

IRB Efficiency Project Researcher Survey Report

Fall 2020

Introduction

As part of the IRB Efficiency Project (IEP), a survey was developed for the research community to provide the project with baseline measures of satisfaction as well as provide the community with the opportunity to provide their suggestions for improving IRB and related processes. This survey was developed in conjunction with the Huron Consulting Group and was vetted by the IEP's Advisory Working Group, several members of which provided valuable feedback incorporated into the final version of the survey. A copy of the survey is attached as an appendix to this report for reference.

Executive Summary

- 285 people completed the survey.
- Across questions, levels of satisfaction (ranging from somewhat to very satisfied) were generally high, especially regarding IRB staff.
- Regarding turnaround time, researchers were more satisfied with the ED/SBS and MR IRBs review times in contrast to the HS IRB.
- Researchers submitting higher numbers of applications per month tended to be more dissatisfied with review times.
- Whether researchers had regulatory support did not generally make a consistent difference in levels of satisfaction.
- The primary areas for suggested improvements were related to ARROW and review times, especially providing a clearer time frame for when studies will be scheduled for a meeting and/or approved.

Distribution

The survey was opened in early September and closed on October 1st. Information about the IEP and the survey was distributed widely across campus, including via:

- Listservs from both IRB offices
- SMPH's Research Administrator's Network listserv
- RSP's listserv
- AWG member assistance
- Direct emails from both IRB offices to study teams who recently contacted the office or are otherwise key contacts in the research community

Combined, the survey announcement was sent to approximately 3000 people.

Profile of Respondents

We received 285 complete responses to the survey. While this is a small fraction of the total number of people notified about the survey, the response rate was largely consistent with previous surveys about the IRBs. Given that the research community has been surveyed several times in recent years regarding the IRB review process as well as the challenges posed by the pandemic, the number and type of responses received is meaningful.

A brief snapshot of who responded to our survey:

- The largest number of respondents were PIs (41%), followed by points of contact (33%)
- When asked about whether respondents had assistance with preparing IRB submissions, 47% indicated Yes, while 53% indicated No.
- Regarding the number of all types of applications submitted to the IRBs each month, 79% submitted 0-3 applications per month.
- By IRB, the breakdown of respondents (who could select more than one) is:
 - ED/SBS IRB: 22%
 - HS IRB: 42%
 - MR IRB: 36%

Analysis of Survey Data

- For Likert scale questions, data was analyzed via SPSS to generate cross-tabulations. This data was further refined using Chi-square statistics. The data presented below focuses on those data that more strongly indicate a solid relationship between data points.
- For text response questions, comments were analyzed via tools available in Qualtrics. These identified the most frequently referenced topics (e.g., ARROW, protocols, staff) and provided sentiment scores for each of these. Each of the comments was reviewed by Monica and Carol, who made some adjustments to sentiment scores to more accurately reflect the nature of the comment. For example, many comments about ways to improve the IRB review process were mixed (e.g., this doesn't work well, but I think the following does), but given a negative score by Qualtrics.
- Summaries of the types of comments that appeared most frequently in response to each question are provided below each keyword plot.

Next Steps

- Feedback from the survey will be especially useful in determining how ARROW will be redesigned as well as how Toolkit documents (including the investigator manual) may need further revisions to address those areas that study teams have identified as especially challenging.

- We will target next September for a follow up survey to help assess how implementation of the Toolkit and related changes may have impacted researcher perspective on the IRB review process.

Survey Responses Question 4

Survey question #4 asked respondents to rate their satisfaction with the following:

- Overall IRB review turnaround time (from submission to IRB determination)
- Resources available for preparing a submission to the IRB
- Clarity of IRB staff instructions during the pre-review process
- Clarity of IRB feedback after IRB member or IRB committee review

Satisfaction with Turnaround Time

Satisfaction with overall review turnaround time by the IRB(s) to which respondents more often submit (Table 1), across all IRBs, 59.0% of respondents indicate being extremely to somewhat satisfied, 8.6% of respondents were neutral, and 32.5% of respondents indicate being somewhat to extremely dissatisfied. Respondents that most often submit to the ED/SBS IRB primarily report being extremely to somewhat satisfied (79.1%). For the Minimal Risk IRB, 66.7% of respondents indicate being extremely to somewhat satisfied. For the HS IRB, just under half (48.3%) of respondents report being extremely to somewhat satisfied with turnaround times.

When satisfaction with overall turnaround time is looked at by role, approximately 59.7% of PIs, 59.0% of points of contact, and 61.5% of regulatory specialists report being extremely to somewhat satisfied. Among those in other roles, 50.1% report being satisfied with turnaround times. Approximately one third of PIs, points of contact, and those in other roles indicate dissatisfaction with turnaround times. Dissatisfaction was lowest among regulatory specialists (23.1%).

