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Reliance agreements and single IRB review of multisite research: Concerns of IRB members and staff

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Abstract

The new National Institutes of Health (NIH) Policy on the Use of a Single Institutional Review Board (sIRB) for Multi-Site Research was adopted primarily to simplify and speed the review of complex multisite clinical trials. However, speeding review requires overcoming a number of obstacles. Perhaps the most substantial obstacle is the time and effort needed to develop reliance agreements among the participating sites. We conducted 102 semistructured interviews with sIRB personnel, including directors, chairs, reviewers, and staff, from 20 IRBs that acted as sIRBs for multisite research, including 6 commercial/independent sIRBs, and 10 university-based academic and 4 federal sIRBs. Almost without exception, the interviewees agreed that reliance agreements were complex, difficult to develop, and time-consuming. A major problem for relying sites was that different agreements specified different responsibilities for the relying sites. Attitudes differed about whether these problems will be resolved as IRB staff and managers become more experienced with sIRBs. However it is clear that the process of developing reliance agreements must be simplified. Federal assistance in standardizing at least some sections of reliance agreements might reduce the difficulties involved.

Keywords

IRB; sIRB; CIRB; reliance agreement; authorization agreement

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ICMJE ITEMS

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Introduction

The new NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research (the "NIH sIRB Policy") (National Institutes of Health 2017) effective on January 25, 2018, is a major change in the procedures for the ethical review of human subjects research.[1] The NIH sIRB Policy requires that all domestic sites of multi-site studies funded by the NIH use a single IRB ("sIRB") to conduct the ethical review of human subjects research. It is a response to the broad perception that separate review by each local IRB ("LIRB") in multi-site studies multiplies the time and effort required for human subjects review for both researchers and IRBs (Ahmed and Nicholson 1996; Dziak et al. 2005). Indeed, the NIH sIRB Policy notes that comments on the draft proposal were generally "supportive of the NIH's goal of enhancing and streamlining IRB review in multi-site research" (National Institutes of Health 2017). Despite this assumption, there has been no systematic assessment of whether and how the sIRB process is likely to improve the efficiency of IRB review of multi-site studies and what problems may arise in its implementation.

The purpose of our NIH-funded study (Central IRBs: Enhanced Protections for Human Research Participants?, 1R01GM113640) was to examine how IRBs acting as sIRBs review multisite research[2]. Our participants - 103 IRB members and administrators from 20 sIRBs who participated in extensive, semi-structured interviews - expressed a variety of opinions, pro and con, about the implementation of the sIRB Policy. We focus here on a particularly salient issue that arose frequently during the course of interviews: concerns about the difficulties of negotiating and implementing "reliance agreements" in the sIRB review of a study. We sought to examine the role that reliance agreements play, and how they might affect sIRB reviews.

A reliance agreement (sometimes called an IRB authorization agreement, master agreement, or cooperative agreement) is a formal, written document that provides the mechanism for an institution to delegate IRB review to another institution's IRB ("Reviewing IRB"). A reliance agreement delineates the roles and responsibilities of the Reviewing IRB and the IRBs of the institutions relying on it ("Relying IRBs"). Approaches to centralized review of multi-site studies date back to the early 1980s (Flynn et al. 2013) and a number of models have been used, from a sIRB providing definitive review for a study to a sIRB offering "facilitated review" for a consortium that local IRBs might accept, modify, or reject (Greene et al. 2010).

The NIH sIRB Policy does not dictate the arrangements made for ethical review of a protocol so long as there is one IRB that has regulatory responsibility for undertaking ethical review of the study for all other institutions in that study. Nor does this policy specify how

[1]The Final Rule: Federal Policy for the Protection of Human Subjects, issued January 19, 2017, also includes a mandate for single IRB review of federally funded multi-site research. However, this provision of the Final Rule does not take effect until January 20, 2020

[2]Our study was initially designed to focus on "central IRBs" ("CIRBs"), that is, sIRBs reviewing multiple sites even if not all of the sites in the study agreed to centralized review. We began our research before the NIH sIRB Policy was in force. However, most interviewees discussed the sIRB concept and how it applied to their work.

other reviews that are often coordinated by IRBs, many of which are specified by the particular institution's policies, as well as those specified by other regulations (e.g., conflict of interest, radiation, pharmacy), should be managed.

