HHS Public Access

Author manuscript

Am J Obstet Gynecol MFM. Author manuscript; available in PMC 2024 June 01.

Published in final edited form as:

Am J Obstet Gynecol MFM. 2023 June ; 5(6): 100861. doi:10.1016/j.ajogmf.2023.100861.

Outcomes of Shared IRB Compared with Multiple Individual Site IRB Models in a Multisite Clinical Trial

Samantha L. Martin, PhD[1,*], **Phillip H. Allman, PhD**[2], **Lorraine Dugoff, MD**[3], **Baha Sibai, MD**[4], **Stephanie Lynch, RN BSN CCRC**[5], **Jennifer Ferrara, RN BSN CRNC**[6], **Kjersti Aagaard, MD PhD**[7], **Christina Zornes, MHR**[8], **Jennifer L. Wilson, MSN RNC-OB**[9], **Marie Gibson, CCRP**[10], **Molly Adams, BSC**[11], **Sherri A. Longo, MD**[12], **Amy Staples, MSN RN**[13], **George Saade, MD**[14], **Imene Beche, MBS CCRP**[15], **Ebony B Carter, MD MPH**[16], **Michelle Y. Owens, MD MS**[17], **Hyagriv Simhan, MD**[18], **Heather A. Frey, MD MSCI**[19], **Shama Khan, MPH MS CGC**[20], **Anna Palatnik, MD**[21], **Phyllis August, MD MPH**[22], **Les'Shon Irby, MPH CCRP**[23], **Tiffany Lee, MPH MS**[24], **Christine Lee, BSN RN**[25], **Paula Schum, MSN, RN, BS**[26], **Rosalyn Chan-Akeley**[27], **Catera Duhon, BSN, RN**[28], **Monica Rincon, MD, MCR**[29], **Kelly Gibson, MD**[30], **Samantha Wiegand, MD**[31], **Donna Eastham, BA**[32], **Suzanne Oparil, MD**[33], **Jeff M. Szychowski, PhD**[1,2], **Alan Tita**[1,34],

Chronic Hypertension and Pregnancy (CHAP) Consortium

[1]Center for Women's Reproductive Health, University of Alabama at Birmingham, Birmingham AL

[2]Department of Biostatics, University of Alabama at Birmingham, Birmingham AL

[3]Department of Obstetrics and Gynecology, University of Pennsylvania, Philadelphia PA

[4]Department of Maternal Fetal Medicine, University of Texas Health Center at Houston, Houston TX

[5]Department of Obstetrics and Gynecology, Columbia University, New York City NY

[6]Department of Obstetrics and Gynecology, Duke University, Raleigh NC

[7]Department of Obstetrics and Gynecology, Baylor College of Medicine and Texas Children's Hospital, Houston, TX

[8]Department of Obstetrics and Gynecology, University of Oklahoma College of Medicine, Oklahoma City, Oklahoma

[*]Address correspondence to: Samantha L. Martin, 1720 2nd Ave South, Birmingham AL, 35294-3360; Tel: 205-975-8873; Fax: 234-7050; jcvessel@uab.edu.

Conflict of Interest

The authors report no conflict of interest.

Condensation: Compared to use of multiple site IRBs, the single shared IRB may be more efficient for multicenter studies.

[9]Department of Obstetrics and Gynecology, Indiana University School of Medicine, Indianapolis IN

[10]Department of Obstetrics and Gynecology, University of Utah, Salt Lake City Utah

[11]Intermountain Healthcare, Salt Lake City Utah

[12]Department of Obstetrics and Gynecology, Ochsner Health, New Orleans LA

[13]Christiana Care Center for Women's & Children's Health Research, Newark DE

[14]Department of Obstetrics and Gynecology University of Texas Medical Branch, Galveston TX

[15]Department of Obstetrics and Gynecology, Saint Peter's University Hospital, New Brunswick NJ

[16]Department of Obstetrics and Gynecology, Washington University School of Medicine, St Louis MO