When satisfaction with turnaround time among PIs is broken down by those with support staff and those without, PIs without support staff indicated higher levels of satisfaction at 63.5% while 55.8% of PIs with support reported some level of satisfaction. PIs without support staff were slightly less dissatisfied with turnaround times (30.7%) than those with support staff (38.5%).

Satisfaction with turnaround times by number of submissions each month showed higher levels of satisfaction (62.0%) than dissatisfaction (29.6%) among respondents that submit 0-3 applications per month. Respondents that submit 4-7 applications per month were split with 44.1% reporting satisfaction and 47.1% indicating dissatisfaction. The majority of respondents that submit 8 or more applications each month (54.6%) indicated some level of satisfaction with turnaround times.

Table 1 - Satisfaction with overall IRB review turnaround time (from submission to IRB determination) by IRB most often used

		often used IF			Total	
		ED/SBS	MR	HS		
Satisfaction with: Overall IRB review turnaround time (from submission to IRB determination)	Extremely satisfied	Count	10	5	5	20
		% within IRB most often used	23.3%	8.8%	4.1%	9.0%
	Very satisfied	Count	12	15	22	49
		% within IRB most often used	27.9%	26.3%	18.0%	22.1%
	Somewhat satisfied	Count	12	18	32	62
		% within IRB most often used	27.9%	31.6%	26.2%	27.9%
	Neutral	Count	3	3	13	19
		% within IRB most often used	7.0%	5.3%	10.7%	8.6%
	Somewhat dissatisfied	Count	3	8	28	39
		% within IRB most often used	7.0%	14.0%	23.0%	17.6%
	Very dissatisfied	Count	1	5	16	22
		% within IRB most often used	2.3%	8.8%	13.1%	9.9%
	Extremely dissatisfied	Count	2	3	6	11
		% within IRB most often used	4.7%	5.3%	4.9%	5.0%

Total	Count	43	57	122	222
	% within IRB most often used	100.0%	100.0%	100.0%	100.0%

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	25.878 ^a	12	.011
Likelihood Ratio	25.483	12	.013
Linear-by-Linear Association	16.380	1	.000
N of Valid Cases	222		

a. 6 cells (28.6%) have expected count less than 5. The minimum expected count is 2.13.

Satisfaction with Resources Available for Preparing a Submission

Satisfaction with resources available for preparing a submission by the IRB(s) to which respondents most often submit, across all IRBs, 76.1% of respondents indicate being extremely to somewhat satisfied, 9.9% of respondents were neutral, and 14.1% of respondents indicate being somewhat to extremely dissatisfied. Respondents that most often submit to the ED/SBS IRB primarily report being extremely to somewhat satisfied (76.8%). For the Minimal Risk IRB, 82.4% of respondents indicate being extremely to somewhat satisfied. For the HS IRB, 72.9% of respondents reported some level of satisfaction with resources.

Across all roles, the majority of respondents reported some level of satisfaction with available resources: 71.1% of PIs, 82.1% of points of contact, 84.6% of regulatory specialists, and 62.6% of other roles. Approximately 10-15% of PIs, points of contact, and regulatory specialists indicate some level of dissatisfaction with available resources. Dissatisfaction was highest among those in other roles (25.1%).

When satisfaction with resources among PIs is broken down by those with support staff and those without, PIs without support staff indicated lower levels of satisfaction at 67.2% while 75.0% of PIs with support reported some level of satisfaction. PIs without support staff were slightly more dissatisfied with turnaround times (17.3%) than those with support staff (11.5%).

Satisfaction with turnaround times by number of submissions each month showed higher levels of satisfaction (74.4%) than dissatisfaction (13.4%) among respondents that submit 0-3 applications per month. Respondents that submit 4-7 applications per month were far more satisfied (82.4%) than dissatisfied (14.7%). The majority of respondents that submit 8 or more applications each month (81.9%) also indicated some level of satisfaction with resources.

Satisfaction with Clarity of IRB Staff Instructions During the Pre-review Process

Satisfaction with clarity of staff instructions during pre-review by the IRB(s) to which respondents more often submit, across all IRBs, 77.9% of respondents indicate being extremely to somewhat satisfied, 9.9% of respondents were neutral, and 12.3% of respondents indicate being somewhat to extremely dissatisfied. Respondents that most often submit to the ED/SBS IRB primarily report being extremely to somewhat satisfied (83.7%). For the Minimal Risk IRB, 82.5% of respondents indicate being extremely to somewhat satisfied. For the HS IRB, 73.8% of respondents reported some level of satisfaction with clarity of staff instructions.

Across roles, 75-80% of respondents reported some level of satisfaction with the clarity of staff instructions: 75.9% of PIs, 80.7% of points of contact, 80.8% of regulatory specialists, and 81.4% of other roles. Approximately 7-15% of PIs, points of contact, and regulatory specialists indicate some level of dissatisfaction with available resources. Dissatisfaction was highest among PIs (14.4%).