There are important organizational differences that may affect sIRB and LIRB reviews. Although both LIRB and sIRB reviews are designed to oversee the same ethical conduct of research, the practical impact on the work of IRB members and staff is quite different. This is not primarily because sIRBs are reviewing more than one site. A key difference is that the reviews take place in different organizational structures. Most LIRBs work within a single institutional structure (i.e., a hospital, university, or clinical research organization)[3] where the IRB staff and members, the researchers, and the other associated committees participate in what organizational theorists call the same "formal organization" (Blau and Scott 1962). Moreover, through past opportunities to work together, they have developed a history of shared experiences and often know each other personally. Even if they have not interacted with one another directly, they have overlapping social networks that facilitate accomplishing their organizational goals, a structure that organizational theorists have called the "informal organization" (Harris and Hartman 2002). In short, both formal and informal organizational structures facilitate the process of LIRB review.

In contrast, sIRB review is undertaken by unrelated institutions without an overarching institutional structure that binds them into a mode of working together. Although they do have a substantial motive for collaborating in that each local institution wishes to participate in the particular study, often for both scientific and financial reasons, there is typically no formal or informal organizational structure to help facilitate this process. Moreover, the various individuals involved in the research may not have had prior personal relationships. As one staff member at a federal sIRB said in an interview with us:

> *There's a different feel, because you don't have those personal relationships with people…because something's gonna get lost in emails and regulations and all kinds of stuff. So not having that is different.* Staff Member 7, government IRB 8

Although the incentive to collaborate exists, and indeed such collaboration is now required by the NIH, how to do so is less clear. While the reviewing sIRB may be thought of as *primus inter pares*, it has limited inherent authority to prescribe the nature of the collaborative relationship. The concrete guidelines for working together are therefore developed through the reliance agreement, *which provides the formal structure for a collaborative relationship and thus is a core feature of sIRB review.*

In this paper we examine the issues involved in developing and implementing reliance agreements, as reflected in our study. Specifically, we consider four issues highlighted for us by our respondents:

- General difficulties in developing reliance agreements
- Challenges in negotiating reliance agreements

[3]Independent IRBs, when reviewing single-site studies, are an exception, because they sit outside of research institutions. However these take place within the well-established structure of contractor and contractee.

- The role of informal networks in sIRB review
- The future of reliance agreements

METHODS

Recruitment of Sites

The data for this paper derives primarily from interviews with individuals involved with review of multi-site research at sIRBs that enrolled in our study. For sIRB sites, we recruited both independent ("commercial") IRBs and IRBs based at federal and academic entities. To identify eligible sIRBs, we relied on lists from the following sources: 1) Association for Accreditation of Human Research Protections Programs website, 2) U.S. Department of Health and Human Services (DHHS) web portal for IRBs, 3) Citizens for Responsible Care and Research, (4) the PRIM&R website, 5) available literature on sIRBs and CIRBs, and, 6) information from other IRBs. Our study inclusion criterion was that the sIRB be registered with the DHHS. We excluded sites that did not currently conduct sIRB reviews, or were based outside of the United States. We initiated contact with each site by emailing a senior administrator an introductory letter describing the study. For academic and government sites, we included a letter from the study Project Officer at NIH encouraging sites to enroll. We followed up by phone and email. Some sites requested more information, which we provided.

In addition, we collected and systematically reviewed 34 publically available reliance agreements that we downloaded from websites.

