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Variation in time to institutional board review approval in a national multicenter clinical trial: experience from the PRIDE trial

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Objectives: Issues about the inconsistency of institutional review board (IRB) decision-making have been raised by experiences of some research teams conducting multisite research for decades. Even if it is unintended, local IRB at each site may often request different changes to be made to the same research protocol, resulting in consuming a considerable amount of time and resources. This study reassessed the decisions made by each local IRB and measured the IRB review process time during an ongoing national multicenter trial.

Methods: The IRB responses and requests of 18 institutions participating in The Pragmatic Randomized clinical trial: twice-weekly vs thrice-weekly Incident hemoDialysis in Elderly patients (PRIDE) supported by National Evidence-based Healthcare Collaborating Agency were obtained.

Results: Average time needed for the IRB response for the first study protocol submission was 23 days (median [range], 23 [14-39]). Five IRBs among 18 sites (28%) approved the study protocol at the first review round of study protocol, 10 IRBs (55%) approved it at the round 2 and remaining 3 sites (17%) required the third review round after further modifications of the protocol to eventually receive its approval. Average time to the protocol approval in all sites was 52 days (45 [17-157]), and the last site received approval almost 6 months after the first site's approval. The sites receiving IRB approval after the third round took more time to enroll their first subjects than sites receiving IRB approval at the second round did (p=0.0458).

Conclusions: We noted significant variability in the time of responses and final approval from each IRB, suggesting that the potential disagreements between IRBs on the same common protocol could delay study subject enrollment as it takes time to manage. To reduce the redundancy and variation seen across the local IRBs within multicenter research, the implementation of a central IRB should be required.