[17]Department of Obstetrics and Gynecology, University of Mississippi Medical Center, Jackson MS

[18]Department of Obstetrics, Gynecology, and Reproductive Sciences, University of Pittsburg School of Medicine, Pittsburg PA

[19]Department of Obstetrics and Gynecology, The Ohio State University College of Medicine, Columbus OH

[20]Department of Obstetrics, Gynecology, and Reproductive Sciences, Rutgers Robert Wood Johnson Medical School, Brunswick NJ

[21]Department of Obstetrics and Gynecology, Medical College of Wisconsin, Milwaukee, WI

[22]Department of Obstetrics and Gynecology, New York Presbyterian/Weill Cornell Medicine, New York City NY

[23]Department of Obstetrics and Gynecology, Emory University School of Medicine, Atlanta GA

[24]Department of Obstetrics, Gynecology, and Reproductive Sciences, University of California San Francisco, San Francisco CA

[25]Department of Obstetrics and Gynecology-Maternal Fetal Medicine, Stanford University, Stanford CA

[26]National Institute of Health Heart Lung and Blood Institute, Bethesda, MD

[27]Lang Research Center, NewYork-Presbyterian Hospital, Queens, NY

[28]USA Children's and Women's Hospital, Mobile, AL

[29]Department of Obstetrics and Gynecology, Oregon Health and Science University, Portland, OR

[30]Department of Obstetrics and Gynecology, Metro Health Case Western University, Cleveland OH

[31]Miami Valley Hospital, Dayton, OH

[32]Department of Obstetrics and Gynecology, Little Rock, AR

[33]Department of Medicine, University of Alabama at Birmingham, Birmingham

[34]Department of Obstetrics and Gynecology, The University of Alabama, Birmingham AL

Abstract

Background: Institutional review boards play a crucial role in initiating clinical trials. Though many multicenter clinical trials utilize an individual IRB model, where each institution uses their own local IRB, it is unknown if a shared (single IRB) model would reduce the time required to approve a standard IRB protocol.

Objective: The objective of this study was to compare processing times and other processing characteristics between sites using a single IRB and those using their own site IRBs in a multicenter clinical trial.

Study Design: This was a retrospective study of sites in an open-label, multicenter randomized control trial from 2014–2021. Participating sites in the multicenter Chronic Hypertension and Pregnancy (CHAP) trial were asked to complete a survey collecting data describing their IRB approval process.

Results: Forty-five sites participated in the survey (7 used a shared IRB and 38 used their own individual IRBs). Most sites (86%) using the shared IRB model did not require a full board IRB meeting prior to protocol approval, compared to one site (3%) within the individual IRB group ($p < 0.001$). Median total approval times (41 vs. 56 days; $p = 0.42$), numbers of submission rounds (1 vs. 2, p=0.09), and numbers of IRB stipulations (1 vs. 4; p=0.12) were lower for the shared than individual site IRB model, but these differences were not statistically significant.

Conclusion: Our findings support the hypothesis that the shared IRB model for multicenter studies may be more efficient in terms of cumulative time and effort required to obtain approval of an IRB protocol. Given that these data have important implications for multicenter clinical trials, future research should evaluate these findings using larger or multiple multicenter trials.

Keywords

Institutional Review Boards (IRB); Federal Regulations; Multicenter Studies; IRB efficiency; Chronic Hypertension and Pregnancy Study

INTRODUCTION

In 1974, federal regulations mandated institutional review boards (IRB) for research with human participants.[1] For decades, many institutions used the individual IRB model in which each institution reviews research protocols to ensure fair treatment of research participants. However, the need for larger, geographically diverse cohorts has increased, leading to a growth in large multicenter research studies.[2–6] For multicenter research studies, each participating site may delegate the primary responsibilities of reviewing a standard research protocol to one participating institution (shared or individual IRB model). Although the National Institutes of Health (NIH) released a policy to promote the use of a shared IRB model for multicenter research studies in 2016, many multicenter studies continue to utilize multiple individual site IRBs.[7–9] More recently, the NIH mandated that multicenter studies with a grant application submitted after January 25, 2018 or an initial IRB approval after January 20, 2020 must utilize the shared IRB model.[10]