When satisfaction with clarity of staff instructions among PIs is broken down by those with support staff and those without, PIs without support staff indicated slightly lower levels of satisfaction at 71.1% while 80.8% of PIs with support reported some level of satisfaction. PIs without support staff were more dissatisfied with clarity of instructions (19.2%) than those with support staff (9.6%).

Satisfaction with turnaround times by number of submissions each month showed higher levels of satisfaction (77.7%) than dissatisfaction (12.8%) among respondents that submit 0-3 applications per month. Respondents that submit 4-7 applications per month were far more satisfied (79.4%) than dissatisfied (8.8%). The majority of respondents that submit 8 or more applications each month (72.8%) also indicated some level of satisfaction with clarity of instructions, while 9.1% report dissatisfaction.

Clarity of IRB feedback after IRB member or IRB committee review

Satisfaction with clarity of feedback after IRB member or committee review by the IRB(s) to which respondents more often submit, across all IRBs, 80.2% of respondents indicate being extremely to somewhat satisfied, 8.1% of respondents were neutral, and 11.8% of respondents indicate being somewhat to extremely dissatisfied. Respondents that most often submit to the ED/SBS IRB primarily report being extremely to

somewhat satisfied (79.1%). For the Minimal Risk IRB, 86.0% of respondent indicate being extremely to somewhat satisfied. For the HS IRB, 77.9% of respondents reported some level of satisfaction with clarity of staff instructions.

Across roles, most respondents reported some level of satisfaction with the clarity of feedback from IRB members or the board: 73.4% of PIs, 87.1% of points of contact, 80.8% of regulatory specialists, and 81.3% of other roles. Approximately 4-19% of PIs, points of contact, and regulatory specialists indicate some level of dissatisfaction with available resources. Dissatisfaction was highest among PIs (19.0%).

When satisfaction with clarity of feedback among PIs is broken down by those with support staff and those without, PIs without support staff indicated lower levels of satisfaction at 66.1% while 80.8% of PIs with support reported some level of satisfaction. PIs without support staff were more dissatisfied with clarity of feedback (24.6%) than those with support staff (13.5%).

Satisfaction with clarity of feedback by number of submissions each month showed higher levels of satisfaction (80.0%) than dissatisfaction (11.7%) among respondents that submit 0-3 applications per month. Respondents that submit 4-7 applications per month were far more satisfied (82.3%) than dissatisfied (8.8%). Most of the respondents that submit 8 or more applications each month (63.7%) also indicated some level of satisfaction with clarity of instructions, while 18.2% report dissatisfaction.

Question 5

Survey question #5 asked respondents to rate their satisfaction with IRB staff on the following:

- Knowledge of the respondent's type of research
- Knowledge of IRB regulations for the respondent's type of research
- Efficiency and timeliness of processing the respondent's submissions
- Responsiveness to the respondent's questions

Satisfaction with Staff Knowledge of the Respondent's Type of Research

Satisfaction with staff knowledge of respondents' type of research by the IRB(s) to which respondents more often submit, across all IRBs, 70.5% of respondents indicate being extremely to somewhat satisfied, 15.4% of respondents were neutral, and 14.0% of respondents indicate being somewhat to extremely dissatisfied. Among respondents that most often submit to the ED/SBS IRB, 60.5% report being extremely to somewhat satisfied, 20.9% were neutral. For the Minimal Risk IRB, 79.0% of respondent indicate being extremely to somewhat satisfied, 7% of respondents were neutral. For the HS IRB, 70.2% of respondents reported some level of satisfaction with clarity of staff instructions, 17.4% were neutral.

Across roles, most respondents reported some level of satisfaction with IRB staff knowledge of their kind of research: 58.6% of PIs, 85.8% of points of contact, 80.8% of regulatory specialists, and 56.3% of other roles. Approximately 4-25% of PIs, points of contact, and regulatory specialists indicate some level of dissatisfaction with available resources. Dissatisfaction was highest among those with other roles (25.1%).

When satisfaction with staff knowledge about their type of research among PIs is broken down by those with support staff and those without, PIs without support staff indicated lower levels of satisfaction at 53.9% while 63.4% of PIs with support reported some level of satisfaction. PIs without support staff were more dissatisfied with clarity of feedback (23.0%) than those with support staff (17.3%).

Satisfaction with staff knowledge of respondents' research by number of submissions each month showed higher levels of satisfaction (69.1%) than dissatisfaction (15.2%) among respondents that submit 0-3 applications per month. Respondents that submit 4-7 applications per month were far more satisfied (70.7%) than dissatisfied (11.7%). Most of the respondents that submit 8 or more applications each month (90.9%) also indicated some level of satisfaction with staff knowledge of their kind of research, while none reported dissatisfaction.