Recruitment of Interviewees

Our study was designed to gather data from individuals at participating sites with diverse roles in sIRB review. Once a site was enrolled in the study, we sought to interview members, staff, and chairs who had experience with the sIRB process. Some sites provided us with contact information for all eligible individuals. Other sites requested that we send a recruitment packet to be distributed to their staff and members. Still other sites identified people whom the senior administrator thought had would be knowledgeable informants about sIRBs. The limitations of the population we interviewed are thus difficult to determine. However, this is not a representative sample of any population and we have not used our data as a representative sample.

Interview Protocols

The semi-structured interview was informed by prior IRB interview research (Lidz et al. 2012) and (Klitzman 2012) and modified during pilot interviews with an LIRB chair and a staff member. The interview broadly examined: 1) sIRB processes, 2) possible changes to federal IRB policies (i.e., NIH and Common Rule proposed and subsequently adopted regulations), 3) conflicts of interest, 4) relationships with local institutions, researchers, and funders, 5) differences between single/central and local IRB reviews, and 6) organizational issues relating to sIRB operations. Slight modifications of the semi-structured interview were made to reflect the roles of the interviewees. The interview guide is available upon

request from the corresponding author. All interviewees were asked to provide basic demographic information (see Table 1).

Procedures

With consenting individuals, we undertook, by phone or in person, an hour-long, semi-structured, audio-recorded interview. The interviewers generally allowed the interviewee to direct the interview, but in all cases attempted to gather the participants' thoughts about: conducting sIRB reviews, the benefits and limitations of the sIRB process, establishment of sIRB procedures, and interactions with LIRBs. The interviews were conducted by two of the co-authors, a licensed clinical psychologist (EP) and a board-certified psychiatrist (RLK). The participants were offered a $20 gift card or cash; however, many declined to accept payment.

Coding and Data Analysis

Interviews were transcribed and identifying information (e.g., site, geographic location, names) was redacted. A detailed codebook was developed, based on a prior study of LIRBs (Candilis et al. 2012; Lidz et al. 2012), and modified with pilot and initial interviews for this study. The coders, all master's level research staff, received training from the PI (CWL), co-I (EP), and project director. The final version was used to establish interrater reliability. Cohen's Kappa reliabilities ranged from .71 to .85 on different interviews, ranging from acceptable to excellent. For this analysis all text coded for reliance agreements was reviewed.

RESULTS

Interviewees

We contacted 49 sIRBs, 30 independent and 19 academic and government sites and enrolled 7 independent sites (23.3% enrollment rate) and 13 academic and government sites (68.4% enrollment rate). The government sites represented 4 different departments of the federal government. One independent site initially agreed to participate, but withdrew after one interview was conducted, without providing an explanation. In total, we interviewed 103 participants from 20 sIRBs. Two participants had their interviews withdrawn after completing them. For this paper we made use of 76 interviews, 43 of administrators and staff and 17 of chairs, both groups that were directly involved with developing and/or implementing reliance agreements. In addition, we reviewed interviews with 16 IRB members who served as reviewers of protocols and who made at least some comments about reliance agreements. Most of these members offered little additional information about reliance agreements. One member who did provide us with considerable information had served as a chair on another IRB.

General difficulties in developing reliance agreements

Developing reliance agreements is a complex process, as our interviewees repeatedly told us. The Clinical Manager of an NIH-supported multi-protocol research network told us about the amount of work involved in developing reliance agreements:

> *You know, it's really problematic to me, and… it just breaks my heart to see these people [research staff] … having to do twice as much work. And, we're… promoting the fact that [a] central IRB is much more efficient to them. It doesn't feel that way at all.* Director, Academic IRB 4

Staff and members of the participating IRBs expressed concerns about the difficulty and inefficiency involved in establishing reliance agreements. The following describes the experience of a director of a Human Research Protection Program (HRPP) that, among other things, served as the sIRB for a NIH-supported, multi-protocol research network:

> We actually had done a little bit of work on a very simple protocol that involved specimens and data review, and we tracked how long it took, using us as the central versus if an institution just reviewed it on its own…and because of some of the infrastructure issues that people did, and things had to go to lawyers, and be reviewed, and all this other stuff… it took much quicker if an institution just reviewed it on its own. […][A]nd I will tell you the biggest issue was the reliance agreement. Director 1, Academic IRB 2

A member of a government sIRB told us about the amount of work involved in developing reliance agreements for her site:

> Interviewer*: But the reliance agreements that you do have at universities and other groups, how was it to establish those?*
>
> Interviewee: *It takes a while. (laughter)… I mean I think that's the bottom line. It, it's not just you know, here, here's the fillable PDF, you know, fill it out and send it back to us, and now we'll have the agreement... I think, I think the biggest part is that, you know, some of the, the non-SITE 5 IRBs just didn't understand kind of the SITE 5 unique requirements and knowledge of our rules.* Member 6, Government IRB 5

Or consider the experience of the chair of the Reviewing IRB for a NIH supported multi-protocol research network:

> *We…drafted a reliance agreement and sent that out to a select few of our regional coordinating centers to look at it, got that back, revised it based on those comments and then sent it out to just the…regional coordinating centers and we got some of them back within a week and then one of them took six months to sign…it still takes long negotiating with people. We…set up calls with them and…talk to them and answer their questions and...some places want us to provide memos clarifying different parts of their reliance agreement*. Chair, Academic IRB 4

In the course of this study, our research team also reviewed 34 reliance agreements, and noted that they can differ in many ways even when the area of research and type of study is similar. Reliance agreements from two sIRBs that are in many ways similarly situated as part of large research institution consortia: NeuroNEXT and Strokenet[4] will demonstrate the diversity of reliance agreements and the difficulties involved in reconciling them. Both

[4]The information for this comparison is based on data drawn from their respective websites, not from our study. Consistent with our confidentiality policy, we are not identifying whether either sIRB participated in our study.

consortia were created to support multi-site neurology trials funded by NINDS at sophisticated institutions. Both have dedicated funding from NINDS to create and manage the sIRB. Despite many commonalities between these two sIRBs, the specifics of how these reliance agreements are documented and implemented differ. These differences illustrate how similar sIRBs might have markedly diferent reliance agreements. We are not concerned here with whether one approach or another is more effective or user-friendly in reviewing multisite studies. NeuroNEXT has a long and detailed reliance agreement. Strokenet's agreement relies heavily on appendices and SOPs. More importantly, perhaps, responsibilities are allocated differently in the agreements. For example:

- NeuroNext specifies that the relying site is responsible for HIPAA compliance. Strokenet provides a model to address HIPAA issues that, with the approval of Strokenet, the relying site can change.
- NeuroNext specifies that once a site cedes review to the sIRB, the change is permanent. Strokenet does not.
- Although both sIRBs view conflict of interest as primarily the relying site's responsibility, NeuroNext reserves the right to impose more mitigation requirements on the researcher. Strokenet does not.

The fact that these two sIRBs that are in many ways so similar in their funding and clinical focus have significantly different reliance agreements suggests that leaving the nature of the reliance agreement to each group yields variability that may not be substantively important, but simply reflects differences that arise when any two groups attempt to address similar problems.

Use of sIRBs could still reduce the overall time and effort required to begin the research, because investigators do not have to submit protocols to multiple IRBs and deal with what may be conflicting requests for changes. Whether there is a net savings in time and effort is a question that could usefully be explored in subsequent research.