The practice of using multiple individual IRBs for a standard research protocol for multicenter research studies has been criticized for wasting valuable time and resources without demonstrable benefits for human subjects.[11, 12] Further, some studies have reported inconsistencies in the interpretation of federal guidelines across institutions, often leading to disparate decisions being made for the same research protocol.[13] We have previously shown that using the multi-site IRB model for multicenter research studies may lead to delays of greater than 60 days due to stylistic requests, as opposed to substantive regulatory requests.[14] Although the shared IRB model falls in line with initiatives implemented by authorities such as the NIH, the National Center for Advancing Translational Science (NCATS), and the Office of Human Research Protections (OHRP),[15] few studies have objectively demonstrated the expected benefits of utilizing a shared IRB model.

The Chronic Hypertension and Pregnancy (CHAP) trial is a large multicenter research study funded by the National Heart Lung and Blood Institute (NHLBI) in 2014.[16] The overall objective of the CHAP trial is to test the effectiveness and safety of antihypertensives for women with mild chronic hypertension during pregnancy. The current study investigated the IRB models used at CHAP trial sites; some sites opted to utilize their own IRB, while others chose a shared IRB model with one center serving as the centralized IRB hub. Our objective was to test for differences in IRB processing times and other characteristics, including stipulations (i.e., editorial modifications, regulatory requests, verbiage/language modifications, formatting etc.) between site (individual) IRBs and shared IRB models.

METHODS

In the CHAP study (5U01HL12338) pregnant women (N=2404) with mild CHTN (<160/105 mmHg) were randomized to either antihypertensive therapy or usual care (antihypertensive medication only if BP ≥160/105 mmHg) prior to 23 weeks of gestation. Exclusion criteria included multifetal pregnancies, known medical co-morbidities, severe chronic hypertension, and contraindications to the antihypertensive therapy. Study startup was in November 2014, and the sites had the option of using their own IRB or a shared IRB at the leading site (UAB). All sites were encouraged to use the shared IRB model at no additional cost to the university-based institution.

The current study was exempt from IRB review at all participating sites. Sites received a pretested data collection instrument (Appendix A) adapted from a previous publication by our group.[14] Trained research team members at each site were responsible for abstracting the data from their IRB regulatory records and submitting the form to the CHAP data coordinating center. The items on the data form included the time from the initial IRB response to the final approval for each institution. The number of IRB stipulations, the number of times the protocol was submitted, specific reasons for delays greater than 60 days for the initial IRB process, and the total number of full board meetings per IRB were also collected. Sites were categorized into two groups: shared IRB and individual site IRB models. Institutions that opted to use the shared IRB model relied on the central IRB hub (The University of Alabama at Birmingham; UAB), while the individual IRB sites utilized their own institutional IRBs. In primary analyses, the central IRB hub was included in the individual group as they had to use their own individual IRB for the original submission.

We conducted additional analyses assuming that the central IRB hub (UAB) site belonged to the shared group. The Kruskal-Wallis test was used to compare continuous and count data between the two IRB models. The data are summarized as median and ranges. Fisher's exact test was used to compare categorical measures (proportions) between the two IRB models. Hypothesis tests are considered statistically significant at the 0.05 alpha level. The analyses for this manuscript were generated using SAS/STAT® software, Version 9.4 of the SAS System.

RESULTS

The CHAP trial screened 73 university-affiliated sites across the United States. Twenty-eight sites did not complete the data collection form for the current study, and were excluded, resulting in inclusion of 45 sites in this analysis. Seven sites utilized the shared IRB model, and 38 utilized their own (individual) IRB. The median (range) number of IRB meetings per month at institutions did not differ between IRB models; 4 (1–10) and 2 (1–20) for the shared and individual models, respectively (p=0.36). All of the protocols for the shared model were submitted electronically, and 89% of the individual IRBs submitted their protocols electronically.

