Perspectives of Researchers and Research Team Members Regarding Their Experience with sIRBs

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Supplemental Digital Appendix A: Full text of survey questionnaire

Provided below are our survey questions on user perspectives on sIRB working experience, cost-effectiveness, and efficiency. This survey is available for public use.

Title: Researcher's Evaluation of Single IRB Usage for Human Subject Research

Short Title: sIRB Experience & Efficiency Evaluation Study (SEEES)
IRB Application Number: IRB00346633
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We wanted to share an opportunity to complete a survey from Johns Hopkins University School of Medicine. We are trying to learn and evaluate your experience and efficiency of the single Institutional Review Board (sIRB) usage for human subject research studies in the United States.
Although you may not directly benefit from completing this survey, you may experience satisfaction from helping researchers gain knowledge about bottlenecks in the sIRB process. We are trying to understand the investigator's and their study team's experience with the sIRB review model.
Participation in the survey is completely voluntary and the data is collected in an anonymous fashion. This survey has been approved by the Johns Hopkins Institutional Review Board (IRB00346633). Your choice to participate in this survey or the answers you provide will not affect the care you receive at Johns Hopkins or at any other institution. Please answer each question to the best of your ability.
Call the principal investigator, Drs. James Segars or Bhuchitra Singh at 410-614-2000. If you wish, you may contact the principal investigator by letter/email. These addresses are on this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-502-2092 or jhmeirb@jhmi.edu.

PLEASE NOTE: Your completion of the survey or questionnaire will serve as your consent to participate in this research study, and certification that you are 18 years old or older.

Thank you!

Survey Questions	Response Options				
Are you involved in conducting human subject research at your institute?	Yes		No		
Have you participated as an investigator or study team member in a study that utilized a sIRB?	Yes		No		
What is your usual role in the sIRB associated studies?	See below for the extensive list* (Participants may only select one option)				
Did you use the sIRB for human subject research or non-human subject research study protocols?	Human Subject Research (HSR)		Not Human Subjects Research (NHSR)/Quality Improvement (QI)		
Do you have experience with sIRB review for minimal risk research or greater than minimal risk research or both?	Minimal risk research only	Greater than minimal risk research only	Both	None	
How many studies subjected to sIRB review process have you worked on?	(Enter a numerical value)				
What type of IRBs have you worked with that served as the sIRB?	Public/Private Academic institution	Commercial/ Independent IRB	Central IRB such as the NCI, CIRB		
Do you believe that there are specific types of study designs that will benefit from the use of sIRB mechanism?	NIH Sponsored Clinical Trials	Pharmaceutical Sponsored Clinical Trials	Studies with IND/IDE	Interventional Studies	Observational Studies
Please rate your overall experience with the sIRB onboarding process?	Poor	Fair	Neutral	Good	Great
Please rate your overall experience working with your sIRB or sIRB point of contacts when using their services for multi-site study protocols.	Poor	Fair	Neutral	Good	Great
Have you faced challenges with timelines while working with a sIRB?	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
How would you rate the time required for your local sIRB review/approval?	Poor	Fair	Neutral	Good	Great
Do you still need to submit all or part of an application to the local institution to obtain permission to rely on an outside IRB?	Yes	No	Don't know		

Do you believe that the sIRB mechanism is more cost effective than the older model where each site secured local IRB approvals for multi-site studies?	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
Do you feel that the new sIRB policy has created difficulty in communication between your team and the sIRB board?	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
Do you feel the sIRB mandate hampers the review process due to the local laws, standards, regulations, and the ethnic, cultural and regional variations according to each study site?	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
Have there been instances where the sIRB did not have the bandwidth, infrastructure, or expertise needed to meet the demands of the relying institutions?	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
Do you think the sIRB process has affected your administrative burden?	Significantly reduced	Slightly reduced	Neutral	Slightly increased	Significantly increased
*Study roles: • Principal Investigator • Co-Investigator • Consent Designee	• Lead Research Nurse • Lead Site Co-Investigator • Lead Study Coordinator	• Non-Conflicted Designee • Regulatory Staff	• Research Manager • Research Nurse • Site Investigator	• Statistician • Study Coordinator • Other Role	