Office of the Vice Chancellor for Research and Graduate Education
UNIVERSITY OF WISCONSIN–MADISON

UW-MADISON IRB SURVEY RESULTS

Review of PI experiences with human subjects regulatory mechanisms and recommendations for improvements.

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Executive Summary

Nationally, there has been a dramatic increase in the time researchers must spend on administrative tasks and compliance, which in turn limits the amount of time available to conduct the research itself. The Office of the Vice Chancellor for Research and Graduate Education (OVCRGE) strives to identify strategies that will reduce administrative and research burden, while upholding the protection of human subjects, research accountability, and compliance with federal regulations.

Methods:

The OVCRGE conducted an online survey from August 29, 2016 through September 25, 2016 to obtain feedback from faculty about their experiences with human subjects regulatory mechanisms. The survey included users of the Education and Social/Behavioral Science (ED/SBS) IRB and the Health Sciences (HS) IRBs, and the data in this report reflect the perceptions and experiences of UW-Madison human subjects researchers who completed the survey.

Jan Greenberg, Associate Vice Chancellor for Research for the Social Sciences, and Ryan Moze, Assistant Director of the Office of Research Policy, led the survey drafting process. They reviewed IRB surveys administered at peer institutions, a survey administered by the HS IRB, and a survey administered by the Research Animal Resource Center (RARC). Based on this initial work, they drafted the survey with the assistance of Norman Drinkwater, the Associate Vice Chancellor for Research for the Biological Sciences.

Greenberg and Moze then sought feedback from Marsha Mailick, Vice Chancellor for Research and Graduate Education; Dan Uhlrich, (then) Associate Vice Chancellor for Research Policy; Susan Ellis Weismer, Deputy Institutional Official for Education and Social Behavioral Research; Marc Drezner, Deputy Institutional Official for Health Sciences Research; and members of the University Committee. Greenberg and Moze also met with Lillian Larson, Director of the ED/SBS IRB, and Nichelle Cobb, Director of the HS IRB, to obtain feedback and discuss the survey methodology. Based on their feedback, the survey was revised and returned to those who were consulted for additional review.

The University of Wisconsin Survey Center assisted with the wording and formatting of survey questions and programmed the survey in Qualtrics to facilitate survey administration and data analysis. A copy of the survey is provided (Appendix A).

The survey was administered to 1,257 principal investigators (PIs) or their designated staff responsible for IRB protocols. All faculty and permanent staff PIs who had an active IRB protocol within the last two years were eligible to participate. Of the 1,257, 17 had left the UW-Madison. A total of 590 responses were received (455 faculty, 125 academic staff, five postdoctoral fellows, and five doctoral students). The overall response rate was 47.6%. Of the 590 respondents, 18 had not submitted a protocol in the past two years and thus, were not eligible. This report also excludes postdoctoral fellows and graduate students. The final sample consisted of 562 respondents. The survey consisted of

multiple choice and open-ended questions. Analysis of qualitative data involved coding over 97,000 words of text.

Major findings:

Survey results indicate that UW-Madison PIs hold IRB staff in high regard and value their expertise, experience, and guidance. Overall, PIs feel respected by the staff and expressed appreciation for the staff's willingness to help them resolve problems. However, almost 50% of the respondents indicated that they had given up or almost given up pursuing a research project out of frustration of getting it through the IRB process. Primary concerns identified included:

- Complexity of the ARROW system
- Length of the IRB approval process
- Inconsistency in the review process
- High user fees
- Over-regulation of minimal risk studies
- A perception that IRBs are more concerned with avoiding institutional liability than properly assessing the risk to human subjects
- A perception that IRBs extend beyond the protection of human subjects to regulating scientific approaches
- A perception that UW-Madison has instituted layers of scrutiny beyond what is required by federal regulation

Recommendations:

1. One of the major frustrations is in the use of ARROW. In response, the Office of the VCRGE has developed an "ARROW Optimization Plan". This plan involves the ARROW team (i.e., the information technology group within the Office of the VCRGE) focusing additional development time specifically on improvements to the user experience, leading to improvements in transparency, usability, efficiency, and reduced duplication. As part of this effort, the ARROW team will conduct an upgrade of ARROW that will improve site navigation. In addition, efforts will continue to look for opportunities to streamline the application for minimal risks studies. This optimization plan is underway and will be ongoing in quality improvements efforts for ARROW. During this process, the ARROW team will seek consultation from the IRB Directors and their staff, the office of the UW-Madison Legal Affairs, and researchers across campus.

2. The OVCRGE has begun a process of benchmarking UW-Madison policies and practices against those of its peer institutions, which will include a review of federal human subjects regulations and interpretation of these federal regulations on campus. The OVCRGE will analyze these benchmarking data, develop a plan to reduce the burden on human subjects researchers, and will consult with the Directors of the HS and ED/SBS IRBs and the office of the UW-Madison Legal Affairs in this process.

3. The survey generated many ideas from respondents for improving IRB processes: developing templates with suggested language for protocols, exploring a centrally-funded

IRB and eliminating IRB fees for non-industry sponsored and non-VA protocols, learning from the RARC's service-oriented culture, creating an ombudsman, and streamlining the application for minimal risk studies. The OVCRGE appointed a committee of faculty and academic staff researchers to review the findings of this report and the benchmarking data, and generate a prioritized list of recommendations to improve the efficiency and user-friendliness of the IRB process. In conducting its work, the committee will seek consultation from the relevant stakeholders (e.g., IRB staff, the Office of Legal Affairs, faculty researchers, permanent PIs).

4. One of the main problems identified by respondents was the apparent lack of uniformity in the criteria applied to reviewing protocols. Many respondents reported that they often received inconsistent and often contradictory comments from different reviewers. To achieve greater uniformity in protocol review, the OVCRGE will use the benchmarking process above to determine how peer institutions strive to achieve consistency, and then develop a recommendation and an action step.

5. PIs expressed frustration with the length of time from submission of an IRB protocol to approval. The OVCRGE will use available data to better understand what factors contribute to the length of the IRB review process to help identify opportunities to reduce the time between the submission of a proposal and the approval of the protocol.

6. The OVCRGE will develop a short IRB survey to receive ongoing feedback. The survey will be administered automatically to an investigator each time the investigator receives notification that his/her IRB protocol has been approved. Many peer institutions have implemented such a survey and found it helpful in obtaining "real time" feedback from users.

This is an ambitious plan that will likely require additional campus resources. It also may require changes in UW-Madison campus policies regarding IRB processes and procedures. The Office of the VCRGE recognizes any effort to implement changes that improve the efficiency and user-friendliness of IRBs must simultaneously support the IRB's primary role of ensuring compliance with federal regulations. As the OVCRGE moves forward in implementing these recommendations, it will work closely with the Directors of the ED/SBS and HS IRBs and the office of the UW-Madison Legal Affairs to ensure that administrative efficiencies and changes do not hamper the IRBs ability to carry out their regulatory responsibility.

Introduction and Background

For the past several years, members of the University Committee, in part, in response to reports from the faculty, had growing concerns about IRB policies and procedures. After discussion with Vice Chancellor for Research and Graduate Education, Marsha Mailick, the University Committee requested that the Office of the VCRGE (OVCRGE) conduct a survey of IRB users. The survey included users of the Education and Social/Behavioral Science (ED/SBS) IRB and the Health Sciences (HS) IRBs. The purpose of the survey was to begin a process of obtaining feedback from faculty and research staff about their experiences with the human subjects regulatory mechanisms. Thus, the data in this report reflect the perceptions and experiences of UW-Madison researchers who completed the survey.

The OVCRGE recognizes that many of the IRB challenges faced at UW-Madison are not unique; some of the issues raised in this report are concerns heard from faculty on campuses across the country. Other issues raised in the report arise from campus-wide policies that the IRB staff and committee are required to implement. With this in mind, the OVCRGE's goal in conducting this survey was to hear from active users of the IRBs about their experiences. These data along with other data (e.g., ongoing data collected as part of the ARROW system, benchmarking data on the practices and policies of peer institutions, and consultation with the IRB staff and the office of the UW-Madison Legal Affairs) will be used to identify whether there are any current practices and university-wide policies that could be modified to improve the experience of PIs with the IRB human subjects process without in any way violating federal policy or jeopardizing UW-Madison's accreditation status, which the campus is committed to maintaining.

Process for Developing and Administering the Survey

Jan Greenberg, Associate Vice Chancellor for Research (AVCR) for Social Sciences, and Ryan Moze, Assistant Director of the Office of Research Policy, took the lead in drafting the survey. As a first step, they scanned the web to locate IRB surveys administered at peer institutions. They also reviewed a past survey administered by the HS IRB and a current survey developed and administered by the Research Animal Resource Center (RARC). Based on this initial work, they drafted the survey with the assistance of Norman Drinkwater, Associate Vice Chancellor for Research for the Biological Sciences.

Greenberg and Moze then sought feedback from Marsha Mailick, Vice Chancellor for Research and Graduate Education; Dan Uhlrich, (then) Associate Vice Chancellor for Research Policy; Susan Ellis Weismer, Deputy Institutional Official for Education and Social Behavioral Research; Marc Drezner, Deputy Institutional Official for Health Sciences Research; and members of the University Committee. On March 23, 2016, Greenberg and Moze met with Lillian Larson, Director of the ED/SBS IRB, and Nichelle Cobb, Director of the HS IRB, to obtain feedback and discuss the survey methodology. Also in attendance were Ulhrich and Moze.

After receiving feedback from all of these individuals, the survey was extensively revised and sent back to the same people for additional review. One recommendation that

emanated from this process was that the survey should be reviewed by the University of Wisconsin Survey Center to benefit from their expertise in the wording and formatting of questions, and to program the survey in Qualtrics to facilitate survey administration and data analysis. During the summer of 2016, the OVCRGE worked closely with John Stevenson, Associate Director of the University of Wisconsin Survey Center, to finalize the survey and program it in Qualtrics. A copy of the survey can be found in Appendix A.