Outcomes of the IRB models including approval times are summarized in Table 1. The total number of days from initial submission until the final protocol approval was a median (range) of 41 (7–165) for the shared IRB group and 56 (0–183) for the individual IRB models ($p = 0.42$). For the individual IRB group, 42% experienced a delay > 60 days for a protocol approval, compared to 29% for the shared IRB model ($p = 0.68$). The median number of stipulations (range) were 4 (0–70) for the individual IRB group and 1 (0–6) for the shared IRB group; $p = 0.12$. The median number (range) of IRB submission rounds prior to approval were 2 (0–6) and 1 (1–2) for the individual and shared IRB groups, respectively ($p = 0.09$). Eighty-six percent of the sites using the shared IRB model did not require a full board review meeting before accepting the study protocol, compared to only 3% for the individual site IRB model. For the individual IRB model, the site with the highest time to approval (183 days) also had the highest number of stipulations (N=70). There were no requests for substantive protocol changes for the shared IRB model.

COMMENT

Principal Findings

This study found that sites utilizing the shared IRB model required fewer IRB meetings before the protocol was approved. In addition, there was a tendency for sites within the shared IRB model to have fewer submission rounds and a lower number of stipulations than sites that utilized the individual IRB model.

Results

To our knowledge, this is one of the first and largest studies directly comparing shared (centralized) vs. individual multisite IRB models within one clinical trial. Although the time to IRB approval was not statistically significantly less with shared IRB vs. individual site IRBs, the shared model required a median of fewer full board IRB meetings to approve the

CHAP study protocol. The shared IRB model also required fewer rounds of IRB submission (albeit not statistically significant) and a smaller number of stipulations to be addressed before protocol approval. Of note, no substantive protocol modifications were required by either model. These results indicate that the shared IRB model may be more efficient for investigators and IRBs by reducing effort and constricting timelines for multicenter clinical studies. These results suggest that implementing a shared IRB model could potentially reduce delays for clinical trial startup and reduce the workload for institutional IRBs. Taken together, this study highlights the potential benefits of collaboration between academic institutions for research efficiency but does not definitively confirm them.

Although one might assume that the use of many individual reviews for multicenter studies might improve the ethical integrity of research, it is also postulated that this is unnecessary, duplicative, and of no direct benefit in protecting human subjects.[11] Others have reported that the individual multisite IRB model leads to greater administrative burden and costs without demonstrable benefit for investigators or institutions.[15,17] For instance, the National Cancer Institute found that participation in a shared IRB model was associated with faster reviews (33.9 days) fewer hours of research staff (6.1 hours), and a net savings of $717 per initial review. [18] Others have shown that implementing a shared IRB can save more than 150 hours. Another study found that implementing a shared IRB saves more than 151 days in redundant protocol review.[19] These findings further suggest that implementing a shared IRB model for multicenter studies across research institutions may save almost half a year for investigators and institutions without weakening regulatory oversight.

We observed wide variability in the number of IRB stipulations requested before approval regardless of model. Many of the stipulations requested by individual IRBs involved grammatical and stylistic changes, including changes to the verbiage of the consent forms. One institution that utilized the individual IRB model requested 70 “major” edits and required edits to the consent forms on four separate occasions, resulting in a delay of >3 months for the protocol to be approved. In contrast, some institutions that utilized the individual IRB model requested no changes at all. In a previous study, we reviewed the characteristics and outcomes of five protocols utilizing individual IRBs at National Perinatal Research Centers.[14] We found that the stipulations requested from individual IRB models often involved only minor stylistic and editorial changes. Another study that examined the effects of an individual IRB review in a multicenter clinical trial found that more than 75% of edits to the original consent form were due to institutional language preferences. They also reported that the revisions requested did not result in significant changes to the study protocol.[15] Others have found that the cost of the IRB review process leads to delays in study conduct and contributes to increases in drug development costs.[20–23] Thus, use of the shared IRB model could result in a more efficient review process and savings for both investigators and institutions.

