



Featured Pearl of the Quarter!

PROS PEARLS

PROS CARES and Safety Check Studies

Effects of Local Institutional Review Board Review on Participation in National Practice-Based Research Network Studies.

- The process and outcomes of local institutional review board (IRB) review were described for practices participating in two Pediatric Research in Office Settings (PROS) studies—Child Abuse Recognition Experience Study (CARES) and Safety Check.
- Practices requiring additional local IRB approval agreed to participate less than those that did not in both studies (CARES: 33% vs 52%; Safety Check: 41% vs 56%).
- The 88 practices requiring local IRB approval were located in 29 states and associated with 75 different IRBs. The majority of the participating practices were located in urban areas (68%) and connected to medical schools or hospitals/clinics (48%).
- Fifty-five of these practices received approval, with nearly 50% needing active PROS help, many requiring consent changes, and 87% beginning data collection. Median days to obtain approval were 81 for CARES practices and 109 for Safety Check practices. Longer approval time was related to the number of requested changes and follow-up questions by the local IRB.
- Minority patients were enrolled at a higher rate into both studies at sites requiring local IRB approval (CARES: 39% vs 23%, $P < .001$; Safety Check: 51% vs 36%, $P < .001$). Also, practices requiring local IRB were more likely to be located in an urban setting than those covered by the AAP's IRB (CARES: 76% vs 28%, $P < .001$; Safety Check: 69% vs 34%, $P < .001$).
- The findings suggest that the need for local IRB approval appears to be an impediment to participation in PBRN-based research, may discourage the inclusion of minority and urban patients, and seems to result in little if any significant change in the research protocols.

These were among the findings from two Pediatric Research in Office Settings (PROS), the AAP's practice-based research network, studies—Child Abuse Recognition Experience Study (CARES) and Safety Check. CARES was conducted in collaboration with the National Medical Association's pediatric practice-based research network, NMAPEDSNET, and funding was received from the Agency for Healthcare Research and Quality (grant R01 HS010746), the Maternal and Child Health Bureau (grant R40 MC 00107), and the American Academy of Pediatrics (AAP). Overall, 434 clinicians participated in data collection and collected information about 15,003 child injury visits. Safety Check funding was provided by the National Institute of Child Health and Human Development/Agency for Health Care Policy and Research (grant RO1 HD42260). Additional funding was provided by the Robert Wood Johnson Foundation, the AAP's Friends of Children, and the AAP. Overall, 203 practitioners participated in data collection, distributed throughout 125 practices and 27 states, Canada, and Puerto Rico.

The following article based on study results recently appeared in *Archives of Pediatrics & Adolescent Medicine*:

Finch SA, Barkin, SL, Wasserman RC, Dhepyasuwan N, Slora EJ, Sege RD. Effects of Local Institutional Review Board Review on Participation in National Practice-Based Research Network Studies. *Archives of Pediatrics & Adolescent Medicine*. 2009; 163(12): 1130-1134.