The survey was administered between August 29, 2016 and September 25, 2016. All faculty and permanent staff PIs who had an active IRB protocol within the last two years were eligible to participate. Faculty members and permanent PIs who delegated IRB tasks to a member of their research team were asked to forward the staff member's name to the Office of the VCRGE. The staff member was sent the survey link. Initially, 1,157 faculty and permanent PIs met the sampling criteria (i.e., had an active protocol within the past two years). Of these, 17 had left UW-Madison. We requested the participation of approximately 100 additional research staff because they had been delegated responsibility for submitting IRB protocols. We received a total of 590 responses (from 455 faculty, 125 academic staff, five postdoctoral fellows, and five doctoral students). The overall response rate was 47.6% (590/1240). Of the 590 respondents, 18 had not submitted a protocol in the past two years and thus were not eligible. For purposes of this report, we excluded postdoctoral fellows and graduate students. The final sample consisted of 562 respondents.

The respondents represent a group of active researchers who have frequent interaction with the university's IRBs. Their utilization of the IRBs was as follows:

- 490 had completed two or more IRB protocols over the past two years
- 271 submitted protocols to the ED/SBS IRB only
- 192 submitted protocols to the HS (including minimal risk) IRBs only
- 92 had submitted protocols to both the ED/SBS and HS IRBs
- 7 respondents did not indicate which IRB they used

Therefore, of the 562 respondents, 284 (51%) had submitted protocols to one of the two HS IRBs, and 363 (65%) had submitted a protocol to the ED/SBS IRB.

The survey consisted of a set of multiple choice questions as well as open-ended questions, from which qualitative data were obtained. AVCR Jan Greenberg was the only individual with access to the file linking respondent names with responses. All identifiers were stripped from the file prior to analysis. Greenberg analyzed responses to the multiple-choice questions. The Wisconsin Survey Research Center coded the qualitative data in NVIVO. The analysis of these qualitative data involved coding over 97,000 words of text. A highly trained PhD qualitative researcher with over 15 years of experience coding such data completed the qualitative coding. In addition, the Survey Center conducted independent checks of the data to ensure the reliability of the coding. Initially there were over 500 individual codes. These data were grouped together into larger themes for this report.

This report presents the quantitative data and uses the qualitative comments to provide descriptive detail. The qualitative quotes are reported verbatim, with the exception of deleting identifying information such as the name of a specific protocol. Greenberg

received permission from each PI quoted here to use his/her comment in this report. Quotes were selected to be representative of the themes identified by the Wisconsin Survey Center.

Since only a few minor differences were found between responses from those who reported using only the ED/SBS IRB and those using the HS IRBs, the results for the entire sample of 562 respondents are reported except for the question on the pre-review process because pre-review has only recently been implemented by the ED/SBS IRB. Appendix B presents the raw data tables that generated the figures contained in this report.

The report concludes with suggestions for improving the process of applying for and obtaining IRB approval, and a brief discussion of the OVCRGE's plans for taking the next steps for improving the IRB experience on campus.

Findings

Ease of Using ARROW

As shown in Figure 1, only about 20% of the survey respondents indicated that ARROW was "very" or "extremely" easy to use. Approximately 40% responded that ARROW was "not at all" or only "a little" easy to use.

In the qualitative data, there were 81 positive comments about ARROW. These included:

The switch over to ARROW was a huge improvement from WebKit. It's still a bit buggy, but having a record of correspondence and changes is extremely helpful.

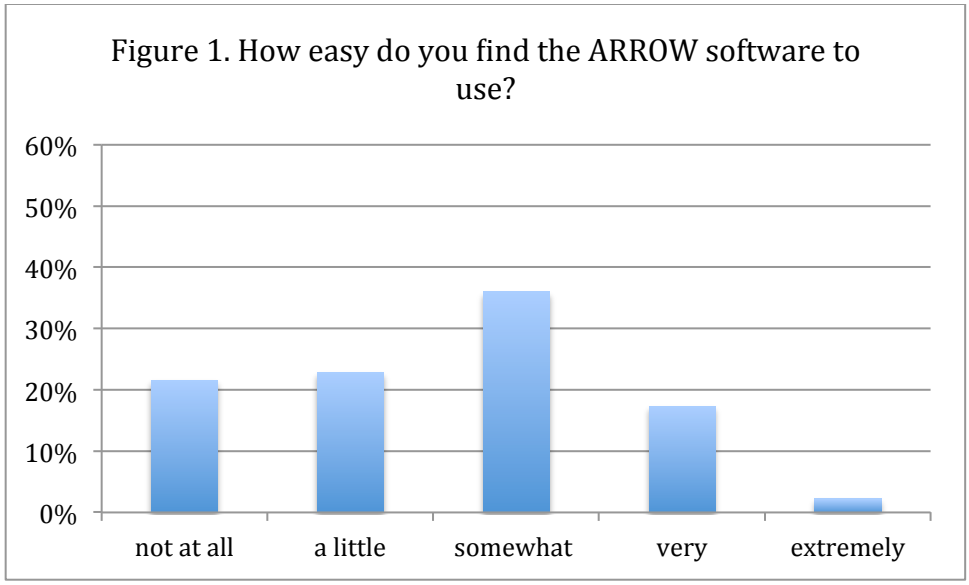
It is easy to log in to Arrow to see the status and content of past and current applications.

Arrow has definitely expedited the process and made it easier to keep track of various projects.

The Arrow software, although sometimes murky, becomes reasonably easy to use with practice.

The arrow interface works very well.

While the Arrow system is not "intuitive" it does work and with practice becomes easier. The system works well in terms of timing of communication between IRB staff and the study team.



However, there were twice as many (161) comments indicating that ARROW was difficult to navigate, cumbersome, repetitive, and confusing regarding protocol submission.

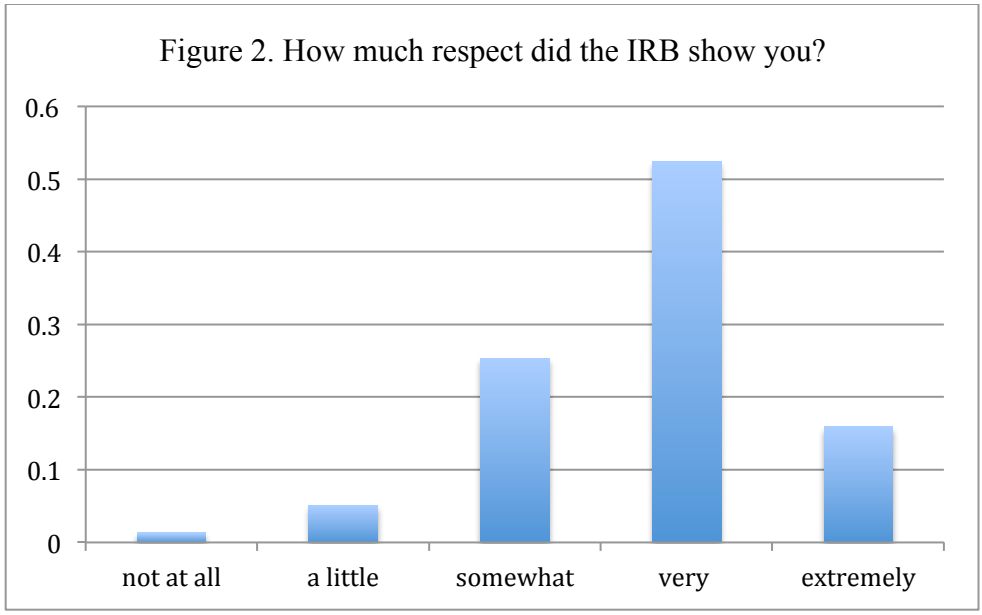
The ARROW system has so many irrelevant questions for many of my projects. It is very frustrating how this process has so little streamlining.

ARROW requires entry of the same info in several places, and submission of the same info in the protocol. What a waste of my time and the reviewers. When I am asked to make revisions I have to make sure these revisions are made at every occurrence in the document. When I miss one place, the staff does not just change it but sends it back to me to correct the location or the grammar, etc. 90% of the revisions have nothing to do with patient safety.

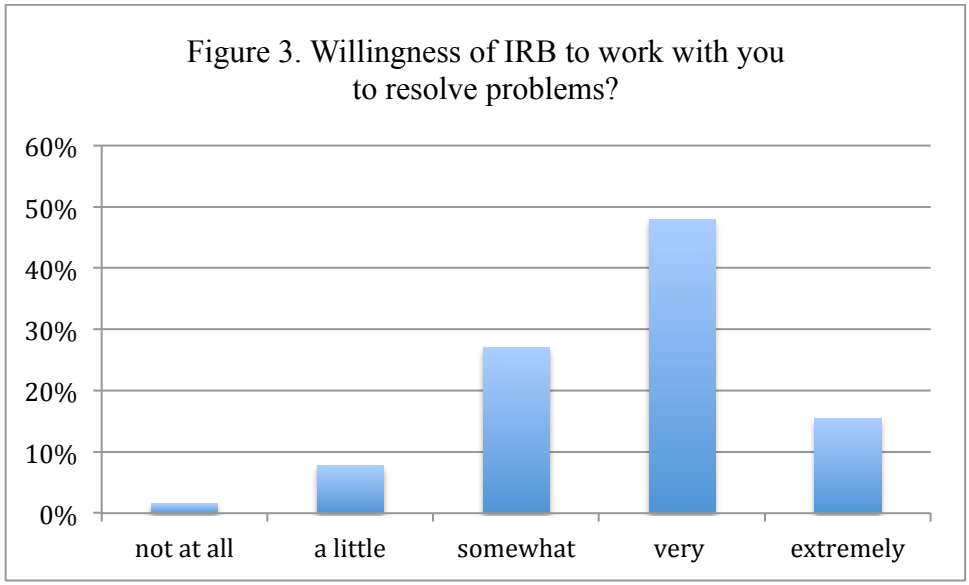
ARROW is impossible to use - it is far too complex and the interface is never intuitive. ARROW might be ok for a professional staff person responsible that uses it regularly. As a faculty member that needs to use it once or twice a year, every use is confusing and frustrating...The complexity is the problem. I understand that the IRB has to deal with many widely differing situations - but is a BIG mistake to try to embody all possibilities into one massive piece of software that everyone has to use. There are so many nuances and branch points that it gets extremely confusing. ARROW is more confusing and difficult to work with than the US tax code.