Strengths and limitations

While this is one of the few and largest studies directly comparing IRB models, our findings are limited by the small number of sites that opted into the shared IRB model and the number of sites excluded from this study. Thus, we were unable to demonstrate significant

differences in times to approval. At the time of initiation of the CHAP trial, shared IRB models were not required, and many institutions were not familiar with the streamlined process in practice. One study that examined perceptions of the shared IRB model found that 76% of the participating centers had never used a shared IRB model despite having several multicenter studies. In addition, more than 73% of the cohort reported that the process seemed unnecessary.[18, 24] Investigators have also reported concerns regarding the feasibility of collaborating with external IRB's, while others have noted concerns for legal liability of outsourcing the IRB process.[25] Despite these findings, larger studies have reported significant results between IRB models. Another limitation is the focus of this study on pregnancy. Though this is the first study to address this question in a cohort of pregnant women, we do not have reason to believe that these findings would be different in non-obstetric studies. The retrospective design of our study may also be associated with misclassification although many of the variables are likely to be reliably abstracted from regulatory records. On balance, these results provide evidence that implementing a shared IRB for multicenter studies could reduce burden for institutions and investigators and the associated costs, and potentially shorten the times to approval and study initiation without compromising regulatory oversight.

Clinical and Research Implications

This study adds to an emerging body of evidence that suggests that a shared IRB model has the potential to reduce study initiation and promote consistency of ethics reviews. This study also highlights a multisite study's ability to eventually reduce institutional burden and research costs. Larger studies involving more sites with shared IRBs and studies including non-pregnant populations are needed to confirm these findings and support the increasing requirements for shared IRB models for multisite studies.

Conclusion

Our study indicates that a shared IRB model may be more beneficial in multi-center obstetric studies. These data also suggest that streamlining the IRB process may be critical in accelerating clinical research for human participants.

Acknowledgements

This work was supported by the National Institutes of Health (Chronic Hypertension in Pregnancy Trial; 5U01HL12338–05). SLM was supported during work on this project with an NIH-funded T32 training award (T32HL007457). The authors would like to thank Lisa Dimperio (University of Alabama at Birmingham), LuAnn Polito RN JD (Case Western Metro Health), Arun Jeyabalan MD, Melissa Bickus RN, Victoria Lopata RN, Jeanette Boyce RN (Magee Women's Hospital), Amy Murtha MD, Breanna Hughes MD, Danielle Lanpher CRC Sr, Kirstin Weaver BS CCRC (Duke University), Kyra Woods (Oklahoma Health sciences Center), Jessica Amezcua BS, Allison O'Leary MPH, Natalie Oman MPH, Naseem Rangwala BA, Nicole Rigler (university of California San Francisco), Sean Esplin MD (Intermountain Healthcare), Torri Metz MD, Michael Varner MD, Amber Sowles RN BSN (University of Utah), Iris Krishna MD MPH (Emory University), Tyler Malone BS (Medical College of Wisconsin), David McKenna MD, Kaye Snow RNC BSN, Kathleen Fennig RN MS (Miami Valley Hospital), Aleta Washington RN, Sheila Belk (University of Mississippi), Dawn Cline RN BSN, Taryn Summerfield MSA, Anna Bartholomew RN BSN, Huban Kutay PHD (Ohio State University) Connie Villasenor (University of Teas Health Science Center), Chris Servay BA, Cathryn Leggio MS, Melissa Hendricks RN, and Kathleen Lata-Arias MPH (Ochsner Baptist Medical Center) for administrative, recruitment, nursing, phlebotomy, and data collection support for this project.