Satisfaction with Staff Knowledge of IRB Regulations for the Respondent's Type of Research

Satisfaction with staff knowledge of respondents' type of research by the IRB(s) to which respondents more often submit, across all IRBs, 82.4% of respondents indicate being extremely to somewhat satisfied, 11.3% of respondents were neutral, and 6.4% of respondents indicate being somewhat to extremely dissatisfied. Among respondents that most often submit to the ED/SBS IRB, 81.4% report being extremely to somewhat satisfied, 11.6% were neutral. For the Minimal Risk IRB, 87.8% of respondents indicate being extremely to somewhat satisfied, 5.3% of respondents were neutral. For the HS IRB, 80.2% of respondents reported some level of satisfaction with staff knowledge of IRB regulations, 14.0% were neutral.

Across roles, most respondents reported some level of satisfaction with IRB staff knowledge of their kind of research: 78.9% of PIs, 85.8% of points of contact, 96.2% of regulatory specialists, and 68.8% of other roles. Approximately 6-8% of PIs, points of contact, and those in other roles indicate some level of dissatisfaction with staff knowledge of IRB regulations for their type of research. Dissatisfaction was highest among PIs (8.6%).

When satisfaction with staff knowledge about their type of research among PIs is broken down by those with support staff and those without, PIs without support staff indicated slightly lower levels of satisfaction at 76.9% while 80.8% of PIs with support reported some level of satisfaction. PIs without support staff were more dissatisfied with clarity of feedback (9.6%) than those with support staff (7.6%).

Satisfaction with staff knowledge IRB regulations by number of submissions each month showed vastly higher levels of satisfaction (79.8%) than dissatisfaction (6.7%) among respondents that submit 0-3 applications per month. Respondents that submit 4-7 applications per month were far more satisfied (91.2%) than dissatisfied (5.9%). All the respondents that submit 8 or more applications each month indicated some level of satisfaction with staff knowledge of IRB regulations for their kind of research.

Satisfaction with Staff Efficiency and Timeliness of Processing the Respondent's Submissions

Satisfaction with staff efficiency and timeliness when processing respondents' submissions by the IRB(s) to which respondents more often submit, across all IRBs, 63.3% of respondents indicate being extremely to somewhat satisfied, 6.3% of respondents were neutral, and 30.3% of respondents indicate being somewhat to extremely dissatisfied (Table 2). Among respondents that most often submit to the ED/SBS IRB, 81.4% report being extremely to somewhat satisfied. For the Minimal Risk IRB, 71.9% of respondents indicate being extremely to somewhat satisfied. For the HS IRB, 52.9% of respondents reported some level of satisfaction with staff efficiency and timeliness with processing submissions.

Across roles, most respondents reported some level of satisfaction with staff efficiency and timeliness of reviews: 64.4% of PIs, 61.1% of points of contact, 69.2% of regulatory specialists, and 56.3% of other roles. Approximately 19-32% of PIs, points of contact, regulatory specialists, and those in other roles indicate some level of dissatisfaction with staff efficiency and timeliness. Dissatisfaction was highest among points of contact (32.5%).

When satisfaction with staff efficiency and timeliness among PIs is broken down by those with support staff and those without, PIs without support staff indicated higher levels of satisfaction at 69.2% while 59.6% of PIs with support reported some level of satisfaction. PIs without support staff were less dissatisfied with staff efficiency and timeliness (26.9%) than those with support staff (36.5%).

Satisfaction with staff efficiency and timeliness by number of submissions each month showed higher levels of satisfaction (46.8%) than dissatisfaction (27.9%) among respondents that submit 0-3 applications per month. Respondents that submit 4-7 applications per month were slightly more satisfied (47.1%) than dissatisfied (44.1%). Many of the respondents that submit 8 or more applications each month indicated some level of satisfaction with staff efficiency and timeliness of reviews (54.6%), with about a third reporting being somewhat dissatisfied (36.4%).

Table 2 - Satisfaction with IRB Staff Efficiency and Timeliness of Processing Submissions by IRB most often Used

			ED/SBS	MR	HS	Total
Satisfaction with IRB staff efficiency and timeliness of processing submissions	Extremely satisfied	Count	8	10	7	25
		% within IRB most often used	18.6%	17.5%	5.8%	11.3%
	Very satisfied	Count	16	18	24	58
		% within IRB most often used	37.2%	31.6%	19.8%	26.2%
	Somewhat satisfied	Count	11	13	33	57
		% within IRB most often used	25.6%	22.8%	27.3%	25.8%
	Neutral	Count	3	3	8	14
		% within IRB most often used	7.0%	5.3%	6.6%	6.3%
	Somewhat dissatisfied	Count	3	7	36	46
		% within IRB most often used	7.0%	12.3%	29.8%	20.8%
	Very dissatisfied	Count	0	4	9	13
		% within IRB most often used	0.0%	7.0%	7.4%	5.9%
	Extremely dissatisfied	Count	2	2	4	8
		% within IRB most often used	4.7%	3.5%	3.3%	3.6%

Total	Count	43	57	121	221
	% within IRB most often used	100.0%	100.0%	100.0%	100.0%

Chi-Square Tests

	Value	df	Asymptotic Significance (2sided)
Pearson Chi-Square	26.082 ^a	12	.010
Likelihood Ratio	29.762	12	.003
Linear-by-Linear Association	15.920	1	.000
N of Valid Cases	221		

a. 8 cells (38.1%) have expected count less than 5. The minimum expected count is 1.56.

