

Use of SmartIRB Does Not Reduce IRB Review Time in a Non-federally Funded, Multi-Site Malnutrition Study

Erin Lamers-Johnson,¹ Vanessa Will,² Julie Long,¹ Lindsay Woodcock,¹ Alison Steiber¹, and Elizabeth Yakes Jimenez¹

¹Academy of Nutrition and Dietetics and ²University of New Mexico Health Science Center

Objectives: We evaluated the efficiency of using the SmartIRB platform compared to other site IRB approval mechanisms in the multi-site Academy and ASPEN Indicators to Diagnose Malnutrition (AAIM) Validation and Staffing Optimization Study.

Methods: Process data on the time to execute reliance agreements were collected when on-boarding sites for the AAIM Study (ClinicalTrials.gov: NCT03928548). Acute care hospital site recruitment occurred from September 2018 to December 2021. Research sites joined the study by either executing a reliance agreement with the single IRB of Record (sIRB) or by obtaining full local IRB approval from their institution. Reliance agreements were established through the SmartIRB model, an IRB authorization agreement (IAA), or a Letter of Support. Data are presented descriptively as number of observations and respective percentages or means \pm standard deviations (SD).

Results: As of September 2021, 82 sites received IRB approval for the AAIM Study through the submission of 69 individual IRB

applications. Sixty sites were affiliated with SmartIRB. Forty-one applications established a reliance agreement with the sIRB: 31 of 69 used the SmartIRB model (44.9%), 7 used an IAA (10.1%), and 3 used a Letter of Support (4.3%). Twenty-eight applications were submitted for full local review (40.6%). For all 69 submissions, the average time from the initial contact to site activation by the sIRB was 496.9 ± 213.6 (SD) days. SmartIRB had the longest review period of 546.1 ± 220 days; followed by full local review (492.6 ± 213.9 days), then IAA (377.4 ± 143.7 days), and Letter of Support (306.3 ± 58.2 days).

Conclusions: The use of an sIRB and the SmartIRB platform did not to reduce the time required for IRB review of this non-federally funded study. These findings should be interpreted acknowledging several disruptions to IRB activity during the study recruitment timeframe (e.g., accelerated implementation of single IRB review starting in 2018, Common Rule changes in 2019, and the COVID-19 pandemic starting in 2020).

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