Experiences Working with the IRB Committee and IRB Staff

As shown in Figure 2, approximately 70% of the respondents indicated that the IRB and the IRB staff were "very" or "extremely" respectful. Less than 7% responded that the staff showed them "little" or "no" respect.



In addition, as shown in Figure 3, the majority of respondents reported that the staff was "very" or "extremely" willing to work with them to resolve problems that arose in the review process. Only a few felt that the staff was unwilling to work together to resolve problems.



Almost 400 positive comments were collected related to IRB staff and 183 comments indicated that the IRBs were working well. The staff was described as dedicated, helpful, polite, and knowledgeable. Respondents recognized that the IRB staff is overburdened and try to be helpful, but is often constrained by policies.

Staff are very helpful and knowledgeable. I never get the sense that what they are doing is working to create barriers, but to ensure a safe and ethically conducted study.

The staff are incredibly knowledgeable, helpful and dedicated and I know they are frustrated by their workload and many of our same issues.

I immensely appreciate IRB staff's willingness to work with me to meet a project deadline. This is especially important and valuable when a grant proposal is pending subject to IRB approval. Sometimes the funding agencies request a super quick turnaround that is out of the PI's control, and IRB's responsiveness and understanding in this regard has been greatly helpful for me to meet the deadline for funded work to come through. I am overall highly satisfied with our IRB staff and their professionalism. I would just recommend that you keep up the great work you are doing.

Several of the staff reviewers have been very responsive and helpful in laying out the expectations for the protocols, clarifying issues or questions I've had when navigating the website, and discussing possible solutions for IRB issues.

They are extremely good at talking through issues if you contact them with questions. Also quite responsive via email for anything tricky. The IRB has also in my experience been pretty good about not getting caught up in small details that do not pose risk, harm, or confidentiality concerns that I have run into problems with at other IRBs.

The staff is very helpful at anticipating some concerns ahead of time, to clarify them or update consent forms, etc., before the committee reviews the study. I believe their efforts are helpful in mitigating some of the problems with the full committee.

Our IRB is respectful and completes their review process in a time period that is likely consistent with the national average. IRB staff are knowledgeable and easily accessible. When I contact the IRB with questions, they get back to me fairly quickly. They are also available for phone calls and face-to-face meetings

I like that my research team can stop by IRB office hours, discuss potential issues and point points, and prepare protocol applications based on this discussion. This has been very very helpful.

Overall the staff is great. I have always been able to pick up the phone and reach someone when I have a question.

IRB staff are very responsive to questions I have before submitting a new protocol. Responses are always quick. I have had productive conversations in person, over the phone, and over email. These conversations always speed up the review process because I am able to address questions before submitting the application.

But consistent with the quantitative data, not all of the survey respondents had positive interactions with the IRB committee and IRB staff. About 60 comments were received that described the relationship with the IRB as adversarial and not collaborative.

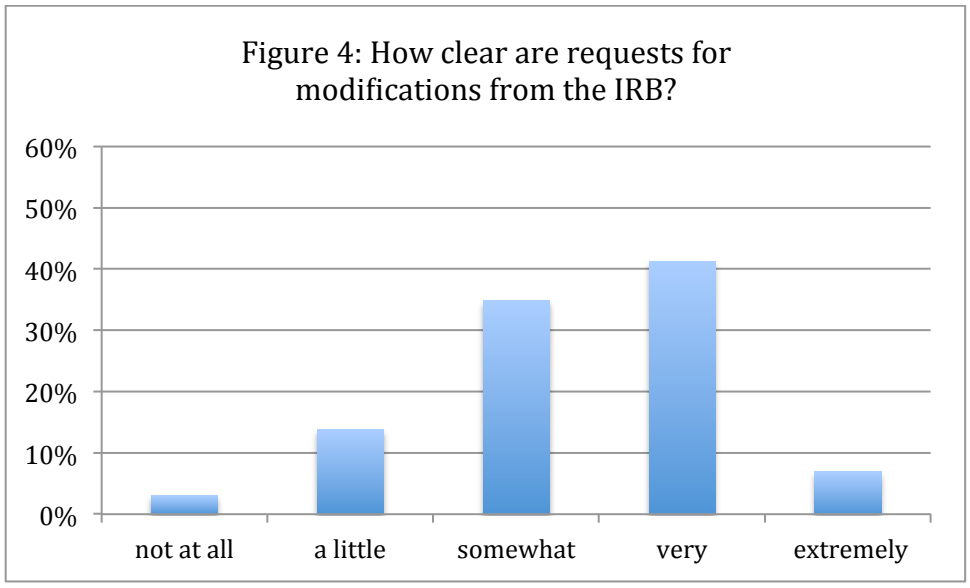
Overall, the implementation feels like "us against them." It would be great if we could get to a place where it felt like "us working together with them to protect our human subjects.

I would like to see the IRB staff develop more of a culture of helping faculty and staff get their research approved rather than being more a research gatekeeper, which is how it often feels on the researcher-side of the process.

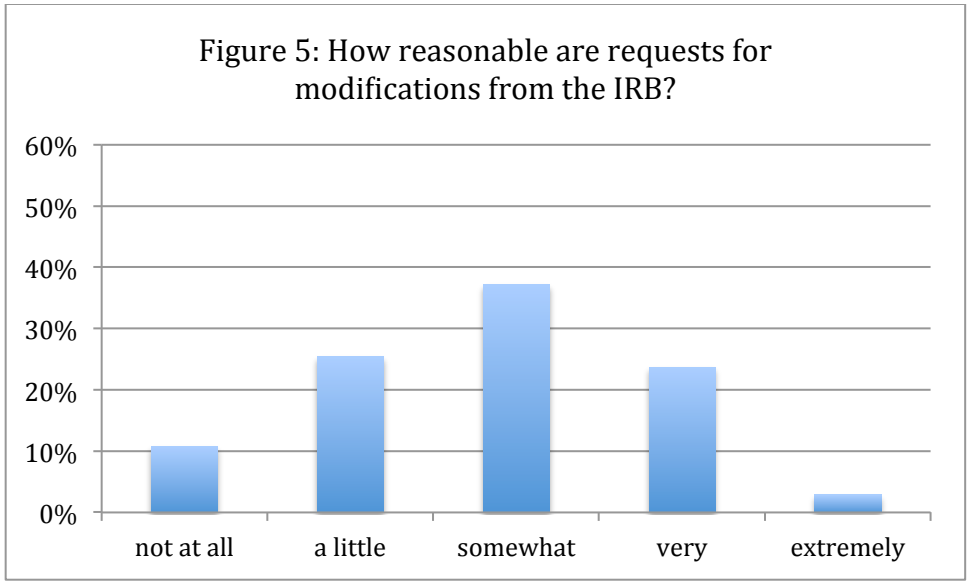
My interactions with IRB staff haven't been super helpful - it doesn't feel like they are there to help us, rather they are there trying to catch our mistakes.

Clarity and Reasonableness of Requests from the IRB

The IRB, including during the staff pre-review process, often requests modifications or clarifications from study teams. In the survey, respondents were asked about the clarity of these requests as well as the reasonableness of these requests. As shown in Figure 4, approximately half of the respondents felt that these requests were "very" or "extremely" clear and another third indicated the requests were "somewhat" clear.



However, the survey respondents rated the reasonableness of the requests less positively (Figure 5). There was a diversity of views about this question. About a quarter of survey respondents indicated that the requests were "very" or "extremely" reasonable but about a third felt that the requests were "not at all" or "a little" reasonable.



Even though the quantitative data indicated that about half of the respondents felt the requested modifications were "very" or "extremely" clear (see Figure 4) and about a third reported them "very" or "extremely" reasonable (Figure 5), only 24 written comments reflected these positive experiences.

I really appreciate the opportunity to speak to the IRB staff directly. Sometimes it was somewhat difficult to understand the questions clearly from ARROW. The staff members made them available through phone calls. We found we could easily solve the problem by a quick phone conversation.

The feedback regarding consent forms is helpful.

The staff is very helpful at anticipating some concerns ahead of time, to clarify them or update consent forms, etc., before the committee reviews the study. I believe their efforts are helpful in mitigating some of the problems with the full committee.

The review comments are very straightforward to follow. I appreciate the direct instructions on what to do/write in order to move forward with an application.

The IRB staff provides very clear instructions on how to respond to specific queries. That is very useful.

Communication with staff is always smooth and the turnaround time is reasonable.

The great majority of the written comments addressing the clarity and reasonableness of requested modifications spoke to the frustrations investigators experienced with requests for protocol modifications. There were 125 such comments that ranged from difficulty understanding reviewers' comments to receiving inconsistent and often contradictory messages from different staff reviewers and/or different IRB committee members over time.

I think the challenge I faced was mostly caused by unclear communication. I did not understand the nuances of what the IRB folks were asking me with regard to what needed to change on my application.

The comments left on the ARROW system are sometimes cryptic or difficult to understand.