REFERENCES

1. United States Congress. “45 CFR 46.” Department of Health and Human Services https://www.hhs.gov/ohrp/regulations-and-policy#46.104
2. Burns KE, Prats CJ, Maione M, et al. The Experience of Surrogate Decision Makers on Being Approached for Consent for Patient Participation in Research. A Multicenter Study. Ann Am Thorac Soc Feb 2017;14(2):238–245. doi:10.1513/AnnalsATS.201606-425OC [PubMed: 27849142]
3. Group TS. The Translating Research Into Action for Diabetes (TRIAD) study: a multicenter study of diabetes in managed care. Diabetes Care Feb 2002;25(2):386–9. doi:10.2337/diacare.25.2.386 [PubMed: 11815515]
4. DATATOP: a multicenter controlled clinical trial in early Parkinson’s disease. Parkinson Study Group. Arch Neurol Oct 1989;46(10):1052–60. doi:10.1001/archneur.1989.00520460028009
5. Svetkey LP, Sacks FM, Obarzanek E, et al. The DASH Diet, Sodium Intake and Blood Pressure Trial (DASH-sodium): rationale and design. DASH-Sodium Collaborative Research Group. J Am Diet Assoc Aug 1999;99(8 Suppl):S96–104. doi:10.1016/s0002-8223(99)00423-x [PubMed: 10450301]
6. Grobman WA, Rice MM, Reddy UM, et al. Labor Induction versus Expectant Management in Low-Risk Nulliparous Women. N Engl J Med Aug 9 2018;379(6):513–523. doi:10.1056/NEJMoa1800566 [PubMed: 30089070]
7. Postuma RB, Iranzo A, Hu M, et al. Risk and predictors of dementia and parkinsonism in idiopathic REM sleep behaviour disorder: a multicentre study. Brain Mar 1 2019;142(3):744–759. doi:10.1093/brain/awz030 [PubMed: 30789229]
8. Comi G, Patti F, Rocca MA, et al. Efficacy of fingolimod and interferon beta-1b on cognitive, MRI, and clinical outcomes in relapsing-remitting multiple sclerosis: an 18-month, open-label, rater-blinded, randomised, multicentre study (the GOLDEN study). J Neurol Dec 2017;264(12):2436–2449. doi:10.1007/s00415-017-8642-5 [PubMed: 29063244]
9. Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research https://grants.nih.gov/grants/guide/notice-files/not-od-16-094.html
10. National Institutes of Health resource for Grants and Funding Ifnormation. Single IRB for Multi-Stie Cooperative Research https://grants.nih.gov/policy/humansubjects/single-irb-policy-multi-site-research.htm
11. Menikoff J The paradoxical problem with multiple-IRB review. N Engl J Med Oct 21 2010;363(17):1591–3. doi:10.1056/NEJMp1005101 [PubMed: 20942660]
12. Silberman G, Kahn KL. Burdens on research imposed by institutional review boards: the state of the evidence and its implications for regulatory reform. Milbank Q Dec 2011;89(4):599–627. doi:10.1111/j.1468-0009.2011.00644.x [PubMed: 22188349]
13. Silverman H, Hull SC, Sugarman J. Variability among institutional review boards’ decisions within the context of a multicenter trial. Crit Care Med Feb 2001;29(2):235–41. doi:10.1097/00003246-200102000-00002 [PubMed: 11246299]
14. Abramovici A, Salazar A, Edvalson T, et al. Review of multicenter studies by multiple institutional review boards: characteristics and outcomes for perinatal studies implemented by a multicenter network. Am J Obstet Gynecol Jan 2015;212(1):110 e1–6. doi:10.1016/j.ajog.2014.07.058
15. Ravina B, Deuel L, Siderowf A, Dorsey ER. Local institutional review board (IRB) review of a multicenter trial: local costs without local context. Ann Neurol Feb 2010;67(2):258–60. doi:10.1002/ana.21831 [PubMed: 20225291]
16. Tita AT, Szychowski JM, Boggess K, et al. Treatment for Mild Chronic Hypertension during Pregnancy. N Engl J Med May 12 2022;386(19):1781–1792. doi:10.1056/NEJMoa2201295 [PubMed: 35363951]
17. Stewart MK, Boateng B, Joosten Y, et al. Community advisory boards: Experiences and common practices of clinical and translational science award programs. J Clin Transl Sci Oct 2019;3(5):218–226. doi:10.1017/cts.2019.389 [PubMed: 31660246]

