## Background

- **Problem Statement:** The requirement for community consultation (CC) in emergency research (ER) continues to challenge investigators and their IRBs. We randomly sampled the emergency room population for their 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 provide meaningful CC efficiently and economically.
- The emergency room setting provides access to a cross-sectional sample of the community served by the hospital. Furthermore this also includes representation of hospital staff members.
- **Research Questions:** 1. Can the emergency room environment be used as a site to perform CC in ER? 2. Can an informational pamphlet and questionnaire be used to inform individuals about specific research studies and obtain their feedback, thus providing a vehicle for consultation between the community in which the intended research is to be performed, the study investigators and their governing IRB?

## Methods

- **Description of the Research**
  After obtaining IRB approval, patients, family members, and staff in the ED of a suburban, level I trauma center were invited to read a pamphlet and complete a short, 10 item questionnaire that requires about an individual’s support for ER. Responses were scored using an 5-point Likert scale and dichotomized (strongly agree and agree vs. disagree and strongly disagree) for analysis. Responses were compared between subgroups (patients, family members, and staff) using the X² test (p < 0.05).

- **Permits to approach patients were obtained from the emergency physician on duty. Patients who were unstable or critically ill were not approached.**

- **The Questions**

  1. I believe medical research should be performed by medical doctors to develop new and better ways to treat disease.
  2. If I was patient and was offered a chance to volunteer in a research study I would likely do so.
  3. Research studies should be done at some other hospital, other than Your Hospital.
  4. Your Hospital is an appropriate institution to do emergency research.
  5. Your Hospital should have access to the latest medical therapies, including experimental medicines.
  6. Medical research is risky business and should never involve human volunteers.
  7. If I was unconscious and brought to the emergency department at Your Hospital and was told I have a life-threatening illness and had a 10% chance of surviving without treatment t that is, you have a 1 in 10 chance of living or a 9 in 10 chance of dying). Suppose there is an approved research study that might increase your chance of living (although it might not help you or even make things worse) I am unconscious and unable to give permission. Under these circumstances, I would be willing to become a volunteer in such a study.
  8. If I was a member of my family was unconscious, from the same life-threatening illness described in question # 7, you would agree to have them become a volunteer in such a study.
  9. Patients should not volunteer to be in research studies.
  10. It is OK to enroll children into medical studies so long as the parents give permission/informed consent.

- **Investigator training program for ER remains to be defined.**
- **IRB’s lack clear, actionable guidance as it relates to the CC component of 21CRF50.24.**
- **ER research continues to be hampered due to barriers related to 21CRF50.24, especially the CC component.

## 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 white, mean age 46 ± 16 years.
- Responses indicated a general acceptance of ER (95% support).
- Interestingly, 54% volunteered themselves for such research, and 79% supported the “exception” for such research, and 79% volunteered a family member.
- Differences among the 3 groups were not statistically significant for any question (p>0.3).

## Conclusions and Future Steps

- **A very high level of support for ER was encountered and is consistent with recent literature.**
- **The methodology lends itself to a cost effective, efficient format to perform CC.**
- **This approach removes a significant barrier (CC) to performing ER: it respects the autonomy of the community, reflects the community’s attitude and offers guidance for IRB deliberations.**
- **Limitations:** The results reflect a population from a single center and therefore may not be generalizable to other centers. Respondents were biased towards a non-critically ill population whose willingness to complete the questionnaires probably reflects a selection bias towards favorable responses.

**Next Steps:** Define criteria for valid and meaningful CC.

- Determine the number of individuals that are invited but decline to participate.
- Perform a poll of IRB chairs as to their level of acceptance of this methodology for providing meaningful CC in the setting of ER.

- 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.

## Literature

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