Received: 16 January 2021 | Revised: 31 March 2021 | Accepted: 6 April 2021

DOI: 10.1111/acem.14264

THE BIROS SECTION ON RESEARCH ETHICS

Meeting unique requirements: Community consultation and public disclosure for research in emergency setting using exception from informed consent

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Funding information
National Heart, Lung, and Blood Institute, Grant/Award Number: U24NS10065502S1; National Institute of Neurological Disorders and Stroke, Grant/Award Number: U24NS1006590 2S1

Abstract

Background: Exception from informed consent (EFIC) regulations for research in emergency settings contain unique requirements for community consultation and public disclosure. These requirements address ethical challenges intrinsic to this research context. Multiple approaches have evolved to accomplish these activities that may reflect and advance different aims. This scoping review was designed to identify areas of consensus and lingering uncertainty in the literature.

Methods: Scoping review methodology was used. Conceptual and empirical literature related to community consultation and public disclosure for EFIC research was included and identified through a structured search using Embase, HEIN Online, PubMed, and Web of Science. Data were extracted using a standardized tool with domains for major literature categories.

Results: Among 84 manuscripts, major domains included conceptual or policy issues, reports of community consultation processes and results, and reports of public disclosure processes and results. Areas of consensus related to community consultation included the need for a two-way exchange of information and use of multiple methods. Public acceptance of personal EFIC enrollment is commonly 64% to 85%. There is less consensus regarding how to assess attitudes, what "communities" to prioritize, and how to determine adequacy for individual projects. Core goals of public disclosure are less well developed; no metrics exist for assessing adequacy.

Conclusions: Multiple methods are used to meet community consultation and public disclosure requirements. There remain no settled norms for assessing adequacy of public disclosure, and there is lingering debate about needed breadth and depth of community consultation.

Supervising Editor: Craig Newgard, MD.

KEYWORDS
clinical trials as topic, community–institutional relations, critical care, disclosure, emergencies, informed consent

INTRODUCTION

United States regulations allowing exception from informed consent (EFIC) for clinical trials in emergency settings (21 CFR 50.24) are central to advancing care for acutely ill, incapacitated patients.[1] These regulations are restricted to clinical trials that would be impracticable to conduct enrolling only individuals who can provide consent or who have an immediately available authorized representative. Trials must present a prospect of direct benefit to participants, and existing therapy must be "unsatisfactory or unproven." In addition, EFIC regulations mandate community consultation prior to approval and public disclosure of the study prior to initiation and after study completion (Box 1).[1,2] This is the only type of research for which these activities are required by U.S. regulations.

Different methods have emerged for defining and engaging communities, defining adequacy, and reporting and interpreting community feedback, and available guidance allows substantial flexibility regarding how best to satisfy regulatory requirements.[2] This can be intimidating for investigators and institutional review boards (IRBs) without EFIC experience, and those with experience may have developed practices that are not grounded in evidence or informed by other approaches. Understanding the range of practices, experiences, and available data are important to realize ethical goals of these activities. The transition to central, rather than local, IRB review of multicenter trials will also be facilitated by understanding of the scope of existing practices, because community consultation and public disclosure are conducted locally and heterogeneous standards and expectations have evolved.

This scoping review includes published literature on community consultation and public disclosure for EFIC. The goal was to identify areas of consensus and persistent gaps. The former may help to provide guidance and promote development of best practices to improve quality and efficiency of the conduct and review of these activities. The latter can clarify areas for further discussion and research designed to help identify effective strategies and inform additional guidance.

METHODS

Scoping review methodology was chosen to synthesize and characterize relevant literature.[3] This method was chosen because this body of literature is heterogeneous, including conceptual and empirical work utilizing different methods. Scoping review methodology allows incorporation of all literature relevant for this research question.[4] We created a search, in collaboration with an informationist, using terms (Data Supplement S1, Appendix S1, available as supporting information in the online version of this paper, which is available at http://onlinelibrary.wiley.com/doi/10.1111/acem.14264/full) to capture literature related to EFIC research and community consultation and public disclosure for emergency research. The search included terms to cover conditions or clinical contexts for which EFIC research has been frequently conducted. The search (Figure 1) included Embase (446), HEIN Online (30), PubMed (470), and Web of Science (180) and included manuscripts published between 1996 (when EFIC regulations were enacted) and 2019.

Titles and abstracts were initially screened by one author (KM). During this process, any manuscripts for which there was a question about eligibility was reviewed by an additional reviewer (NWD or CDS). Selection criteria were broad to fully represent the range of literature. Among manuscripts selected for full-text review, we narrowed the sample to manuscripts with content focusing on community consultation or public disclosure. These included empirical reports; descriptions of process/approach; opinions/policy/ethics pieces; and attitudes of IRBs, investigators, and providers. There was overlapping content across categories. Many reports of consultation results, for example, included process descriptions.

A standardized extraction tool was created by the team of primary reviewers (KM, CDS, and NWD) using Google Forms and was designed to capture key domains in each category (Appendix S2). For example, information extracted for empirical reports of community consultation included consultation method, study type, assessment method, key questions, population targeted, and implications. Among ethics and policy papers, extracted content included views of the value and purpose of community consultation and public disclosure (including views on particular methods), of the extent of community consultation or public disclosure needed, and definitions of "community."

The extraction tool was refined by the entire research team, pilot tested, and further refined prior to implementation. Each category of manuscripts included open-ended fields to allow recording of relevant findings outside of predetermined domains. All full-text manuscripts were reviewed by at least two reviewers. Any discrepancies were resolved by consensus.