18. Wagner TH, Murray C, Goldberg J, Adler JM, Abrams J. Costs and benefits of the national cancer institute central institutional review board. J Clin Oncol Feb 1 2010;28(4):662–6. doi:10.1200/JCO.2009.23.2470 [PubMed: 19841324]

19. Western Institutional Review Board Case Study https://www.wcgirb.com/insights/save-151-days-in-irb-review-with-a-seamless-coordinated-submission-process/

20. Burman WJ, Reves RR, Cohn DL, Schooley RT. Breaking the camel's back: multicenter clinical trials and local institutional review boards. Ann Intern Med Jan 16 2001;134(2):152–7. doi:10.7326/0003-4819-134-2-200101160-00016 [PubMed: 11177319]

21. Jester PM, Tilden SJ, Li Y, Whitley RJ, Sullender WM. Regulatory challenges: lessons from recent West Nile virus trials in the United States. Contemp Clin Trials Jun 2006;27(3):254–9. doi:10.1016/j.cct.2006.02.004 [PubMed: 16603417]

22. McNay LA, Tavel JA, Oseekey K, et al. Regulatory approvals in a large multinational clinical trial: the ESPRIT experience. Control Clin Trials Feb 2002;23(1):59–66. doi:10.1016/s0197-2456(01)00183-0 [PubMed: 11852166]

23. DiMasi JA, Hansen RW, Grabowski HG. The price of innovation: new estimates of drug development costs. J Health Econ Mar 2003;22(2):151–85. doi:10.1016/S0167-6296(02)00126-1 [PubMed: 12606142]

24. Loh ED, Meyer RE. Medical schools' attitudes and perceptions regarding the use of central institutional review boards. Acad Med Jul 2004;79(7):644–51. doi:10.1097/00001888-200407000-00007 [PubMed: 15234914]

25. Vardeny O, Hernandez AF, Cohen LW, et al. Transitioning to the National Institutes of Health single institutional review board model: Piloting the use of the Streamlined, Multi-site, Accelerated Resources for Trials IRB Reliance. Clin Trials Jun 2019;16(3):290–296. doi:10.1177/1740774519832911 [PubMed: 30866676]

AJOG at a glance

A. Why was this study conducted?

This study was conducted to test the efficiency of a single shared IRB compared to multiple site IRBs for a multicenter clinical trial.

B. What are the key findings?

A single shared IRB may be more efficient for multicenter clinical trials.

C. What does this study add to what is already known?

This study highlights the importance of streamlining the IRB process for a multicenter clinical trial to reduce the time, effort, and potential costs required to process and approve IRB protocols.

Table 1.

Outcomes of IRB models used in CHAP trial.

	Shared IRB (N=7)	**Individual IRB (N=38)**	***p*-value**
Time from initial submission to final approval, days	41 (7–165)	56 (0–183)	0.424†
Time from initial submission to final approval greater than 60 days: N (%)	2 (29%)	16 (42%)	0.684‡
Number of IRB submission rounds	1 (1–2)	2 (0–6)	0.087†
Number of stipulations from IRB prior to approval	1 (0–6)	4 (0–70)	0.122†
Total number of full IRB meetings prior to approval; N (%) None One Two Three	 6 (86%) 1 (14%) 0 (0%) 0 (0%)	 1 (3%) 25 (63%) 11 (29%) 1 (3%)	<0.001‡

† Kruskal-Wallis Test

‡ Fisher's Exact Test

All data are median (range) unless otherwise specified (Hub site=Individual IRB).