Challenges in Negotiating Reliance Agreements

A major reason for the difficulties in negotiating reliance agreements is that IRBs play a variety of roles relating to human subjects in their organizations. Simply put, although the responsibilities that federal regulations mandate for IRBs are specific and limited, research institutions often give IRBs additional responsibilities to ensure that other protections relating to human subjects research are in place for a given project. As the chair of an independent IRB put it:

> *There are all sorts of internal committees. There are all sorts of institutional requirements: funding, conflict of interest, billing plans, Medicare coverage analysis, radiation safety, and these other committees and the IRB ends up being the one who gives the final stamp and the green light.* Director, Independent IRB 4

There are a variety of different aspects of IRB review that are managed differently by different sIRBs, including conflict of interest, the qualification of investigators, HIPAA compliance, and quality assurance. The director of an IRB serving as the Reviewing IRB for

a NIH-supported network framed the problem in terms of sIRBs assuming responsibility for different aspects of the overall review for different projects:.

> *We're participating in several central IRB initiatives, and each central IRB takes a little different piece of it so you have to really keep track of what piece you have to follow here…There's just subtle nuances to each agreement that's like, "You're not reviewing for HIPAA on this one, but we are for this one." And then we have to figure out how to make a stand-alone review process just for those pieces… if every HRPP looked the same…then I think you could really work through the differences in interpretation of the regulations and policies. But I think because so many HRPP programs have taken different pieces within their institution that they're responsible for, it's difficult*. Director, Academic IRB 3

Another difficulty with negotiating reliance agreements is that they are legal documents that bind both the Reviewing and Relying IRBs to act in certain ways that could create potential liability for one or the other institution. The legal issues are complicated by the fact that the relying institution may bear the consequences of potential non-compliance with federal rules, even when the review is being handled by a sIRB. Because non-compliance with regulatory requirements may have a profound impact on a research institution, including suspension of federal funding, most institutions are very concerned about such agreements. Likewise, the reliance agreement can affect which institution is responsible for personal injuries to research participants for negligent IRB review, and thus may impose financial and reputational costs on an institution.

The result is that institutions, with few exceptions, want a legal review of any reliance agreement that they are asked to sign. The IRB professionals and members whom we interviewed repeatedly cited "the lawyers" as a major hurdle to rapid reliance agreement approval. The problems took multiple forms. One was simply that legal review was time-consuming. However, more importantly, the legal review often raised concerns about one or another specific provisions in the reliance agreement (e.g., personal injuries, insurance coverage). This often led to a situation in which the Relying IRB wanted to protect its specific interests contractually, while the Reviewing IRB wanted as much standardization as possible, so as to minimize the administrative complexity of dealing differently with each site.

A final problem is that every study may involve somewhat different issues that need to be covered in the reliance agreement, depending on the division of responsibilities between the sIRB and the Relying IRBs. A university IRB member stated:

> *I definitely feel like each time we encounter a new protocol we're, we're trying to figure out how the process works.* Member, Academic IRB 7

What the relevant issues are, and consequently what needs to be overseen and by whom, can differ from study to study. A study that involves interviewing subjects about health behaviors in different languages across 6 countries raises a different set of issues than a study of implanted devices in 20 U.S. hospitals. The content of the reliance agreement will often need to vary because special issues require different responsibilities on the part of the

reviewing and relying IRBs. For example, not every site has the same role in a study. Thus, a IRB specialist at a pediatric hospital reported:

> *The process would start out by determining how that other institution is engaged… Sometimes you'll get institutions [that] are just involved in particular components of the protocol, other times you'll get where all sites are doing everything from A to Z in the protocol. And then after figuring out how they're engaged, making that determination whether we'd be comfortable with, with providing oversight for that engagement.* Staff Member, Academic IRB 2

These difficulties reflect, in part, the fact that the sIRB process, unlike the LIRB process, is not embedded in a single formal organization with a shared set of institutional policies and procedures that cover all aspects of the IRB review. The reliance agreement provides something of a replacement for the institutional controls but the lack of a standard structure for reliance agreements makes their development difficult.

The Role of Informal Networks

Informal networks that evolve within organizations often facilitate the accomplishment of organizational goals. Something like this was described by one of our interviewees, a HRPP director at an academic institution, who related the development of a central IRB that initially included a variety of universities and research hospitals within the state and later expanded to other regional research institutions.