Satisfaction with Staff Responsiveness to the Respondent's Questions

Satisfaction with staff responsiveness when responding to questions by the IRB(s) to which respondents more often submit, across all IRBs, 83.2% of respondents indicate being extremely to somewhat satisfied, 7.7% of respondents were neutral, and 9.1% of respondents indicate being somewhat to extremely dissatisfied. Among respondents that most often submit to the ED/SBS IRB, 95.4% report being extremely to somewhat satisfied. For the Minimal Risk IRB, 91.2% of respondents indicate being extremely to somewhat satisfied. For the HS IRB, 75.2% of respondents reported some level of satisfaction with staff responsiveness.

Across roles, most respondents reported some level of satisfaction with staff responsiveness: 81.8% of PIs, 83.2% of points of contact, 88.5% of regulatory specialists, and 87.6% of other roles. Approximately 4-10% of PIs, points of contact, and regulatory specialists indicate some level of

dissatisfaction with staff responsiveness; none of the respondents in other roles indicated dissatisfaction. Dissatisfaction was highest among PIs (10.6%).

When satisfaction with staff responsiveness to questions among PIs is broken down by those with support staff and those without, PI without support staff indicated slightly higher levels of satisfaction at 82.7% while 80.7% of PIs with support reported some level of satisfaction. PIs without support staff were more dissatisfied with staff responsiveness (11.5%) than those with support staff (7.6%).

Satisfaction with staff responsiveness by number of submissions each month showed much higher levels of satisfaction (84.3%) than dissatisfaction (8.4%) among respondents that submit 0-3 applications per month. Respondents that submit 4-7 applications per month were far more satisfied (91.2%) than dissatisfied (5.9%). Approximately 45% of the respondents that submit 8 or more applications each month indicated some level of satisfaction with staff responsiveness, with about a third reporting being somewhat dissatisfied (27.3%).

Question 6

Respondents were asked to rate how well they understand IRB regulations and requirements on a 5-point Likert scale from extremely well to not well at all.

Knowledge of IRB regulations and requirements by the IRB(s) to which respondents more often submit, across all IRBs, 93.3% of respondents indicate extremely well to somewhat well, 5.4% of respondents indicate slightly well, and 1.4% of respondents indicate not well at all. Among respondents that most often submit to the ED/SBS IRB, the majority of respondents (51.2%) indicate knowing the regulations very well. For the Minimal Risk IRB, the highest percentage of respondents (45.6%) indicate knowing the regulations somewhat well, and 42.1% indicating very well. For the HS IRB, 49.6% of respondents reported knowing the regulations very well, with 34.7% indicating somewhat well.

Across roles, 8.5% of respondents report knowing IRB regulations and requirements extremely well, 48.4% very well, 36.3 somewhat well, 5.4% slightly well, and 1.3% not well at all. The majority of PIs (92.3%) indicate knowing regulations extremely to somewhat well, with 7.7% indicating either slightly well to not well at all. Among points of contact, 91.0% indicate knowledge of regulations as extremely to somewhat well and 9.0% indicated slightly well to not well at all. All regulatory specialists indicated extreme to somewhat well, with the highest percentage reporting very well (68.0%). All of the respondents with other roles indicated knowing the regulations extreme to somewhat well, with half (50.0%) indicating somewhat well.

As shown in Table 3, when knowledge of regulations among PIs is broken down by those with support staff and those without, PIs without support staff indicated knowing the regulations at a lower percentage (88.5%) than PIs with support (96.1%). Approximately 11% of PIs without support staff report knowing the regulations slightly well. Among PI with support staff, 3.8% indicate knowing the regulations not well at all.

Table 3 – Understanding of IRB Regulations and Requirements by PI’s with and without support

		PI		Total	
		No Support Staff	Yes Support Staff		
Understanding of IRB regulations and requirements	Extremely well	Count	4	8	12
		% within PI	7.7%	15.4%	11.5%
	Very well	Count	22	27	49
		% within PI	42.3%	51.9%	47.1%
	Somewhat well	Count	20	15	35
		% within PI	38.5%	28.8%	33.7%
	Slightly well	Count	6	0	6
		% within PI	11.5%	0.0%	5.8%
	Not well at all	Count	0	2	2
		% within PI	0.0%	3.8%	1.9%
	Total	Count	52	52	104
		% within PI	100.0%	100.0%	100.0%

Chi-Square Tests

	Value	df	Asymptotic Significance (2sided)
Pearson Chi-Square	10.558 ^a	4	.032

Likelihood Ratio	13.677	4	.008
Linear-by-Linear Association	3.059	1	.080
N of Valid Cases	104		

a. 4 cells (40.0%) have expected count less than 5. The minimum expected count is 1.00.

