



EFIC Research Recommendations: Rethinking Public Engagement Criteria

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Background

- 20 year moratorium on emergency medicine (EM) research following Common Rule legislation → no systematic way to develop EM therapies
- 1996 EFIC legislation (21 CFR 50.24) passed
 - Community consultation (CC) stipulation
 - Public disclosure (PD) stipulation



Empirics of CC

- CC is intended to inform study design, permitting relevant communities to shape research
- My research illustrates that
 - CC is not always pursued with relevant communities
 - CC results are highly subject to the way clinical coordinators convey information to CC participants
 - CC results rarely inform study design



The Issue

- Assumptions about the utility of CC in evoking meaningful public opinions, and assumptions about the potential of CC to influence study design do not align with the actualities of CC in practice
- Unfulfilled promises, lack of transparency, and theatrical practices (i.e., those that are purely for show) performed by biomedical personnel have historically eroded relationships between biomedical researchers and urban U.S. publics
- Pursuing CC with the misguided notion that it achieves meaningful public participation in research will further damage public trust in biomedical institutions



Recommendations

- 21 CFR 50.24 should be revised to stipulate ways in which CC must yield meaningful, relevant data that shapes study design

OR

- 21 CFR 50.24 should be rid of the CC requirement AND biomedical institutions should make concerted efforts to cultivate public trust whilst better addressing local community needs