topics that are equally important from both scientific and ethical perspectives (e.g., animal number justification, species justification, importance of the question being asked) were not given the same depth of consideration. Did this reflect the perception that these issues were not important or that the committee members did not have a clear sense of how to address them? Intensive qualitative interviews with committee members would help to clarify the problem and facilitate a solution.

We have highlighted the impact of the protocol presenters on the topics discussed. However, this is different than the outcome of the review. Do different types of protocol presenters affect whether a research activity using animals is approved and does it affect the changes requested? This question requires further research.

Education Implications

IACUCs provide much of the ethical oversight of animal use in biomedical research and teaching. However, key findings from this study suggest the need for possible changes in the way in which IACUCs function because they raise questions about the nature of the protocol review process. It may be that graduate students, early in their careers, need additional training to help them think creatively about some of the more difficult questions concerning animal use that IACUCs are supposed to be evaluating. This might help young scientists who join an IACUC to address some of the difficult animal use topics (e.g., alternatives) that our data show are often marginalized. Likewise, we need to consider upgrading the training and education of non-scientist members so that they can more actively address the scientific dimensions of animal care and use.

If an IACUC is to perform its intended function successfully, it requires active, informed participation of all its members and their values and knowledge. Without full member participation some of that strength can be lost. We found that all groups of IACUC members contributed to the FCR discussions but community members spoke up at least once on only 24% of the protocols discussed compared to the much larger group of scientists who spoke up at least once on 88% of all protocols discussed. This suggests that additional efforts should be made by IACUCs to incorporate the views of the community members into IACUC discussions. We also found that the post-presentation discussions of protocols were likely to focus on the topics mentioned during the summary presentation, without regard to

the presenter being a scientist or a veterinarian. However, with scientists presenting most of the protocols and potentially framing the discussions based on their own training and interests, it would seem reasonable that IACUCs make efforts to have a broader sample of protocol presenters. Using the same reasoning, IACUCs should consider whether scientists from multiple disciplines are necessary to represent the institution's scientific community or if a reduced number of scientists could provide adequate representation while leading to an increase in the number of other voting members.

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Table 1
Number of “mentions” by role and odds ratios of scientists compared to other study participant groups.

Topic code	Total n=183	Scientists n=68		Other voting members n=36			Chairperson n=10			Attending Veterinarian n=10		
		Total	Avg. per person	Total	Avg. per person	Odds ratio (confidence interval)	Total	Avg. per person	Odds Ratio (confidence interval)	Total	Avg. per person	Odds Ratio (confidence interval)
Pain or distress	816	273	4.0	134	3.7	.73* (.58 to .93)	184	18.4	.75* (.60 to .94)	82	8.2	.68* (.50 to .91)
Procedures performed	770	232	3.4	187	5.1	1.03 (.81 to 1.3)	169	16.9	.75* (.59 to .95)	58	5.8	.55* (.39 to .78)
Study design	659	211	3.1	140	3.9	.98 (.77 to 1.25)	175	17.5	.98 (.77 to 1.2)	65	6.5	.75 (.54 to 1.04)
Completeness of protocol form	561	188	2.8	138	3.8	1.4* (1.1 to 1.8)	89	8.9	.69* (.52 to .92)	58	5.8	.97 (.68 to 1.37)
Animal death (euthanasia, study endpoints)	543	150	2.2	108	3.0	1.00 (.76 to 1.3)	122	12.2	.97 (.74 to 1.3)	61	6.1	1.02 (.71 to 1.4)
Research personnel skill, experience and training	358	93	1.4	98	2.7	1.23 (0.89 to 1.70)	63	6.3	.66* (.46 to .94)	48	4.8	1.42 (.95 to 2.1)
Animal husbandry	356	109	1.6	87	2.4	1.09 (.80 to 1.5)	74	7.4	.87 (.63 to 1.2)	33	3.3	1.19 (.76 to 1.8)
Animal number justification	297	128	1.9	41	1.1	.42* (.29 to .61)	66	6.6	.53* (.38 to .74)	25	2.5	.38* (.24 to .63)
Animal health and welfare	281	105	1.5	63	1.8	1.02 (.72 to 1.43)	56	5.6	.73 (.51 to 1.04)	40	4.0	1.00 (.66 to 1.54)
Speculative comments or uncertainty	273	89	1.3	66	1.8	1.15 (.81 to 1.6)	58	5.8	.71 (.49 to 1.01)	34	3.4	.83 (.53 to 1.3)
Biosafety	186	39	0.6	60	1.7	2.39* (1.6 to 3.7)	51	5.1	1.30 (.83 to 2.04)	27	2.7	1.21 (0.70 to 2.10)
Auxiliary documents (e.g., emergency plans)	180	65	1.0	32	0.9	.73 (.47 to 1.1)	28	2.8	.44* (.27 to .70)	18	1.8	.60 (.33 to 1.07)
Species justification (moral importance, applicability)	171	57	0.8	24	0.7	.75 (.45 to 1.24)	27	2.7	.49* (.30 to .81)	27	2.7	.75 (.44 to 1.27)
Purpose/aims of study	83	45	0.7	8	0.2	.27* (.13 to .60)	12	1.2	.30* (.15 to .56)	8	0.8	.37* (.16 to .85)