We had a project that required data collections with two separate samples using the exact same protocol (same instrument, consent forms etc.), only to get two completely different reviews, requests for modifications etc. In other words, there is zero consistency in how existing rules are applied.

Inconsistency in approval of protocols with very similar risks and structures is very frustrating. What may be approved at one time is later denied. The committee has very little internal consistency and memory of prior decisions.

I submit a number of very similar protocols over the past 10 years. However, despite the fact that some of the protocols are similar and submitted within a 6-month time frame, the protocol requirements and documentation processes are often very different from protocol to protocol. There is no consistency whatsoever.

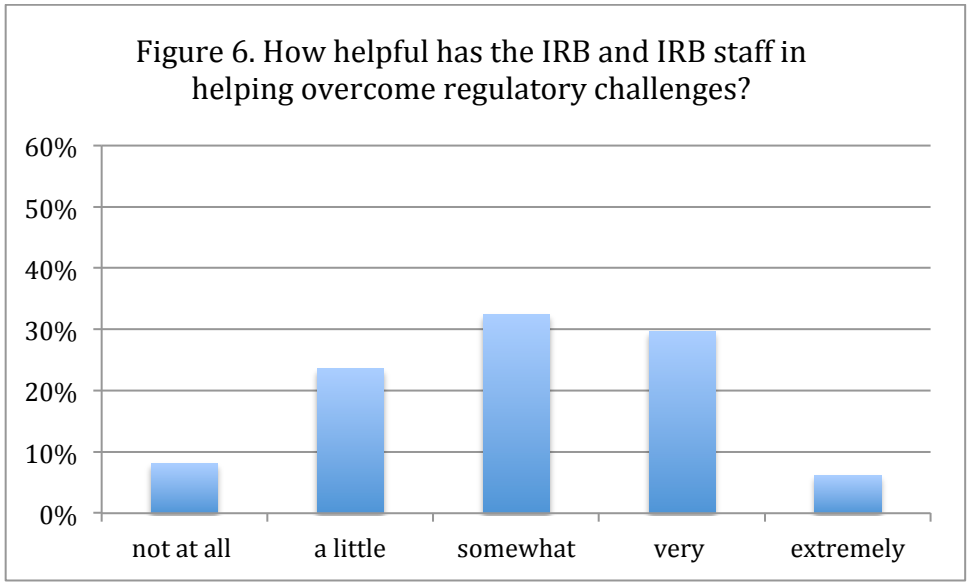
Wording that worked on one protocol doesn't work on another, when the situation is exactly the same. It's absolutely infuriating.

An extremely frustrating part of the IRB pre-review process is trying to navigate inconsistencies between staff reviewers. Research teams should not have to alter a procedure or process (e.g. a recruitment plan) to accommodate each staff reviewer's interpretation of research regulations, policies, or guidance. It would be unreasonable to expect to work with a single staff review but, perhaps there could be some acknowledgement of information previously vetted by the IRB.

The IRB process is incredibly frustrating, lengthy, and inconsistent. Our most recent protocol was the most frustrating to date. We submitted correspondence that was approved for one protocol about a month prior, with only minimal changes, and it got shredded when we submitted it under a new protocol for a nearly identical study and had a different reviewer. When we ask about the inconsistencies, we're told, "Well, each of us looks at different things when we review, and each of us cares about different things when we review..." ...The amount of detailed revision requested by some reviewers consumes an incredible amount of our staff time. We are told a half dozen things we need to change on the consent document, and we make the changes. We're then told the consent document is too long after we made the required changes, and we have to change it again. Mind you, this language was perfectly acceptable on a different protocol accepted just a month earlier by a different reviewer.

Helpfulness of IRB and IRB Staff in Overcoming Regulatory Challenges

As shown in Figure 6, approximately a third of respondents felt that the IRB and IRB staff were "very" or "extremely" helpful in overcoming regulatory challenges and another third felt the IRB committee and IRB staff were "somewhat" helpful.



In the open-ended questions, some respondents wrote comments that spoke of the positive role the IRB committee and IRB staff played in ensuring the compliance with federal IRB policy.

The IRB seeks to help me get my protocol prepared to meet regulatory standards and keep patient safety at the forefront.

The staff are experts at the regulation and regulatory environment and given excellent advice about how to submit a protocol. Their feedback is well informed and they are strong advocates for the IRB and compliance.

The IRB process serves an important purpose of shaping research protocols so that they protect human subjects in a way that is compliant with federal regulations. In serving that purpose the IRB is helping to protect both human subjects and the research enterprise at the UW.

Several commented that the IRB and IRB staff are doing their best, but constrained by UW-Madison's interpretation of federal policies and UW-Madison bureaucracy.

I think they're trying, but burdened down by the bureaucracy

IRB process seems more focused on bureaucracy and control, than on striking a balance. This may be a problem with how the systemic aspects are designed, rather than a problem of good faith intentions of individual staff.

However, over 150 comments expressed the view that the IRB committee had moved away from a primary focus on protecting human subjects to one of avoiding all risks and pursuing an overly cautious interpretation of federal regulations.

I have been part of multiple IRB review submissions outside UW; UW seems to have a reputation as being not just tough, but overly technical and applying rules in situations when legally, ethically, regulatory-wise, UW does not need to be as strict.

I know from conversations with faculty at other institutions that interpretations of the federal policy varies widely. UW seems to almost uniformly adopt the most stringent and restrictive interpretations. The threat of internal audits has a chilling effect-- there seems to be an attitude of over compliance -- let's always be safe from the regulatory perspective regardless of the significance or cost of the regulation.

While I am respectful for the need to protect the institution and continue the research process here generally, the IRB seems to have forgotten that the main duties are to protect research participants and promote research because research is a public good. It seems all too often the UW IRB's mission is to ensure regulatory compliance which seems to be more about interpretation of the regs than the actual regs themselves.

*The IRB should model their services after RARC (*Research Animal Resource Center*) which provides much better service to faculty and researchers. In complex regulatory situations RARC is much more likely to assist the researcher in finding solutions to allow the work to go forward.*

We are assessing the efficacy of an investigational medical device. Despite being determined a minimal risk intervention and a non-significant risk technology by both the IRB and the FDA, the protocols are consistently subjected to the same administrative policy and procedural oversight that would be expected for a large, multi-site, investigational drug study or an invasive surgical procedure. It would appear that the IRB is focused on the administrative details, making sure all the right boxes are checked, and not on truly understanding the risk/benefit profile of the protocols and acting accordingly.

I have found the requirements through the IRB increasingly onerous through the years. I have been at Madison for over a decade, and the most frustrating thing is that over that time, what I am allowed to do in research has diminished, IRB requirements have increased, and thus protocols that would pass without problem 5 years ago are now deemed not allowed.…the entire process has become one in which adherence to rules for rules' sake is the overriding principle. This doesn't reflect federal regulations. Other colleagues at other institutions are still allowed to carry on the same research structure that I no longer can at UW.

The regulatory hurdle is excessive to perform new/exploratory analyses collected on previous protocols, and that there is no flexibility in fees levied once protocols are initially submitted through ARROW. The level of detail required by the reviewer in duplicate (in protocol and in ARROW application) is a major regulatory hurdle that should not be

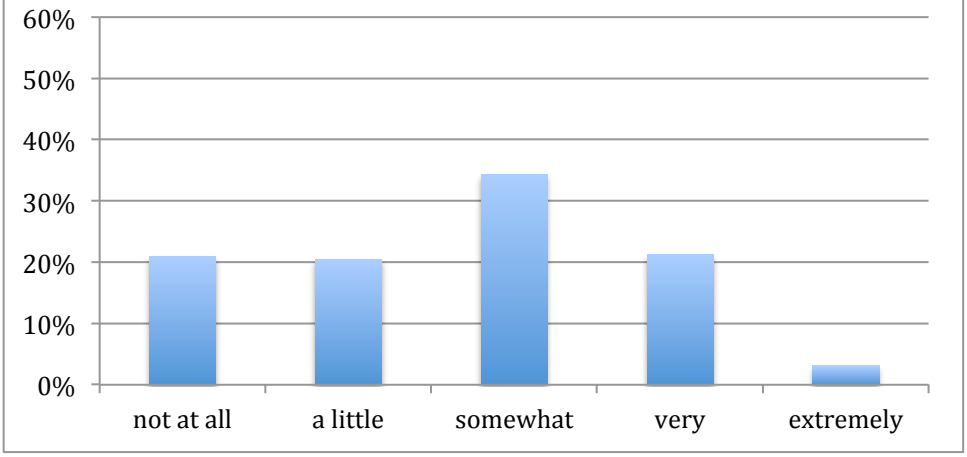
undertaken for small, pilot analyses, especially when using tissue obtained from a prior protocol, even if directly performing an analysis for which patients were consented.

Time to Obtain IRB Approval of Protocols

Although data from ARROW indicate that the time (in days) from submission to approval at UW-Madison is at or below the median number of days compared to our peer institutions, many respondents expressed frustration with length of the approval process. Only a fourth of survey respondents thought the time it took the IRB to approve a protocol, defined in the survey question as the time the protocol was first submitted to pre-review to the time it was finally approved, was "extremely" or "very acceptable" (see Figure 7).

Fully, 42% of the survey respondents felt that the time to approval was "not at all" or only "a little" acceptable. Responses from users of the different IRBs had different perspectives on this question. Whereas, fully half of respondents who used the HS IRBs indicated that they found the time "not at all" or "a little" acceptable, less than one-third of respondents who used the ED/SBS IRB reported a similar sentiment.

Figure 7. How acceptable do you find the time it takes the IRB to approve your protocol?



Among those respondents who added written comments about their satisfaction or dissatisfaction with the time it takes a protocol to be approved, approximately 90 commented that the process was efficient and timely.

Once a protocol or change is submitted the response has been timely

I find the IRB here to be very good at timely review of protocols and understanding of typical research designs.