> *And they're geographically not far away, which is important. We've always thought that the homeground aspect of our networks is key. So we got together. We had one-day and two-day meetings at each other's institutions and got face-to-face...We'd all get in a room. We talk about the degree to which we had successful models that we'd like to promote...So that's the fundamental…can we learn enough about each other's operation by being face-to-face, by being not so geographically far that we don't have information about you?* Director, Academic IRB 7

A number of our interviewees, especially those who had long-standing relationships with other institutions, emphasized the importance of *trust*. The relationships described above closely mimic the informal networks that are critical in a well-functioning organization. Unfortunately, as effective as such local or regional networks are, they cannot easily solve the problem of large national or international studies where sites must rely on sIRBs—and vice versa—with whom they have little or no personal connection and have not had the opportunity to build inter-institutional trust. The absence of that trust results in more concerns about every aspect of the relationship and consequently more detailed and debated wording of the reliance agreements.

Although such informal networks may not be easily developed, it is not impossible that they might play a role in facilitating efficiency in sIRB reviews. The coordinating centers in some large federally funded networks might play a role in developing trust among IRBs in such networks. Many of our interviewees referred to other IRB professionals whom they respected and had met at PRIM&R and other professional meetings. It is possible that such relationships could develop into extensive networks in which even IRB professionals who

did not know each other personally might be able to trust a mutually respected acquaintance, much as informal networks work within organizations. However, such networks are quite limited at present and will probably always play a limited role. In addition, trust does not eliminate the need to establish clearly the division of functions in a study. It may facilitate negotiation, but it does not eliminate the underlying issues.

What Is the Future of Reliance Agreements?

Our interviewees differed in their views on the prospects for resolving the obstacles faced by sIRBs, including negotiation of reliance agreements. Some were relatively optimistic that as IRB members and staff became more familiar with the process, some of the current obstacles would fade away. One IRB director who has done a considerable amount of sIRB work noted that initially every reliance agreement had to be approved by university counsel but:

> I'm familiar enough now that [the hospital's] general counsel said to me 'Look [Director], you can look this over and as long as it looks like these things, you don't have to send it to us.' Director, Academic IRB 2

However, many of our interviewees also identified more entrenched problems that would not be easily resolved. As recounted by the business manager of an independent IRB:

> *The limitation of the NIH's proposal is that it focuses on the IRB as sort of a rate-limiting step, but it's not the only piece of the puzzle. So I think that it addresses one piece of the puzzle, but a lot of what academic medical centers doing NIH-sponsored research deal with are regulatory requirements and all sorts of different institutional concerns that are integrated with the IRB review. Those are not accounted for in the policy, or at least there's not any guidance on, on those pieces.* Director, Independent IRB 4

Others, such as the assistant director of an IRB at a large university, identified specific actions by NIH to ease the transition to sIRBs:

> *I think … the most beneficial thing that NIH or OHRP can do is to release a template reliance agreement… and some standards for what should be included in central IRB review and what should not… and therefore that will take away a lot of the discussions that happened… around setting up these agreements.* Director, Academic IRB 7

Discussion and Conclusion

Although the formal task of conducting the ethical review of human subjects research studies is substantially similar for both LIRBs and sIRBs, the difference in the organizational structures in which LIRB and sIRB reviews take place has real consequences. sIRBs suffer from the absence of the formal structures of a single organization as well as the limited availability of informal organizational networks. Although some multi-site structures such as clinical trial coordinating centers provide some informal networks, most organizations that participate in multi-site studies using sIRB review need to develop substitute rules through formal reliance agreements.