The majority of respondents that submit 0-3 applications per month indicate knowing the regulations extremely to somewhat well (91.6%), shown in Table 4. Among respondents that submit 4-7 applications per month, 88.3% indicate knowing the regulations extremely to somewhat well. 100% of respondents that submit 8 or more applications per month indicate knowing the regulations extremely to somewhat well with the largest percentage reporting very well (90.9%).

Table 4 – Understanding of IRB Regulations and Requirements by Number of Submissions Per Month

			Number of submissions per month			
			0-3	4-7	8 or more	Total
Understanding of IRB regulations and requirements?	Extremely well	Count	14	4	1	19
		% within Number of submissions per month	7.9%	11.8%	9.1%	8.5%
	Very well	Count	77	21	10	108
		% within Number of submissions per month	43.3%	61.8%	90.9%	48.4%
	Somewhat well	Count	72	9	0	81
		% within Number of submissions per month				

	% within Number of submissions per month	40.4%	26.5%	0.0%	36.3%
Slightly well	Count	12	0	0	12
	% within Number of submissions per month	6.7%	0.0%	0.0%	5.4%
Not well at all	Count	3	0	0	3
	% within Number of submissions per month	1.7%	0.0%	0.0%	1.3%
Total	Count	178	34	11	223
	% within Number of submissions per month	100.0%	100.0%	100.0%	100.0%

Chi-Square Tests

	Value	df	Asymptotic Significance (2sided)
Pearson Chi-Square	16.374 ^a	8	.037
Likelihood Ratio	22.449	8	.004
Linear-by-Linear Association	11.227	1	.001
N of Valid Cases	223		

a. 8 cells (53.3%) have expected count less than 5. The minimum expected count is .15.

Question 7

Respondents were asked to rate how well they understand the IRB process/workflow on a 5-point Likert scale from extremely well to not well at all.

Knowledge of the IRB process/workflow by the IRB(s) to which respondents more often submit, across all IRBs, 83.7% of respondents indicate extremely well to somewhat well, 11.8% of respondents indicate slightly well, and 4.5% of respondents indicate not well at all. Among respondents that most often submit to the ED/SBS IRB, the majority of respondents (74.4%) indicate knowing the workflow extremely to somewhat well, with a quarter (25.6%) indicating slightly to not well at all. For the Minimal Risk IRB, most respondents (87.7%) indicate knowing the workflow extremely to somewhat well, and 12.3% indicating slightly to not well at all. For the HS IRB, 85.1% of respondents reported knowing the process extremely to somewhat well, with 14.8% indicating slightly to not well at all.

Across roles, 8.5% of respondents report knowing the IRB process/workflow extremely well, 42.6% very well, 32.7% somewhat well, 11.7% slightly well, and 4.5% not well at all. The majority of PIs (80.8%) indicate knowing the IRB process extremely to somewhat well, with 19.2% indicating either slightly well to not well at all. Among points of contact, 83.4% indicate knowledge of regulations as extremely to somewhat well and 16.6% indicated slightly well to not well at all. Ninety-two percent of regulatory specialists indicated extreme to somewhat well, with the highest percentage reporting very well (48.0%). Most of the respondents with other roles indicated knowing the regulations extremely to somewhat well (93.8%).

When knowledge of the IRB process among PIs is broken down by those with support staff and those without, PIs without support staff indicated knowing the workflow at a lower percentage (78.8%) than PIs with support (82.6%). Approximately 21% of PIs without support staff report knowing the workflow slightly well to not well at all. Among PI with support staff, 17.3% indicate knowing the workflow slightly to not well at all.

The majority of respondents that submit 0-3 applications per month indicate knowing the IRB workflow extremely to somewhat well (82.0%). Among respondents that submit 4-7 applications per month, 91.1% indicate knowing the workflow extremely to somewhat well. Most of respondents that submit 8 or more applications per month indicate knowing the regulations extremely to very well (90.9%) with 9.1% indicating not well at all.