They have also accommodated requests to "rush" the review process to adhere to school district deadlines for external research protocol submission.

I really appreciate their 'speedy' e-mail responses (usually within a couple of hours) even on weekends.

However, almost 300 comments expressed frustration with the time the IRB process took and a perception that the UW-Madison IRB process takes longer than at other universities, or is required by federal standards.

For research that is unquestionably going to be exempt, the amount of effort to get a protocol accepted seems exorbitant and can take months.

The biggest issue for me is that all of my research is ultimately determined exempt (or gets expedited approval) because I work with secondary data from which all identifying information has been removed. However, it takes several hours of work and multiple iterations of the protocol to actually get to the already given conclusion…for those of us working with secondary data the frustration of spending so much time navigating a complicated interface…and the frustration of having to respond to multiple requests for little bits of largely irrelevant incremental information is frustrating. It would be wonderful if there was some way to provide an alternative sequence of questions (or branch within the existing sequence) that was actually relevant for people whose work consists primarily of the analysis of secondary data (some of which is freely available for download and thus exempt and some of which requires a pro-forma application for use).

Anonymized national survey data, from a federal source and commonly used in the field, required the full review and several months of time and rules about access from a particular server that made it difficult to use.

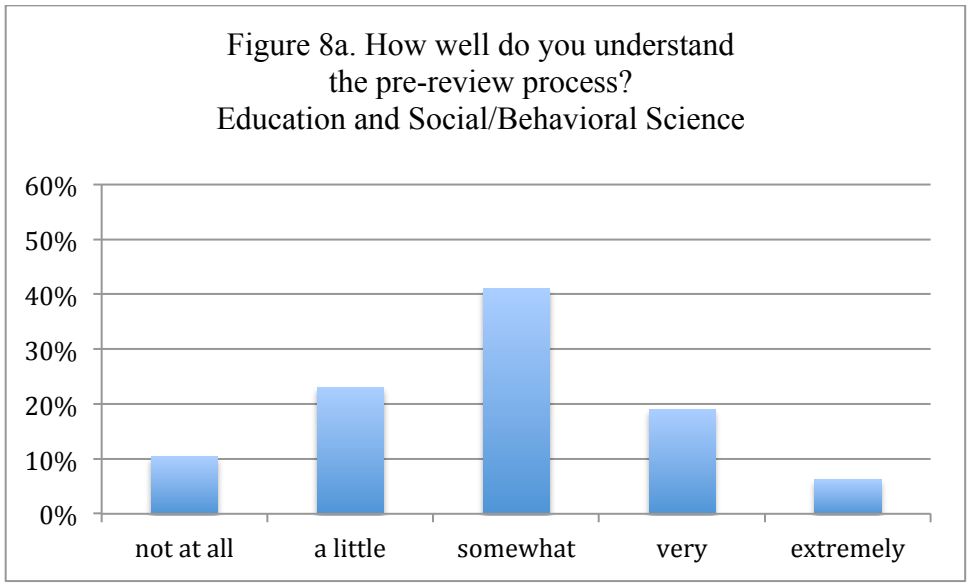
We were approached by a colleague at a peer institution about a retrospective chart review… The request was straightforward, the methods clear, and the endpoints were doable. The protocol itself was essentially two pages long, and it met criteria for minimal risk as defined…and prepared for a full IRB submission. Once the process was completed, the process of review took so long that all of the other institutions (six) had completed their chart review before ours could even get an approval. The entire data collection process…took about six hours. The process of going through the IRB took me and a regulatory specialist about 30 person-hours to navigate.

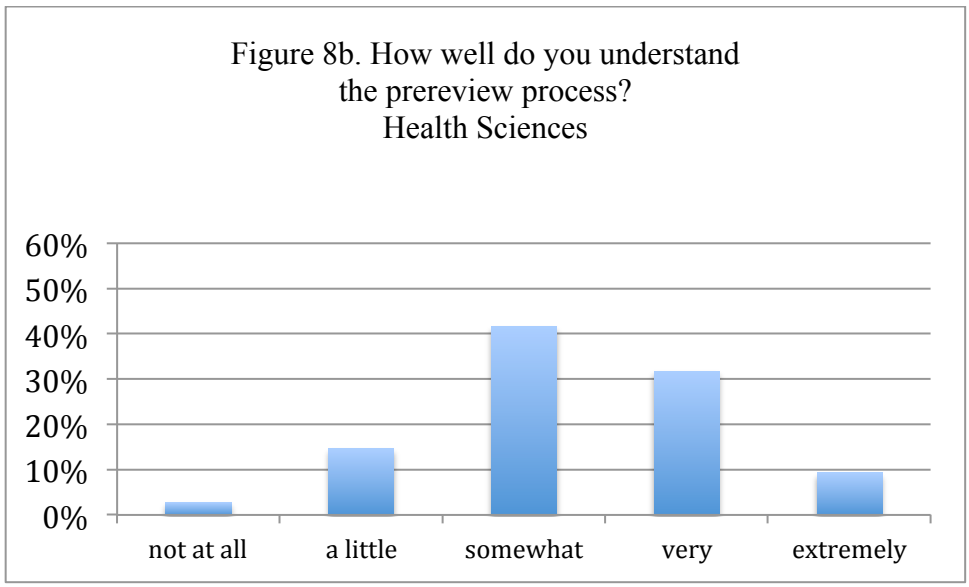
The administrative overhead our IRB imposes to get the work done is excessive. Annual review of unchanging enrollment materials and the necessity of an IRB 'stamp.' Review of the several surveys took some time. Tweaking the consent language took some time. It all takes time.

I am currently trying to get approval for a time-sensitive outside funded project that likely will never launch because of the amount of time it will take to secure IRB approval, even though I have performed nearly-identical research in the past with IRB approval.…my colleagues at other schools tell me that their experiences securing IRB approval for similar research are very different, and much less time-intensive.

Understanding of the Pre-review Process

We asked respondents how well they understand how the pre-review process, also called the staff review process, works. Since the ED/SBS IRB does not conduct a scientific review and only recently has had a sufficient staff to conduct pre-reviews, separate analyses were conducted for the ED/SBS and HS IRBs. As shown in Figure 8a, among those who only submitted protocols to the ED/SBS IRB, 25% reported understanding the process "very" or "extremely" well, whereas nearly 34% had "little" or "no" understanding of the preview process. For those using one of the two HS IRBs, approximately 40% indicated understanding the preview process "very" or "extremely" well, and only 17% had "little" or "no" understanding of the process (see Figure 8b).





Effect of IRB on Faculty Research

In the survey respondents were asked, "Have you given up or almost given up pursuing a research project out of frustration of getting it through the IRB?"

Almost half (49.4%) responded affirmatively.

There were many reasons given for "giving up or almost giving up", including the amount of time and effort to receive approval, administrative burden, the IRB staff raising questions about the scientific design of a study that had already completed a prior rigorous scientific peer review, and the fee structure for undergoing a review in the Health Sciences (the ED/SBS IRB does not charge fees).

The following quotes describe some of these reasons.

I have now been told that I need to submit an IRB protocol to perform non-human subjects research.…I am actively looking for new job opportunities because the leadership of this institution does not reign-in IRB overreach, which is supposed to be limited to protecting human subjects. None of my peers have faced these kinds of requests, including Harvard, Johns Hopkins University…and others.

It is our opinion that the administrative burden is disproportionate to the degree of risk posed by the interventions, causing a frustratingly incremental pace of decision making and approval. These delays make it increasingly difficult to make meaningful scientific progress. Scientific collaborators at other institutions have grown impatient with the pace of our investigations, despite the fact that we are the project lead, leading to missed opportunities for subsequent funding and research. We are seriously considering terminating our research this area at UW, despite the recognition and prestige it would bring our lab and the university.
I applied twice for exemptions, once as an umbrella effort on behalf of four researchers, requesting access to de-identified materials held at the biobank, and the other to gain access to an NIH-designated core supplying de-identified cell lines to researchers. Both of these were extremely simple requests that might have been one paragraph long or a simple face-to-face discussion. Both were granted but turned out to be onerous and protracted processes, even with expert assistance. I would estimate that I spent 80 hours on the first, and 25 on the second. At other Institutions where I give seminar…and find that our Institution is by far the most resistant to research requests (most recently, University of Michigan and University of Alabama, Birmingham).…the IRB process at the UW is the biggest hurdle to keeping and procuring funding and researchers in the biomedical sciences.

There are projects that I have not initiated because it will simply take too much time to initiate or modify basic minimal risk projects due to the amount of work needed to achieve approval of an IRB protocol. Even a single sentence modification to a protocol that introduces no increased risk to subjects and would be even less risk of breach of confidentiality than basic patient care spawns a dozen comments and questions from IRB staff. Further, many of the IRB staff requests are to re-write information in multiple places,

a waste of time. Additional IRB staff requests cause unnecessary burden on the research team when subject risk has not been increased.

The process simply takes too long. This is unacceptable. It has caused us to miss out on national collaborative projects, has caused delays in starting projects which in turn delays finishing projects and renewed or new funding.

I am considering leaving the university because of the impossibility of getting projects through the IRB in any type of timely basis. It is a real tragedy and it is going to put this institution far behind as time passes.

Of all the academic places I worked at, this is the first place that charges money for the IRB, and it is not a negligible amount. This prevents us from pursuing many projects, unless we get a grant to cover the costs. It will be helpful if these costs are removed, these costs are reduced, someone explains to us why UW IRB in particular are asking for fee.

The whole IRB situation at UW is too cumbersome and expensive. I've never had so much difficulty with protocols. The review process is slow (my record is almost a year....). I had a meeting with our research division last month to express my frustration and to inform them that I'm decreasing my involvement in research.