Topic code	Total n=183	Scientists n=68		Other voting members n=36		Chairperson n=10		Attending Veterinarian n=10	
		Total	Avg. per person	Total	Avg. per person	Total	Avg. per person	Total	Odds Ratio (confidence interval)
Importance of the research	43	16	0.2	5	0.1	15	1.5	0	.92 (.42 to 1.02)
Alternatives to animal use or painful or distressful procedures	29	9	0.1	11	0.3	6	0.6	2	0.2
Preliminary data	26	16	0.2	0	0	1	0.1	5	.50 (.17 to 1.44)
Total	5632	1825	36.8	1202	33.2	1196	119.6	591	59.1

Topic code	Community Members n=8			Non-voting IACUC Staff n=37			Non-Voting Veterinarians n=14		
	Total	Avg. per person	Odds Ratio (confidence interval)	Total	Avg. per person	Odds Ratio (confidence interval)	Total	Avg. per person	Odds Ratio (confidence interval)
Pain or distress	30	3.8	1.70* (1.05 to 2.76)	46	1.2	.60* (.42 to .86)	67	4.8	1.50* (1.05 to 2.2)
Procedures performed	21	2.6	.35* (.21 to .59)	54	1.5	.61* (.42 to .86)	49	3.5	1.57* (1.05 to 2.36)
Study design	19	2.4	.78 (.45 to 1.34)	25	0.7	.36* (.23 to .56)	24	1.7	.78 (.48 to 1.28)
Completeness of the protocol form	14	1.8	1.20 (.65 to 2.23)	53	1.4	1.23 (.86 to 1.74)	21	1.5	.68 (.40 to 1.14)
Animal death (euthanasia, study endpoints)	34	4.3	2.95* (1.81 to 4.82)	32	0.9	.96 (.63 to 1.46)	36	2.6	1.35 (.85 to 2.14)
Research personnel skill, experience and training	16	2.0	.44* (.24 to .82)	33	0.9	.70 (.45 to 1.10)	7	0.5	.62 (.27 to 1.43)
Animal husbandry	8	1.0	.47 (.21 to 1.03)	30	0.8	.91 (.58 to 1.42)	15	1.1	2.14* (1.12 to 4.12)
Animal number justification	18	2.3	1.83 (.99 to 3.37)	15	0.4	.52* (.30 to .93)	4	0.3	.11* (.04 to .31)
Animal health and welfare	6	0.8	.83 (.34 to 2.06)	1	0	.04* (.00 to .26)	10	0.7	.59 (.29 to 1.22)
Speculative comments or uncertainty	7	0.9	.67 (.29 to 1.56)	7	0.2	.26* (.12 to .56)	12	0.9	.65 (.33 to 1.29)
Biosafety	5	0.6	1.56 (.57 to 4.3)	4	0.1	.40 (.14 to 1.15)	0	0	.000
Auxiliary documents (e.g., emergency plans)	2	0.3	.42 (.10 to 1.80)	30	0.8	2.02* (1.25 to 3.28)	5	0.4	.36* (.13 to .95)
Species justification (moral importance, applicability)	7	0.9	1.08 (.45 to 2.63)	4	0.2	.19* (.07 to .54)	25	1.8	1.46 (.82 to 2.60)

