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Research Ethics Board Approval For An International Thromboprophylaxis Trial

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Rationale: IRB approval of scientific protocols is crucial to ensure that the safety and rights of research participants are retained. This study's objective was to describe the scope and predictors of questions and conditions from hospital IRBs reviewing a multicenter thromboprophylaxis protocol.

Methods: We conducted a self-administered survey for research coordinators (RCs) or physicians (MDs) involved in PROTECT, focusing on 4 domains: application process and content of the IRB procedures, and respondent and institutional demographics (quantitative). We conducted document analysis of IRB applications and IRB critiques to identify emergent themes (qualitative).

Results: From 64 centers, there were 58 unique IRB applications [document analysis participation rate: 42/58 (72.4%); survey response rate: 44/58 (75.9%)]. The median (IQR) page length of the protocol application and consent form were 14 (10,22) pages and 5 (4,7) pages, respectively. 8/44 (18.2%) applications were approved with no revisions; among 36 (81.8%) requested revisions, second revisions were requested by 7 (19.4%) IRBs and third revisions by 1 (2.8%) IRB. Document analysis of the protocol and consent form yielded 5 themes: protocol clarification, data management, consent procedures, cataloguing, and miscellaneous; 3 additional unique themes of the document analysis were trial implementation, external critiques, and budget feedback; 1 other unique theme from the consent form document analysis was risks and benefits. The most frequent IRB protocol comments were in the themes of methodology and miscellaneous (formatting, typographical errors and signatures). The most frequent IRB comments on the consent form were in the themes of miscellaneous (formatting, typographical errors and signatures), methodology, and risks and benefits. RCs responding to the survey were from Canada (54.5%), Australia (29.5%), USA (9.1%) and Saudi Arabia (6.8%). RCs completing the IRB applications had 8 (5,11) years experience in ICU trials, and completed 3 (3,4.75) IRB trial applications in the past 5 years. Critical care was represented on 54.8% of IRBs. In multivariable analysis, the only significant predictor of IRB submission to approval time was involvement in a national research consortia (87.8 vs. 33.1 days, $p<0.03$).

Conclusions: Since the ultimate goal of this study was to improve the comprehensiveness, transparency and efficiency of the IRB application process for future RCTs in critically ill patients, these findings have implications for practice and policy. Some factors associated with variation in IRB processes are suitable targets for better prepared IRB applications; other factors may be suitable targets for IRB reform.