We have seen that the development of reliance agreements is often problematic. This difficulty might suggest the need for a standardized reliance agreement that will not require renegotiation with each study. The DHHS Office of Human Research Protections (“OHRP”) and the National Center for Advancing Translational Sciences (“NCATS”) in its Streamlined, Multisite, Accelerated Reserouces for Trials IRB Platform (“SMART IRB”) have both presented models. The OHRP reliance agreement has the virtue of simplicity since it consists of barely one page and recent data suggest that it is widely used (Resnick et al. 2018). However it does not provide guidance as to the relationship between the Relying and Reviewing IRBs concerning the issues we have described. Use of the SMART IRB has also substantially increased since our data collection. Its reliance model addresses more of the operational issues that are present in conducting a study, but it leaves many of the issues to be settled by standard operating procedures (SOPs). Although this SMART IRB approach seems promising and may be a major step toward a solution, the findings of Resnick et al. (2018) suggest that it is likely to be used in combination with other approaches. Without some sort of a national standard, the goal of accelerating approval of research may not be met. What is clear at this point is that simply specifying that an sIRB must provide the federally required ethics review for multi-site trials, although an important step, will not by itself resolve the inefficiencies of regulatory review of multi-site trials. It may be, as some of our interviewees suggested, that as the use of sIRBs becomes more routine, some of these difficulties will be resolved. However, differences in the ways in which IRBs deal with other aspects of HRPPs makes standardization difficult. SMART IRB has made a useful, but so far partial, start.

The results of our study have several critical implications for future research policy. OHRP, the Secretary’s Advisory Committee on Human Research Protections (SACHRP), PRIM&R, or other entities could develop guidance in several areas, and explore whether some parts of reliance agreements could be standardized. These organizations may be able to facilitate discussion that will make the process simpler. In addition, these organizations could address how other regulatory issues that IRBs often coordinate, such as conflict of interest, privacy matters, and compliance should be handled.

The present study also highlights the need for further research in this area. Such investigations could examine what kinds of provisions are included in reliance agreements, how long these agreements take to negotiate and finalize, whether the time taken to develop reliance is greater or less than review by multiple LIRBs, what factors may be involved in either shortening or lengthening these processes, which processes may be able to be standardized, whether sIRBs differ systematically in how they negotiate reliance agreements, how institutions divide responsibilities concerning oversight of the conduct of a study, and whether institutions alter their approaches to reliance agreements over time as they become more experienced and familiar with the process.

This study has several limitations. The resistence of the large commercial IRBs to being studied limited our ability to compare them to academic and governmental sIRBs. There is some reason to believe that their use of reliance agreements differs from sIRBs with less experience with their use. Moreover, although we interviewed IRB personnel about their experiences regarding reliance agreements, we did not systematically examine reliance

agreements themselves. Future research can be designed to examine these documents. In addition, we captured participants' views at a particular point in time, prior to the implementation of the NIH sIRB policy. Their views may evolve as all participants gain more experience with this process.

However, the present data highlight certain potential obstacles concerning reliance agreements with sIRBs that, unless overcome, may negatively impact future research policy and practice.

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Table 1.

Demographic Background

Age[a]**,y**	**N=103 n(%)**
20 − 39	20 (19.4)
40 – 49	21 (20.4)
50 – 59	25 (24.3)
60 +	29 (28.2)
Gender	
Female	65 (63.1)
Male	38 (36.9)
Race[b]	
Black	5 (4.9)
White	91 (88.3)
Latino(a)	3 (2.9)
Role	
Chair	20 (19.4)
Director	27 (26.2)
Member	30 (29.1)
Staff	26 (25.2)
Educational Background[c]	
< and Bachelor's	31 (30.1)
MA/MS	28 (27.2)
JD	4 (3.9)
MD/DO	24 (23.3)
Phd/PsyD	11 (10.7)
PharmD	4 (3.9)
IRB Experience[d]**, y**	
< 1	3 (2.9)
1 – 4	22 (21.4)
5 – 9	23 (22.3)
10 – 19	29 (28.1)
20 +	16 (15.5)

Note: Missing participant data for

[a] = 8

[b] = 3

[c] =1

[d] = 10