Topic code	Community Members n=8			Non-voting IACUC Staff n=37			Non-Voting Veterinarians n=14		
	Total	Avg. per person	Odds Ratio (confidence interval)	Total	Avg. per person	Odds Ratio (confidence interval)	Total	Avg. per person	Odds Ratio (confidence interval)
Purpose/aims of study	5	0.6	.90 (.31 to 2.59)	1	0	.07* (.01 to .49)	4	0.3	.44 (.14 to 1.35)
Importance of the research	4	0.5	1.85 (.51 to 6.72)	0	0	.000	3	0.2	.44 (.12 to 1.70)
Alternatives to animal use or painful or distressful procedures	0	0		0	0		1	0.1	
Preliminary data	0	0	.000	3	0.1	.57 (.12 to 2.63)	1	0.1	.000
Total	196	24.8		338	9.2		284	20.5	

* p 0.05

Table 2

Participation indexes by role on IACUC

	Scientist (n=68)	Other voting member (n=36)	Chairperson (n=10)	Attending veterinarian (n=10)	Community member* (n=8)	Non-voting IACUC staff (n=17)	Non-voting veterinarian (n=14)
Percentage of protocols with at least one mention, by role	88%	68%	84%	51%	24%	54%	32%
Number of protocols presented, by role#	77	10	12	9	5	1	5

* Three meetings had no community member present

Some members presented more than one protocol. Some protocols were presented by two members.

Table 3

Likelihood of having further IACUC discussion of the topic shown when the presenter of the protocol is a scientist or a veterinarian. Odds ratios are adjusted for the protocol reviewed.

Topic	Scientist as presenter		Veterinarian as presenter	
	Odds ratio	Confidence interval	Odds ratio	Confidence interval
Pain or distress	2.56 *	1.82 to 3.60	2.74 *	1.95 to 3.83
Procedures performed	2.33 *	1.64 to 3.31	2.31 *	1.63 to 3.27
Study design	8.29 *	5.89 to 11.65	8.41 *	6.00 to 11.18
Completeness of the protocol form	2.00 *	1.33 to 2.90	2.06 *	1.40 to 3.03
Animal death (euthanasia, study endpoints)	2.61 *	1.80 to 3.82	2.50 *	1.72 to 3.63
Research personnel skill, experience and training	1.05	0.58 to 1.88	1.00	0.56 to 1.79
Animal husbandry	1.25	0.73 to 2.13	1.27	.75 to 2.15
Animal number justification	5.48 *	3.76 to 8.02	6.28 *	4.33 to 9.11
Animal health and welfare	2.23 *	1.39 to 3.59	2.48 *	1.55 to 3.96
Speculative comments or uncertainty	2.32 *	1.43 to 3.76	2.40 *	1.49 to 3.88
Biosafety	0.64	0.23 to 1.77	0.57	0.21 to 1.56
Auxiliary documents (e.g., emergency plans)	2.76 *	1.61 to 4.72	2.97 *	1.75 to 5.04
Species justification (moral importance, applicability)	9.07 *	5.94 to 13.87	9.10 *	6.02 to 13.76
Purpose/aims of study	133.39 *	75.98 to 234.21	142.67 *	82.62 to 246.38
Importance of the research	49.39 *	25.40 to 96.07	43.58 *	23.10 to 82.21
Alternatives to animal use or painful or distressful procedures	Model does not converge		Model does not converge	
Preliminary data	Model does not converge		Model does not converge	

*
p 0.05