I have become wary because of the fees that I consider to be somewhat exorbitant for investigator-initiated unfunded research. It makes me not want to submit projects with students, whose participation evolves, and I actually have stopped participation in some multi-center clinical research projects as a result.

The IRB tends to believe that without data they can anticipate a risk of our protocols. My laboratory studies of…and the IRB tends to react very strongly, but totally intuitively, to what the implications of the manipulations are and how well we can extinguish them. They also tend to ignore the fact that other similar studies have been conducted without incident at UW and elsewhere in the past. My laboratory is very tired of working with the IRB on studies of…The IRB returned my application with requests for modifications that were incompatible with biology and against common ethics. I therefore "farmed out" my study to (name removed) *University. Their IRB approved it with very few changes within 3 weeks and* (name removed) *university got the ICR for the entire grant.*

I no longer participate in multicenter studies because our IRB wants me to change a multicenter protocol.

The IRB process is taxing and is a disincentive to do clinical or translational research…. The…process is too long and too concerned with minutia. Some details ARE important, but most of the time I find myself thinking - really? Is the really putting someone at risk? Or is this a clarification requested by someone who is overthinking the problem?

Blurring of Boundaries between Protection of Human Subjects and Scientific Review

In the qualitative data, 81 comments expressed a growing concern about the IRB committee and staff blurring the distinction between the protection of human subjects and the scientific evaluation of a study. Those concerns most frequently mentioned are described below.

One frustrating thought that often occurs to me is why I sometimes face additional scientific questions for studies that are already scientifically reviewed by an NIH panel of experts and for which we have already dealt with a number of safety questions that arose during review.

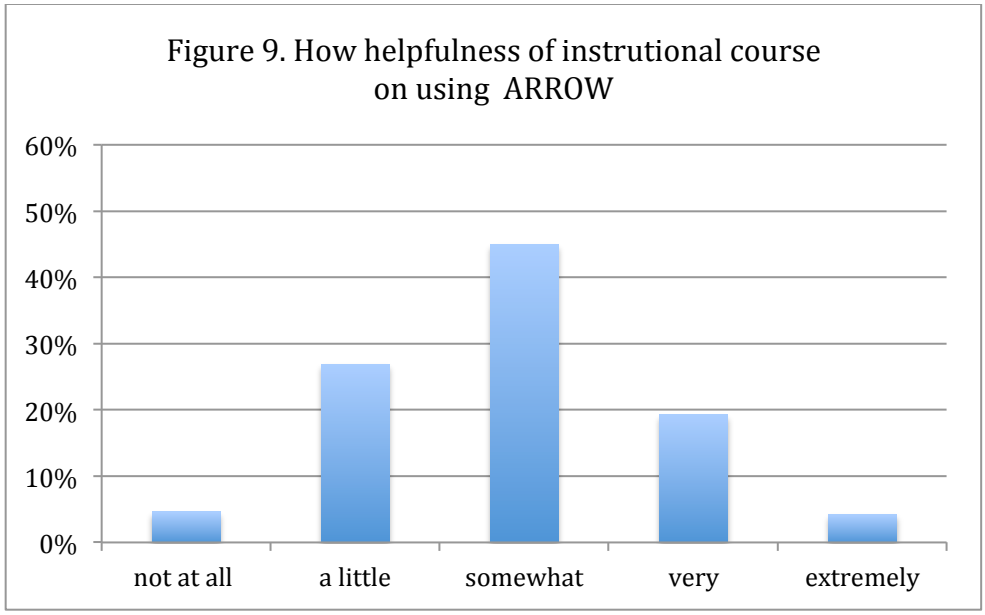
I feel IRB at UW goes way beyond (what I believe is) their stated goal of protecting human subjects. They've made me make many changes that seem completely unrelated to protecting human subjects. One time they critiqued my use of a self-reported LIkert-scale because they didn't think it was the best measure of the concept I was trying to assess. Is IRB now in charge of critiquing and improving faculty research? I have so many examples of IRB making changes to items that seem completely unrelated to protecting human subjects.

In several cases, the IRB staff determined that my protocol was "not research", which apparently means that it cannot be published as research. Obviously, I contend that the work I do for the university is, indeed, research. In each case there were multiple back and forth emails in which I explained the reasons why my study should be considered research. At one point, a staff member informed me that my study had no hypothesis. I needed to explain that not all research starts with a hypothesis -- especially qualitative research, which should never start with a hypothesis. Recently, I submitted a protocol that was a collaborative project with another major research university. The other university's IRB exempted the study, but the UW IRB determined it was "not research." I finally decided to give up and allow UW to certify the study as "not research" even though we are combining our dataset with the dataset collected by my colleagues at the other university. Without a doubt, the problems I have faced with the IRB at UW have been my biggest barrier to conducting research… I have seriously considered leaving the university because of this barrier.

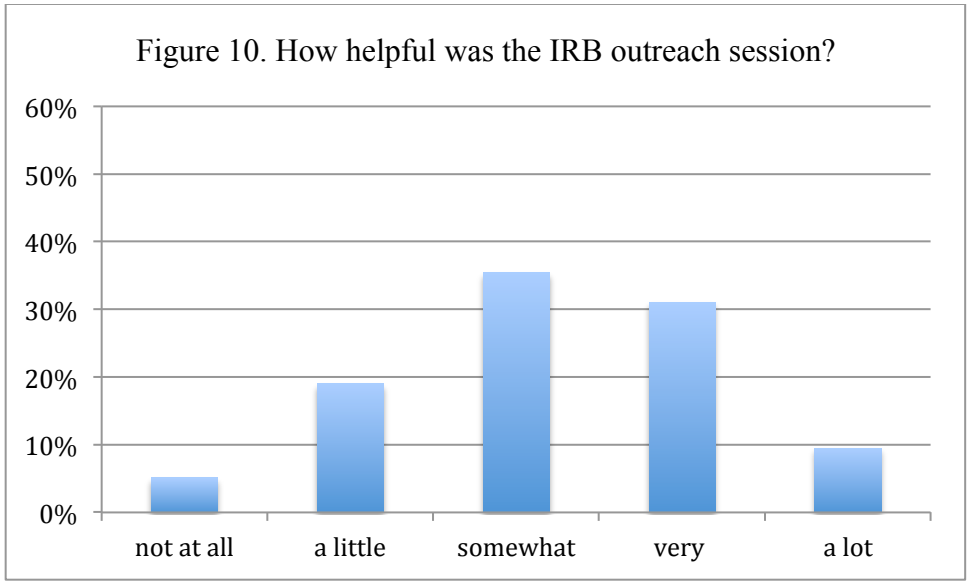
Investigator Use of IRB Resources

The IRB staff has several resources for investigators. These include an instructional course for using ARROW; outreach IRB sessions for departments, classes and groups; and IRB training sessions such as IRB 101 and IRB 200. Respondents were asked if they had used any of these resources, and if yes, how helpful they found the resource.

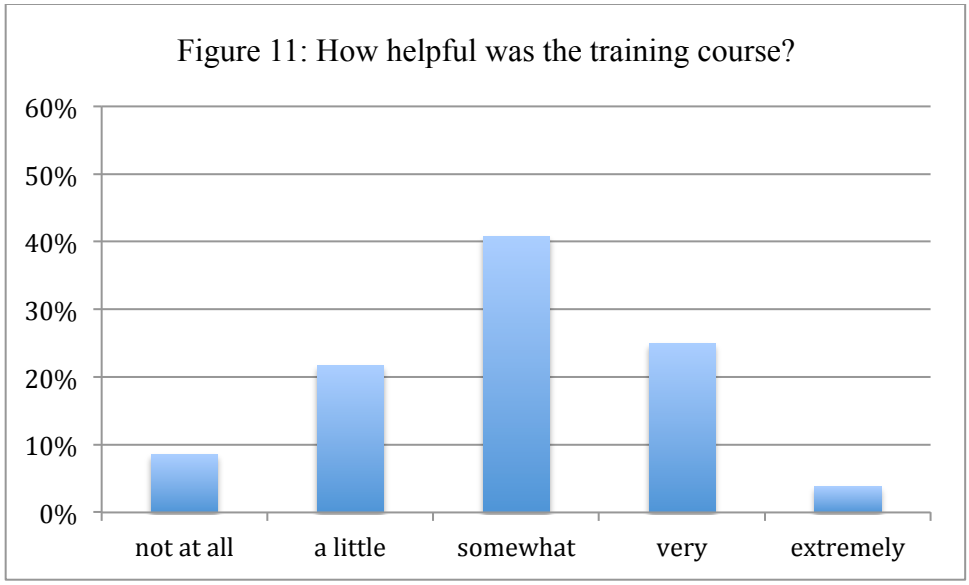
Of the 562 respondents, 42.5% indicated that they had completed an instructional course for using ARROW. Of these, about a fourth found them “very” or “extremely” useful, and approximately half found them “somewhat” useful (see Figure 9).



As shown in Figure 10, 28.5% indicated that they had attended an outreach session with IRB staff. Approximately 40% found the sessions "very" or "extremely" useful, and another third found them "somewhat" useful.



Of the 562 respondents, 27.4% indicated that they had completed an IRB topic-based training session course (e.g., International Research, Consent Considerations). Of these, about 30% found them "very" or "extremely" useful, and 41% found them "somewhat" useful (see Figure 11).