Table 5- Understanding of the IRB Process/Workflow Overall by Number of Submissions Per Month

		Number of submissions			Total	
		0-3	4-7	8 or more		
Understanding of the IRB process/workflow overall	Extremely well	Count	12	6	1	19
		% within Number of submissions per month	6.7%	17.6%	9.1%	8.5%
	Very well	Count	74	12	9	95
		% within Number of submissions per month	41.6%	35.3%	81.8%	42.6%
	Somewhat well	Count	60	13	0	73
		% within Number of submissions per month	33.7%	38.2%	0.0%	32.7%
	Slightly well	Count	23	3	0	26
		% within Number of submissions per month	12.9%	8.8%	0.0%	11.7%
	Not well at all	Count	9	0	1	10
		% within Number of submissions per month	5.1%	0.0%	9.1%	4.5%
	Total	Count	178	34	11	223
		% within Number of submissions per month	100.0%	100.0%	100.0%	100.0%

Chi-Square Tests

	Value	df	Asymptotic Significance (2sided)
Pearson Chi-Square	16.332 ^a	8	.038
Likelihood Ratio	21.045	8	.007
Linear-by-Linear Association	5.031	1	.025
N of Valid Cases	223		

a. 8 cells (53.3%) have expected count less than 5. The minimum expected count is .49.

Question 8

Respondents were asked to rate how well they understand where their submission is in the process at any given point in time on a 5-point Likert scale from extremely well to not well at all.

Understanding of where the submission is in the process by the IRB(s) to which respondents more often submit, across all IRBs, 87.8% of respondents indicate extremely well to somewhat well, 8.1% of respondents indicate slightly well, and 4.1% of respondents indicate not well at all. Among respondents that most often submit to the ED/SBS IRB, the majority of respondents (90.8%) indicate understanding where their submission is extremely to somewhat well, with 9.3% indicating slightly well. For the Minimal Risk IRB, most respondents (86.0%) indicate understanding extremely to somewhat well, and 14.1% indicating slightly to not well at all. For the HS IRB, 87.6% of respondents reported understanding extremely to somewhat well, with 12.4% indicating slightly to not well at all.

Across roles, 18.8% of respondents report understanding where their submission is in the review process extremely well, 43.9% very well, 25.1% somewhat well, 8.1% slightly well, and 4.0% not well at all. The majority of PIs (85.5%) indicate understanding where their submission is extremely to somewhat well, with 14.4% indicating either slightly well to not well at all. Among points of contact, 89.7% indicate understanding

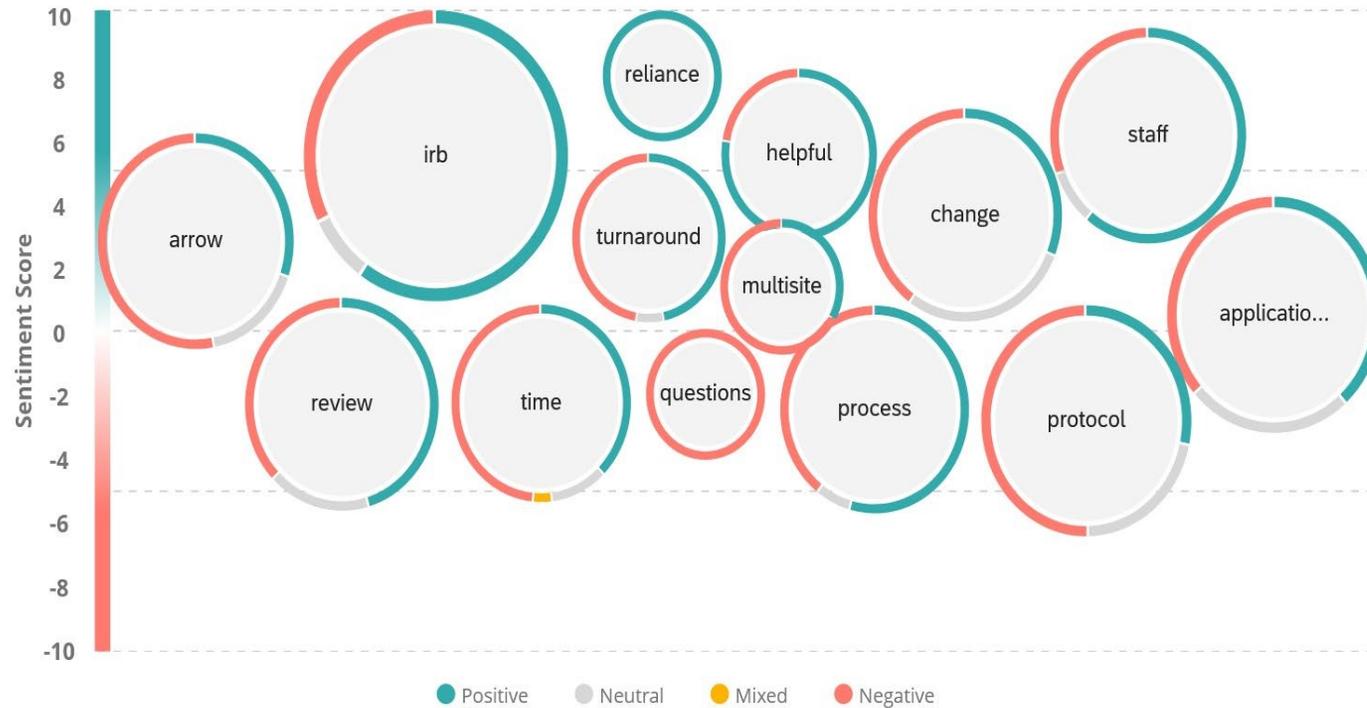
where their submission is in the process as extremely to somewhat well and 10.3% indicated slightly well to not well at all. Eighty-eight percent of regulatory specialists indicated extreme to somewhat well, with 12.0% indicating slightly well. Most of the respondents with other roles indicated understanding where their submission is in the process extremely to somewhat well (93.8%).

