Single IRB Expenses Could Jeopardize the Success of Multicenter Trials in Orthopaedic Trauma

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Purpose: Within the clinical research enterprise, it was expected that the single IRB would improve multicenter trial efficiency. However, new burdens have emerged with its compulsory use. The single IRB costs are significant and usurping funding for programmatic activity. Consequentially, there are constraints on the number of sites, which impacts efficiency, ability to achieve sample sizes, and population external validity. We quantify the impact of the single IRB on total direct costs, time to study completion, and external validity for multicenter studies in orthopaedic trauma. We hypothesize the single IRB has a negative effect, particularly for studies with smaller budgets.

Methods: This retrospective marginal analysis leverages a financial management tool that used administrative, financial, and enrollment data from 12 completed multicenter studies to quantify the impact of key cost drivers on 3 outcomes: total direct costs, time to completion, and the optimal number of sites. The key cost drivers were study site startup costs, coordinating center overhead, and enrollment costs. This analysis added single IRB costs as a fourth key cost driver and modeled the 3 outcomes for each study.

Results: The single IRB had a negative impact on at least one of the outcomes for every study. Losses in efficiency attributable to the single IRB ranged from 0- 7.2 months; direct cost increases ranged from $26K to $141K with a mean of $86K. These costs averaged 6% of the study budgets. The single IRB reduced the optimal number of sites by up to 9, with an average of 4 fewer sites.

Conclusion: Any efficiencies eventually gained by using a single IRB must be weighed against trade-offs to external validity, overall efficiency, and total direct costs. The single IRB's impact on any one of the main outcomes isn't catastrophic, but it is still concerning in the context of dwindling research funding and when trials are already under tremendous scrutiny for inefficiency. Moreover, the negative consequences are skewed. Investigators are required to make room for single IRB costs in their budgets, but government sponsors are not required to grant supplemental funding to cover the new expense, which was previously paid for by awardee and subawardee institutional indirects, not programmatic funding.