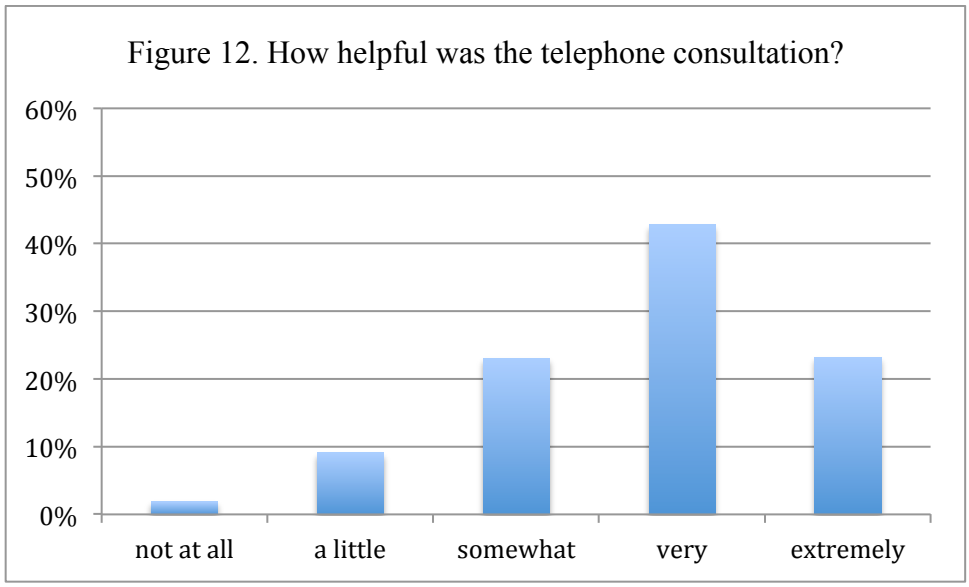


In summary, of the various resources for investigators, PIs rated the outreach sessions as most helpful.

Consultations with IRB staff

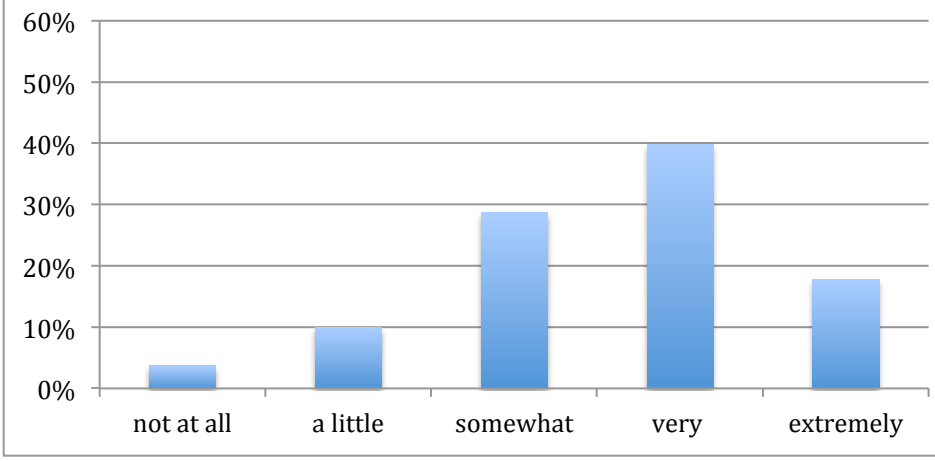
The IRB staff spends a significant amount of time consulting with investigators on their individual protocols. A series of questions asked respondents about whether they had consulted with IRB staff via phone, email or in-person, and if they had, how helpful the consultation had been.

Fully 75% of the respondents indicated that they had consulted with the IRB over the telephone. As shown in Figure 12, more than 65% found these consultations "very" or extremely helpful and another quarter found them "somewhat" helpful.



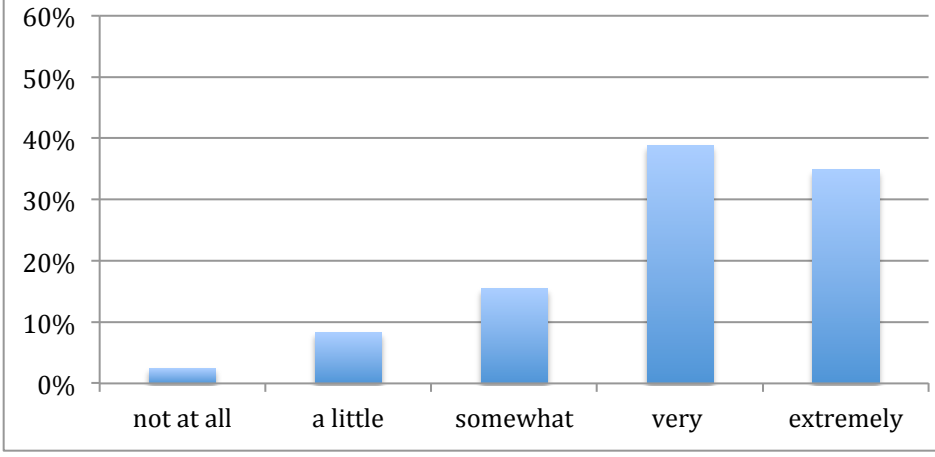
Almost 90% of the respondents had sought consultation with IRB staff via email. As seen in Figure 13, almost 60% found this consultation "very" or "extremely" helpful and another 30% found the email consultation "somewhat" helpful.

Figure 13. How helpful did you find the email consultation?



Approximately half of the survey respondents indicated that they had consulted with the staff in-person. Of these, 74% found the in-person consultation "very" or "extremely" helpful and another 15% found it "somewhat" helpful (see Figure 14).

Figure 14. How helpful did you find the in-person consultation?



Summary

The survey results indicate that faculty and research staff across campus hold the IRB staff in high regard, and value their expertise, experience, and guidance. Overall, the PIs felt respected by the staff and appreciated the staff's willingness to help them resolve problems.

However, almost 50% of the respondents indicated that they had given up or almost given up pursuing a research project out of frustration of getting it through the IRB. In the extensive qualitative comments (approximately 100,000 words of text), many concerns and problems were identified. These included the unnecessary complexity of the ARROW system, the slowness of the IRB approval process, inconsistencies in the review process, high user fees, the perception that the IRBs are now more concerned with avoiding institutional liability than properly assessing the risk to human subjects, the over-regulation of minimal risk studies, and a general sense that UW-Madison has instituted additional layers of scrutiny beyond what is required by federal regulation.

Based on the survey results, the Office of the VCRGE will put into action the following steps:

Recommendations:

1. One of the major frustrations is in the use of ARROW. In response, the Office of the VCRGE has developed an "ARROW Optimization Plan". This plan involves the ARROW team (i.e., the information technology group within the Office of the VCRGE) focusing additional development time specifically on improvements to the user experience, leading to improvements in transparency, usability, efficiency, and reduced duplication. As part of this effort, the ARROW team will conduct an upgrade of ARROW that will improve site navigation. In addition, efforts will continue to look for opportunities to streamline the application for minimal risks studies. This optimization plan is underway and will be ongoing in quality improvements efforts for ARROW. During this process, the ARROW team will seek consultation from the IRB Directors and their staff, the office of the UW-Madison Legal Affairs, and researchers across campus.

2. The OVCRGE has begun a process of benchmarking UW-Madison policies and practices against those of its peer institutions, which will include a review of federal human subjects regulations and interpretation of these federal regulations on campus. The OVCRGE will analyze these benchmarking data, develop a plan to reduce the burden on human subjects researchers, and will consult with the Directors of the HS and ED/SBS IRBs and the office of the UW-Madison Legal Affairs in this process.

3. The survey generated many ideas from respondents for improving IRB processes: developing templates with suggested language for protocols, exploring a centrally-funded IRB and eliminating IRB fees for non-industry sponsored and non-VA protocols, learning from the RARC's service-oriented culture, creating an ombudsman, and streamlining the application for minimal risk studies. The OVCRGE appointed a committee of faculty and academic staff researchers to review the findings of this report and the benchmarking data,

and generate a prioritized list of recommendations to improve the efficiency and user-friendliness of the IRB process. In conducting its work, the committee will seek consultation from the relevant stakeholders (e.g., IRB staff, the office of Legal Affairs, faculty researchers, permanent PIs).

4. One of the main problems identified by respondents was the apparent lack of uniformity in the criteria applied to reviewing protocols. Many respondents reported that they often received inconsistent and often contradictory comments from different reviewers. To achieve greater uniformity in protocol review, the OVCRGE will use the benchmarking process above to determine how peer institutions strive to achieve consistency, and then develop a recommendation and an action step.

5. PIs expressed frustration with the length of time from submission of an IRB protocol to approval. The OVCRGE will use available data to better understand what factors contribute to the length of the IRB review process to help identify opportunities to reduce the time between the submission of a proposal and the approval of the protocol.

6. The OVCRGE will develop a short IRB survey to receive ongoing feedback. The survey will be administered automatically to an investigator each time the investigator receives notification that his/her IRB protocol has been approved. Many peer institutions have implemented such a survey and found it helpful in obtaining "real time" feedback from users.

This is an ambitious plan that will likely require additional campus resources. It also may require changes in UW-Madison campus policies regarding IRB processes and procedures. The Office of the VCRGE recognizes any effort to implement changes that improve the efficiency and user-friendliness of IRBs must simultaneously support the IRB's primary role of ensuring compliance with federal regulations. As the OVCRGE moves forward in implementing these recommendations, it will work closely with the Directors of the ED/SBS and HS IRBs and the office of the UW-Madison Legal Affairs to ensure that administrative efficiencies and changes do not hamper the IRBs ability to carry out their regulatory responsibility.

Appendix A

Institutional Review Board Survey

Introduction:

We are conducting this survey in an effort to find out how the Office of the Vice Chancellor for Research and Graduate Education can work with the IRBs to provide a high quality experience for you. This survey is completely confidential and any identifying information will be removed by Associate Vice Chancellors Jan Greenberg and Norman Drinkwater from the data once the survey is closed. Only aggregate results will be shared with the IRBs as part of our quality improvement efforts. The survey takes about 10 minutes to complete. You can take the survey in parts or all at once. We would greatly appreciate if you could find the time to tell us about your experiences. To move between pages please use the back and forward arrows at the bottom of the page. Please do not use the back button on your browser. This can take you out of the survey, causing loss of data. Please only use the red back and forward buttons at the bottom of the page to avoid losing any information you have already entered. If you have any questions about the survey please feel free to contact Jan Greenberg or Norman Drinkwater.

