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How U.S. Research Institutions are Responding to the Single Institutional Review Board Mandate

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Abstract

One of the most significant changes to the Common Rule is the requirement that institutions use a single institutional review board (IRB) for cooperative research in the U.S., unless more than one IRB is required by state, local or tribal law, or a signatory federal agency decides an exception is warranted. We surveyed human research protection program (HRPP) officials at the top U.S. research institutions to understand their knowledge and opinion of the mandate, what steps their institutions are taking, and difficulties their institutions are facing. 107 institutions (56.9%) responded to the survey. While support for the single-IRB mandate was positive overall, most respondents acknowledged that their institution is likely to face some difficulties complying with it. Regulatory agencies can help institutions to comply with the mandate by providing guidance concerning such issues as exceptions to the mandate, local context review, oversight and implementation of reliance agreements, and development of policies, procedures, and best practices.

Keywords

human research regulation; Common Rule; institutional review boards; reliance agreements; legal liability

Introduction

On January 19, 2017, the Obama Administration announced much-anticipated revisions to the Common Rule, a regulation for research involving human subjects adopted by 16 federal agencies (Department of Homeland Security et al. 2017). The Trump Administration has delayed implementation of these revisions until January 21, 2019 (Department of Homeland Security et al. 2018) One of the most significant changes to the Common Rule is the

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requirement that institutions use a single institutional review board (IRB) for cooperative research in the U.S., unless more than one IRB is required by state, local or tribal law, or a signatory federal agency decides an exception is warranted. The single IRB mandate provision does not become effective until January 20, 2020 (Department of Homeland Security et al 2017) The National Institutes of Health (NIH) has adopted a similar policy for research funded by the agency, which became effective on January 25, 2018 (National Institutes of Health 2016)

The primary rationale behind the single IRB mandate is to eliminate redundant review, maintain consistency across different research sites, reduce administrative burdens on investigators and IRBs, and save time and money (Wolinetz and Collins 2017, Silberman and Kahn 2011). Some have also suggested that relying on a single IRB in cooperative research may improve the quality and consistency of review (Wolinetz 2017). Although many investigators, IRBs, and government officials have showed strong support for the single IRB mandate, some have expressed concerns about this new requirement and its implementation (Klitzman et al. 2017). Chief among these are potential difficulties with negotiating contracts (known as reliance agreements or authorizations) to allow one institution to rely on another for IRB review; taking local context issues (such as culture, language, or community values) into account during review; adequate guidance from federal agencies concerning compliance with the mandate; and financial support for implementing the mandate (Wisconsin Consortium 2011, Resnik 2012, Association for American Medical Colleges 2017, Klitzman et al. 2017)

The single IRB mandate is potentially the most disruptive change to the Common Rule because it requires institutions to develop policies and procedures for negotiating and implementing reliance agreements, delineating institutional responsibilities, and ensuring that review of cooperative research addresses local context issues. Institutions may need to devote staff time and other resources to deal with reliance agreements and ensure compliance with the regulations. To facilitate reliance agreements, many institutions are using common templates, such as a document developed by the Office of Human Research Protections and one used by institutions that belong to the SMART IRB (Streamlined, Multisite, Accelerated Resources for Trials IRB) consortium (Resnik et al. 2018, Office of Human Research Protections 2011, SMART IRB 2018).

The purpose of this study was to survey human research protection program (HRPP) officials at the top U.S. research institutions to understand their knowledge and opinion of the mandate, what steps their institutions are taking, and difficulties their institutions are facing. A secondary goal was to determine whether institutional characteristics, such as the number of human studies reviewed per year, are associated with types of survey responses. Information obtained from this survey may prove useful to investigators, IRBs, HRPP officials, and federal agencies when making decisions concerning compliance with the mandate and best practices for single-IRB review.

Materials and Methods

We obtained a list of the top 200 U.S. research institutions ranked by total research funding from the Center for Measuring University Performance (2014) for the most recent available year, 2014. We eliminated 4 institutions from the list because they were duplicates; 4 because their human research oversight was covered by another (parent) institution; and 4 because they do not conduct research with human subjects. This left us with 188 institutions to contact. We sent an email to HRPP officials at these institutions (e.g. IRB managers, IRB chairs, or IRB office staff charged with overseeing reliance agreements) inviting them to participate in an anonymous online survey. The email included text needed to obtain informed consent (e.g. description of the study, benefits, risks, voluntary nature of participation, etc.) and included a link to the survey. The survey consisted of 13 closed-ended and open-ended questions (see Supplementary Material). We sent two reminder emails. For data analysis, we presented descriptive statistics by count and percentage. We used Spearman's correlation test and Fisher's exact test to assess the association between responses to survey questions and institutional characteristics. The NIH Office for Human Subjects Research Protections determined that our study qualified as exempt research.