When understanding of where the submission is in the process among PIs is broken down by those with support staff and those without, PIs without support staff indicated knowing the workflow extremely to somewhat well at a slightly higher percentage (86.7%) than PIs with support (84.6%). Approximately 13% of PIs without support staff report understanding slightly well to not well at all. Among PI with support staff, 15.4% indicate understanding slightly to not well at all.

The majority of respondents that submit 0-3 applications per month indicate understanding where their submission is extremely to somewhat well (86.6%). Among respondents that submit 4-7 applications per month, 94.1% indicate knowing the workflow extremely to somewhat well. Most of respondents that submit 8 or more applications per month (91.0%) indicate understanding where their submission is extremely to somewhat well.

Q9 – Suggestions for improvements to the IRB review process (including ARROW)

All Topics



This item generated 125 responses. Most of these comments were more than just a sentence and a few were extensive. As with responses to question 10, respondents find **staff** to be **helpful** and responsive (including the Reliance and Navigation Team [RELIANT]). Respondents did express some frustration with inconsistencies across boards and among staff, which is a concern that has been noted in previous surveys. Positive comments about **the IRB** focused not just on staff but acknowledgement of resources available to study teams (e.g., Knowledgebase website, IRB help email addresses, consultations) as well as recent efforts to improve the IRB process.

The majority of respondents commented on the either the **application** process or **ARROW** specifically. Regarding ARROW, while some respondents noted that ARROW has undergone significant improvements, others noted that they find the system hard to navigate, especially for those who are not frequent ARROW users. Some applications types include template language and where called out in the comments, this

functionality was appreciated. On the other hand, many respondents expressed frustration with both providing a protocol and needing to fill out a full application, which they feel is unnecessarily burdensome. These respondents are likely those who conduct clinical trials, for which a standalone protocol document already exists outside the IRB review process.

Turnaround time is also an area of concern for many respondents, although several noted that times have improved over the years. The emphasis on turnaround time was often less the time frame itself than the difficulty in getting a clear answer as to when a study might be reviewed by staff and/or scheduled for an IRB meeting.

Q10 – What respondents like about the UW IRB review process

All Topics



Of the open text questions, this is the one that received the largest number of responses: 147. The majority of respondents listed **helpful and knowledgeable staff** as a positive feature of the IRB process. Staff are described as friendly, professional, responsive, and accessible. Respondents indicate that the IRB consultation service is of great value, as are the Knowledgebase guidance documents. The research community describes working with IRB staff as a collaboration resulting in an efficient and thoughtful review process.

Respondents describe **ARROW** as a great improvement from the paper process that has gotten easier to use over time. ARROW features highlighted as positive included: ability track progress of submission, error detection, preservation of communication with staff rather than

relying on emails, simplifications of IRB approval stamps on consents. Some respondents mentioned the guidance boxes outlining information required for the ARROW responses and the suggested language menus as helpful to ensuring consistency across protocols, promoting good practice, and efficient completion of applications. Links within the ARROW application to KB documents was also identified as a resource to the research community.

Many respondents described **pre-review** as a component of the process that makes IRB review easier and faster. Respondents indicated an appreciation for the opportunity to consult with a reviewer to address questions or obtain feedback so that many issues are resolved prior to the board reviewing the application.

Q11 – Suggestions for future research community training topics

All Topics



This item received 51 responses. Respondents primarily indicated interest in training regarding **application submission**: when is an IRB application needed, most common mistakes in applications, best practices for submission, what qualifies as an acceptable application, explainer on IRB requirements, and **ARROW** navigation.

Respondents suggested trainings related to **consent**, specifically: waivers of consent, tips for creating consent forms, remote consent processes, and the difference between consent for medical procedures and consent for research.

Additional suggestions included:

Submission and review of **changes of protocols**: pro-tips on efficiently approaching the change application process, best practices.

Data sharing: workflow for these processes and resources on campus to assist, when and what type of agreements are required.

Multi-site research: key personnel guidance, when to contact the RELIANT team, navigating cede applications.

Other topics: HIPAA overview for non-HCC researchers, good IRB practices related to community-based research, enhancing diversity and equity in studies, training requirements, issues of non-compliance, tips for research related to technology and software development.