A New Option for Obtaining Community Consultation (CC) in Emergency Research (ER)

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Problem Statement Background: The requirement for CC in ER continues to challenge investigators and their IRBs. We chose to randomly sample the emergency room population their opinion regarding the performance of ER, per guidelines stated in 21 CFR 50.24, “Exception from informed consent requirements for emergency research.” This work will introduce a methodology that can be performed economically and efficiently to provide valid CC.

Research Questions: 1. Can the emergency room be used as a site to perform CC in research? 2. Can an informational pamphlet and questionnaire be used to inform individuals about specific research studies and obtain their feedback?

Description of the Research Methods: After obtaining IRB approval, patients, family members, and staff in the emergency room of a suburban, level I trauma center were invited to read a pamphlet and complete a short 12 item questionnaire about individual's support for ER. Responses were scored using a 5-point Likert scale and dichotomized (strongly agree and agree categories indicating “support”) for analysis. Responses were compared subgroups (patients, family members, and staff) using the X2 test (α = .05).

Results: Of the 400 questionnaires, 389 (97%) were completed. Breakdown by subgroup was: 29% patients, 19% family members, and 52% staff members. Women comprised 53%, 79% were whites, mean age 46 ± 16 years. Responses indicated a general acceptance of ER (95% support). Interestingly, 54% volunteered themselves for such research, and 79% volunteered a family member. Differences among the three groups were not statistically significant for any question (P = 0.36). Direct printing costs equaled $250.

Limitations: These results reflect a population from a single center. These results may not be generalizable to other centers.

Conclusions: A very high level of support for ER was encountered. The methodology lends itself to a cost effective, efficient format to acquire meaningful and valid community consultation and remove a significant barrier to human research in the emergency setting.

Next Steps: 1. A multicenter study is underway that will look at three additional hospital settings, including two additional urban, level I trauma centers and one suburban, level II trauma center. 2. Determine the number of individuals that are invited, but declined. 3. Perform a national poll for IRB chairs as to their level of acceptance of this methodology to provide valid and meaningful CC in the setting of ER.