107 institutions (56.9%) responded to the survey, which is much higher than the typical response rate of 33% for online surveys (Nulty 2008). An overwhelming majority (96.3%) of the respondents were universities, medical schools or academic medical centers. 73.8% were public, and 67% review 200 or more human research protocols each year. See Table 1.

The majority of respondents (67.1%) rated their knowledge of the single IRB mandate as excellent or very good. Approval of the mandate was mixed, however. Slightly more respondents (38.6%) strongly approve or approve of the mandate than those who strongly disapprove or disapprove of it (34%), and 27.4% neither approve nor disapprove of it. Most respondents agreed that the mandate is likely to have some benefits, including reducing redundant IRB review (80.1%), encouraging cooperative research (46.2%), saving money or resources (27.9%), and enhancing the quality or consistency of IRB review (22.1%). Respondents also recognized, however, that the mandate could create some difficulties, including problems with negotiating reliance agreements (71.2%); reviewing the local research context (68.2%), legal liability (68.2%); securing adequate resources to comply with the mandate (65.4%); educating or training investigators, IRB members, or IRB support staff 69 (64.5%); implementing reliance agreements (63.6%); and developing policies or standard operating procedures (46.7%). See Table 2.

Although the quantitative data indicate that most respondents approve of the mandate, some of the comments we received expressed strong disapproval for it or stated that their institution is likely to have serious problems complying with it. In the responses to the open-ended questions 25 addressed concerns related to addressing the local context when a single IRB reviews research, 14 mentioned problems with securing adequate resources (such as HRPP staff) needed to negotiate and implement reliance agreements, and 9 suggested that institutions may outsource human subjects review to commercial IRBs in some cases to comply with the mandate. (Text of comments available upon request.)

Respondents said their institutions were taking various steps to comply with the mandate, including developing policies or standard operating procedures (81.2%); educating or training investigators, IRB members, or staff (77.1%); negotiating reliance agreements with other institutions (60.0%); developing or acquiring reliance agreement templates (58.1%); and allocating resources to comply with mandate (43.8%). 11 respondents who responded “other” to the question related to complying with the mandate indicated that their institution was joining the SMART IRB consortium.

35.5% of respondents said they expected their institution to have no difficulty or minimal difficulty complying with the mandate; 29.9% said they expected their institution to have more than minimal but not significant difficulty complying; and 34.6% said they expected their institution to have significant or serious difficulty complying. 46.7% of respondents said that their institution has faced difficulties with negotiating or implementing reliance agreements in the past five years, but only 13.3% said they had decided not to engage in cooperative research because of such problems.

Respondents from larger institutions tended to have a better knowledge of the mandate (correlation coefficient, $r = 0.19$; $p\text{-value} = 0.053$) but also a less favorable opinion of the mandate ($r = -0.18$, $p\text{-value} = 0.074$) than those from smaller ones. Respondents from larger institutions were also more likely to have had difficulties with negotiating reliance agreements ($r = 0.21$; $p\text{-value} = 0.035$). Respondents from medical schools, academic medical centers and institutions in the “other” category tended to have better knowledge of the single IRB mandate compared to colleges or universities (Fisher’s exact test $p=0.016$). Respondents from private institutions were more likely to decide not to engage in cooperative research due to problems with reliance agreements ($r = -0.21$, $p=0.034$). (See Tables 3–7).

Discussion

While support for the single-IRB mandate was positive overall, most respondents acknowledged that their institution is likely to face some difficulties complying with it, such as those related to reviewing the local context, dealing with legal liability issues, securing resources, education/training, and negotiating or implementing reliance agreements. Respondents from larger institutions tended to have a less favorable opinion of the mandate than those from smaller ones, perhaps because they anticipate that their institution will have more difficulty related to negotiating or implementing reliance agreements required by the mandate, securing adequate resources for compliance, or being required to be the institution responsible for the IRB review because of its size. Adopting common reliance agreement templates could help minimize problems with negotiating these agreements but not necessarily those related to implementing them, since implementation requires collaborating institutions to share information pertaining to research review and oversight and to meet their respective responsibilities.

It remains to be seen whether the single-IRB mandate will have its intended effect of reducing administrative burdens. Drawing on the quantitative data from this survey as well as the open-ended comments made by participants, it is reasonable to infer that the mandate

may simply shift administrative burdens from the IRB to the HRPP and research staff as they deal with complexities related to reliance agreements, local context, and legal liability. Comments made by some of the survey respondents express these concerns:

Although only one IRB may review, the workload on IRB Administrative staff increases because of the “mandate”. Local administrative view and work to coordinate and negotiate reliance agreement remains, and now can no longer handle each in ways that are most efficient given the context of the project (Respondent 1).