Thanks,

Jan Greenberg Associate Vice Chancellor for Research, Social Sciences jan.greenberg@wisc.edu (262-1044)

Norman Drinkwater, Associate Vice Chancellor for Research, Biological Sciences norman.drinkwater@wisc.edu (262-1044)

Q1 This questionnaire is about your experience with IRBs at the University of Wisconsin-Madison. You may be named on protocols at other institutions, but this questionnaire is only about protocols with an IRB at UW-Madison. What is your primary role at the UW-Madison?

- ❍ Faculty
- ❍ Academic staff
- ❍ Postdoctoral fellow
- ❍ Graduate student

Q2 Human subjects protocol submissions include both initial applications and continuing reviews. Since 2014, how many human subjects protocols have you submitted?

- ❍ 0
- ❍ 1
- ❍ 2 – 3
- ❍ 4 – 5
- ❍ 6 – 7
- ❍ 8 – 10
- ❍ More than 10

Q3 Since January 2014, have you submitted an application to the following UW-Madison IRBs.

	Yes	No
Education and Social/Behavioral Science IRB	❍	❍
Health Sciences IRB	❍	❍
Health Sciences Minimal Risk IRB	❍	❍

Q4 How well do you understand how the pre-review, also called the staff review, process works?

- ❍ Not at all
- ❍ A little
- ❍ Somewhat
- ❍ Very
- ❍ Extremely

Q5 How respectfully did the IRB and IRB staff treat you when they reviewed your protocol(s)?

- ❍ Not at all respectfully
- ❍ A little respectfully
- ❍ Somewhat respectfully
- ❍ Very respectfully
- ❍ Extremely respectfully

Q6 How willing is the IRB and IRB staff to work with you to resolve problems that arise during the review process?

- ❍ Not at all
- ❍ A little
- ❍ Somewhat
- ❍ Very
- ❍ Extremely

Q7 How easy do you find the ARROW software platform to use?

- ❍ Not at all
- ❍ A little
- ❍ Somewhat
- ❍ Very
- ❍ Extremely

Q8 How acceptable do you find the time it takes the IRB to approve your protocol(s), from the time the protocol is first submitted to pre-review to the time it is finally approved?

- ❍ Not at all
- ❍ A little
- ❍ Somewhat
- ❍ Very
- ❍ Extremely

Q9 How helpful has the IRB and IRB staff been in helping you overcome regulatory challenges?

- ❍ Not at all
- ❍ A little
- ❍ Somewhat
- ❍ Very
- ❍ Extremely

Q10 The IRB, including during the staff review process, often requests modifications or clarifications from study teams before they can approve a study. In general ...

	Not at all	A little	Somewhat	Very	Extremely
... how clear are the requests from the IRB?	❍	❍	❍	❍	❍
... how reasonable are the requests from the IRB?	❍	❍	❍	❍	❍

Q11 Have you given up or almost given up pursuing a research project out of frustration of getting it through the IRB review process?

- ❍ Yes
- ❍ No

Q12 Please tell us more about the situation:

Q13 Based on your overall experience with the IRB submission and review process, what do you see as working well?

Q14 Based on your overall experience with the IRB submission and review process, what do you see as not working well?

Q15 Where would you turn for help if you have concerns about IRB processes or policies?

Q16 Have you ever used any of the following resources offered by the Education and Social/Behavioral Science IRB?

	Yes	No
Instructional course for using ARROW	❍	❍
Outreach sessions for your department, group, or class	❍	❍
IRB training sessions such as IRB 101 or IRB 200	❍	❍

Q17 How helpful were the following resources offered by the Education and Social/Behavioral Science IRB?

	Not at all helpful	A little helpful	Somewhat helpful	Very helpful	Extremely helpful
Instructional course for using ARROW	❍	❍	❍	❍	❍
Outreach sessions for your department, group, or class	❍	❍	❍	❍	❍
IRB training sessions such as IRB 101 or IRB 200	❍	❍	❍	❍	❍

Q18 Have you ever used any of the following resources offered by the Health Sciences IRB or the Health Sciences Minimal Risk IRB?

	Yes	No
Instructional course for using ARROW	❍	❍
Outreach sessions for your department, group, or class	❍	❍
IRB training sessions such as IRB 101 or IRB 200	❍	❍

Q19 How helpful were the following resources offered by the Health Sciences IRB or the Health Sciences Minimal Risk IRB?

	Not at all helpful	A little helpful	Somewhat helpful	Very helpful	Extremely helpful
Instructional course for using ARROW	❍	❍	❍	❍	❍
Outreach sessions for your department, group, or class	❍	❍	❍	❍	❍
IRB training sessions such as IRB 101 or IRB 200	❍	❍	❍	❍	❍

Q20 Have you ever consulted the Education and Social/Behavioral Science IRB staff ...

	Yes	No
... over the phone?	❍	❍
... over email?	❍	❍
... in person?	❍	❍

Q21 How helpful was the consultation with the Education and Social/Behavioral Science IRB staff...

	Not at all helpful	A little helpful	Somewhat helpful	Very helpful	Extremely helpful
... over the phone?	❍	❍	❍	❍	❍
... over email?	❍	❍	❍	❍	❍
... in person?	❍	❍	❍	❍	❍

Q22 Have you ever consulted the Health Sciences IRB or the Health Science Minimal Risk IRB staff ...

	Yes	No
... over the phone?	❍	❍
... over email?	❍	❍
... in person?	❍	❍

Q23 How helpful was the consultation with the Health Sciences IRB or the Health Science Minimal Risk IRB staff...

	Not at all helpful	A little helpful	Somewhat helpful	Very helpful	Extremely helpful
... over the phone?	❍	❍	❍	❍	❍
... over email?	❍	❍	❍	❍	❍
... in person?	❍	❍	❍	❍	❍

Q26 Please identify any ways that you think the Education and Social/Behavioral Science IRB could improve services to you, or any comments that you have about issues that were or were not addressed by this survey?

Q27 Please identify any ways that you think the Health Sciences IRB or the Health Science Minimal Risk IRB could improve services to you, or any comments that you have about issues that were or were not addressed by this survey?

Q28 The Survey was intended to be completed by researchers who have submitted a protocol in the past 2 years. You indicated that you have not submitted any protocols during this time frame. If you have submitted a protocol in the past 2 years, please use the back arrow and correct your response. Otherwise, please use the forward arrow at the bottom of the page to exit the survey.

Q29 We thank you for the time you spent taking the survey. Once you submit the survey you will not be able to go back and change your response. If you would like to review your responses, please use the back button at the bottom, otherwise, click the forward button to submit your responses.

Appendix B

Table 1. Data for Figures

Question	Not at all	A little	Somewhat	Very	Extremely
Figure 1. How easy do you find the ARROW software platform to use?	21.3%	23.3%	35.8%	17.5%	2.1%
Figure 2. How respectful did the IRB and IRB staff treat you when they reviewed your protocol(s)?	1.2%	5.2%	25.4%	52.3%	15.8%
Figure 3. How willing is the IRB and IRB staff to work with you to resolve problems that arise during the review process?	1.6%	7.9%	27.2%	47.6%	15.7%
The IRB, including during the staff review process, often requests modifications or clarifications from study teams before they can approve a study.					
Figure 4. In general, how clear are the requests from the IRB?	3.2%	13.7%	35.1%	41.2%	6.8%
Figure 5. In general, how reasonable are the requests from the IRB?	11.2%	25.4%	36.9%	23.7%	2.9%
Figure 6. How helpful has the IRB and IRB staff been in helping you overcome regulatory challenges?	8.0%	23.5%	32.8%	29.2%	6.5%
Figure 7. How acceptable do you find the time it takes the IRB to approve your protocol(s) from the time the protocol is first submitted to pre-review to the time it is finally approved?	20.9%	20.7%	34.1%	22.1%	3.0%
Figure 8a. How well do you understand how the pre-review, also called the staff review process, works? (Education and Social/Behavioral Science)	10.4%	23.1%	41.0%	19.0%	6.3%
Figure 8b. How well do you understand how the pre-review, also called the staff review process, works? (Health Sciences)	2.8%	14.6%	41.6%	31.7%	9.3%
Have you given up or almost given up pursuing a research project out of frustration of getting it through the IRB review process? (% Yes)	49.2%				

Question	Not at all	A little	Somewhat	Very	Extremely
Figure 9. Have you ever attended an instructional course for using ARROW? (% Yes)	42.5%				
How helpful was the instructional course for using ARROW?	4.6%	26.9%	4.5%	19.3%	4.2%
Figure 10. Have you ever attended any outreach sessions for your department, group, or class? (% Yes)	28.5%				
How helpful was the outreach session offered by the IRB?	5.1%	19.0%	35.4%	31.0%	9.5%
Figure 11. Have you ever attended IRB training sessions such as IRB 101 or IRB 200? (% Yes)	27.4%				
How helpful were the IRB training sessions such as IRB 101 or IRB 200?	8.6%	21.7%	40.8%	25.0%	3.9%
Figure 12. Have you ever consulted the IRB staff over the phones? (% Yes)	75.0%				
How helpful was the consultation over the phone?	1.9%	9.1%	23.0%	42.8%	23.2%
Figure 13. Have you ever consulted the IRB staff over email? (% Yes)	87.1%				
How helpful was the consultation over email?	3.7%	10.0%	28.7%	39.8%	17.8%
Figure 14. Have you ever consulted the IRB staff in person? (% Yes)	49.6%				
How helpful was the consultation in person?	2.5%	8.3%	15.5%	38.8%	34.9%