On the few done so far, it is a tremendous amount of work for the IRB office and has been very, very confusing to determine what is covered by whom for the first large cooperative/collaborative research venture which involved databank samples. It was much simpler just to do a one-on-one IIA than undertake this sIRB model (Respondent 2).

I think it is important for institutions to realize that while the IRB Committee workload may decrease when relying on another IRB, the institutional workload most likely will increase. When serving as the Reviewing IRB, the IRB Staff and Expedited Reviewer workloads have the potential to increase significantly (Respondent 3).

Others were very concerned about securing funding for increases in HRPP staff needed to comply with the mandate:

NIH required this without providing the funding to implement it. We need at least 2 staff members to do all this additional work related to reliance agreements, legal reviews, and requests to rely, yet no funding is available. People expect a quick turnaround but the administrative reviews for other IRBs still take time. And the ability to charge for the reviews is quite complex (Respondent 4).

[We are] creating new budget models to assist PIs with ascertaining costs associated with the use of external (commercial) IRBs in the event that our institution does not choose to be IRB of Record. We are not only “allocating resources,” we needed to seek new funding to cover the new work within the IRB office (Respondent 5).

Reliance agreements can take a significant amount of time to negotiate (including educating PIs about their responsibilities, etc.) and we don’t have the staff/resources to deal with these agreements on a large scale (Respondent 6).

Some respondents speculated that the increased costs associated with mandate will lead institutions to outsource IRB review to private companies:

Ethical reviews may be outsourced to commercial IRBs because of fear of liability or lack of institutional resources (Respondent 7).

Counter-intuitively, I’ve had investigators design research to NOT be cooperative because they don’t want to deal with sIRB, especially since my IRB is outsourcing the sIRB review to a commercial IRB, so investigators don’t want to have to learn the ins and outs of a whole new IRB (Respondent 8).

[We] have spent a lot of time and energy determining how to track sIRB protocols since we are relying on a commercial IRB to conduct all of our sIRB reviews and we don't have great communication among the IRB, grants and contracts, and investigators (Respondent 9).

A potential limitation of our study is that our sample was small (107 responding institutions) and focused on the top 200 U.S. research institutions. Such institutions may have more resources which may influence perceptions regarding the inclusion of single IRBs. However, the strength of this survey lies in the specializations of the individuals that were included (i.e. HRPP officials) who are likely to have excellent or very good knowledge of the mandate and the steps their institutions are taking to comply with it.

Another potential limitation is our survey addressed general concerns with the single IRB mandate and did not include detailed questions concerning institutions' specific experiences with collaborative research involving review by a single IRB. While it would be useful to obtain this information, we chose not to solicit it in order to keep our survey short enough to promote a high response rate. Follow up studies related to specific experiences with single IRB review could help to provide data that would be useful to policymakers. Since the recent modifications to Common Rule implies the broad use of single IRBs in cooperative research, this area of study will become timely and necessary in order to understand benefits and challenges of this new model.

In conclusion, our survey indicates that the single-IRB mandate is likely to have both positive and negative impacts on ethical and legal oversight of research with human subjects. Regulatory agencies, such as OHRP and NIH, can help institutions to comply with the mandate by providing guidance concerning such issues as exceptions to the mandate, local context review, oversight and implementation of reliance agreements, and development of policies, procedures, and best practices. It remains to be seen whether the single IRB mandate will reduce administrative burdens without compromising protection of human subjects. Fortunately, the mandate does not become effective until early in 2020. Between now and then there is still much work to do.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1:**Characteristics of Responding Institutions (107)**

<u>Type of Institution</u>	
University	69 (64.5%)
Medical School or Academic Medical Center	34 (31.8%)
College	1 (0.9%)
Other	3 (2.85%)
<u>Public vs. Private</u>	
Public	79 (73.8%)
Private	28 (26.2%)
<u>Number of New Human Studies Reviewed per Year</u>	
1-50	6 (5.7%)
51-100	4 (3.8%)
101-150	8 (7.6%)
151-200	17 (16.0%)
More than 200	71 (67.0%)

Table 2:

Answers to Closed-Ended Survey Questions

Question	Responses	
1. What is your knowledge of the single IRB mandate, including knowledge of requirements, exceptions, and effective date?	Excellent	35 (33.0%)
	Very Good	36 (34.1%)
	Good	27 (25.5%)
	Fair	8 (7.6%)
	Poor	0 (0.0%)
	Total responses	106
2. What is your opinion of the mandate for a single IRB for cooperative research found in the revised Common Rule and NIH policy?	Strongly approve	7 (6.6%)
	Approve	34 (32.0%)
	Neither approve nor disapprove	29 (27.4%)
	Disapprove	28 (26.4%)
	Strongly disapprove	8 (7.6%)
	Total responses	106
3. What are some of the benefits of the mandate? Check all that apply.	Reduces redundant IRB review	84 (80.1%)
	Encourages cooperative research	48 (46.2%)
	Saves money or resources	29 (27.9%)
	Enhances quality or consistency of IRB review	23 (22.1%)
	Other (please describe)	17 (16.4%)
	Total responses	104
4. What are some of potential problems with the mandate? Check all that apply.	Negotiating reliance agreements	77 (71.2%)
	IRB review of the local research context	73 (68.2%)
	Legal liability	73 (68.2%)
	Problems with securing adequate resources to comply with the mandate	70 (65.4%)
	Problems with educating or training investigators, IRB members, or IRB support staff	69 (64.5%)
	Problems with implementing reliance agreements	68 (63.6%)
	Problems with developing policies or standard operating procedures	50 (46.7%)
	Other (please describe)	24 (22.4%)
	Total responses	107
5. What steps, if any, is your institution taking to comply with the single IRB mandate? Check all that apply.	Developing policies or standard operating procedures	86 (81.2%)
	Educating or training investigators, IRB members, or staff	81 (77.1%)
	Negotiating reliance agreements with other institutions	63 (60.0%)
	Developing or acquiring reliance agreement templates	61 (58.1%)

Question	Responses	
	Allocating resources to comply with the single IRB mandate	46 (43.8%)
	Other (please describe)	27 (25.7%)
	Total responses	105
6. What level of difficulty do you expect your institution will have with complying with the single IRB mandate?	No difficulty	6 (5.6%)
	Minimal difficulty	32 (29.9%)
	More than minimal not significant difficulty	32 (29.9%)
	Significant but not serious difficulty	31 (29.0%)
	Serious difficulty	6 (5.6%)
	Total responses	107
7. To the best of your knowledge, has your institution faced any problems with negotiating or implementing reliance agreements in the past five years?	Yes	50 (46.7%)
	No	57 (53.3%)
	Total responses	107
8. To the best of your knowledge, has your institution ever decided not to engage in cooperative research in the past five years due to problems with reliance agreements?	Yes	14 (13.3%)
	No	91 (86.7%)
	Total responses	105

Table 3.

Cross table of Q1 and Number of Human Studies Reviewed per Year

	50 or less	51-100	101-150	151-200	More than 200	Row Total
Fair	0(0)	1(0.25)	2(0.25)	1(0.06)	4(0.06)	8
Good	4(0.67)	0(0)	3(0.38)	3(0.18)	17(0.24)	27
Very good	2(0.33)	0(0)	2(0.25)	10(0.59)	22(0.31)	36
Excellent	0(0)	3(0.75)	1(0.12)	3(0.18)	27(0.39)	34
Column Total	6	4	8	17	70	105

Spearman's $r=0.19$ $p=0.053$; Fisher's exact test $p=0.02$

Table 4.

Cross table of Q2 and Number of Human Studies Reviewed per Year

	50 or less	51-100	101-150	151-200	More than 200	Row Total
Strongly Disapprove	0(0)	0(0)	0(0)	1(0.06)	7(0.1)	8
Disapprove	0(0)	0(0)	2(0.25)	5(0.29)	20(0.29)	27
Neither approve nor disapprove	5(0.83)	1(0.25)	1(0.12)	3(0.18)	19(0.27)	29
Approve	1(0.17)	1(0.25)	5(0.62)	8(0.47)	19(0.27)	34
Strongly approve	0(0)	2(0.5)	0(0)	0(0)	5(0.07)	7
Column Total	6	4	8	17	70	105

Spearman's $r = -0.18$, $p = 0.074$; Fisher's exact test $p = 0.12$

Table 5.

Cross table of Q7 and Number of Human Studies Reviewed per Year

	50 or less	51-100	101-150	151-200	More than 200	Row Total
No	4(0.67)	2(0.5)	7(0.88)	11(0.65)	33(0.46)	57
Yes	2(0.33)	2(0.5)	1(0.12)	6(0.35)	38(0.54)	49
Column Total	6	4	8	17	71	106

Spearman's $r=0.21$, $p=0.035$; Fisher's exact test $p=0.16$

Table 6.

Cross table of Q1 and Type of Institution

	College	University	Medical school or academic medical center	Other (please describe)	Row Total
Fair	0(0)	7(0.1)	1(0.03)	0(0)	8
Good	0(0)	22(0.32)	4(0.12)	1(0.33)	27
Very good	1(1)	24(0.35)	11(0.32)	0(0)	36
Excellent	0(0)	15(0.22)	18(0.53)	2(0.67)	35
Column Total	1	68	34	3	106

Fisher's exact test p=0.016

Table 7.

Cross table of Q8 and Public vs. Private Status

	Private	Public	Row Total
No	21(0.75)	70(0.91)	91
Yes	7(0.25)	7(0.09)	14
Column Total	28	77	105

Spearman's $r = -0.21$ $p = 0.034$; Fisher's exact test $p = 0.05$