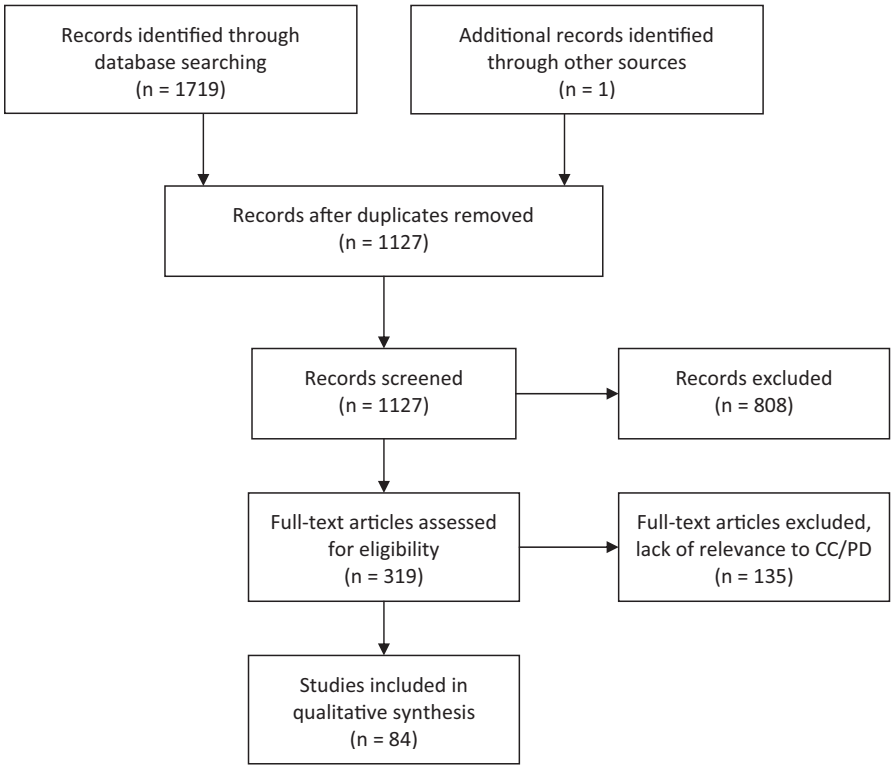
RESULTS

Findings are grouped into three major domains: conceptual or policy-focused literature, community consultation processes and reports, and public disclosure processes and reports.

Conceptual or policy-focused literature

Thirty-one articles focused on conceptual ethical or policy issues related to community consultation or public disclosure. These more

FIGURE 1 PRISMA Chart



often addressed community consultation. Some empirical reports contained substantive discussion about these issues as well.

Value and purpose of community consultation

Two types of value for community consultation were frequently emphasized: 1) the ability to clarify impact of trial enrollment on potential enrollees and ways to refine the study and 2) the potential to promote trust, provide transparency, and demonstrate respect.[5–13] There were questions raised about the extent to which community consultation accomplishes these goals, especially identifying changes.[14–19] A key theme was the reiteration that community consultation is not intended to be a "consent" process or vote, although acceptance is relevant.[6,9,20,21] As emphasized in the regulations, the primary purpose of community consultation is to provide an opportunity for public comment and feedback.[2]

Challenges related to community consultation

Commentators reiterated difficulties defining the relevant community for consultation, and some studies empirically assessed how this should be defined.[9,11,13,22-26] It is clear that individuals see themselves as being members of many different types of communities, many of which lack defined spokespersons and may not have any connection to health care or to emergency research.[23] The literature also reflects difficulties interpreting data related to acceptance or objection.[8–10,27] Estimated acceptance of personal enrollment in EFIC trials by participants in community consultation activities is typically around 70% (Appendix S3).[28] This compares favorably with consent rates in most clinical trials, but some commentators have emphasized that this may represent concerning disagreement when patients are enrolled by default.[28–30] No standards or metrics exist regarding what level of acceptance is "too low" for a trial to proceed.

Views on consultation methods and populations

Four distinct themes emerged regarding consultation methods and populations they should engage. First, there was an emphasis that consultation should be context specific and tailored to the community and trial. For example, some commentators have argued that the extent and nature of consultation should be scaled to study risks.[8,11,31] Second, commentators emphasized the "two-way" nature of consultation and the importance of alignment between chosen methods and this goal.[6,9,32,33] There have been explicit arguments against use of quantitatively oriented, less interactive, forms of consultation, emphasizing the ability of more interactive methods to facilitate substantive input and that views change during discussions.[5,8–10,34] In contrast, some commentators have emphasized representation of broad communities, grounding support for quantitatively oriented methods in their ability to generate "representative" samples that account for demographic diversity.[32,35,36] Others have noted the importance of deliberate inclusion of communities in which there may be less trust and greater real and perceived risks based on past research abuses.[7,30] Finally, some commentators emphasize the importance of focusing efforts on persons at risk for or with connections to the study condition, based on the notion that they have personal experience that will help them to provide more

TABLE 1 Common community consultation methods

Method	Interaction	Described advantages	Described limitations	References
Interactive, discussion-based consultation				
Town hall–style meetings	In-person presentation	—Face-to-face interaction —Allows substantive description of the study —Opportunities for open feedback and discussion —Ability for IRB to observe —Can pair with survey —Opportunity for interested people not in targeted groups to be included	—Lower attendance than at existing group meetings —Response bias from those choosing to attend meetings —Significant effort for few participants —Labor-intensive to summarize.	Holsti (2015)[41] Kremers (1999)[57] Nelson (2008)[48] Salzman (2007)[69] Santora (1998)[70] Tisherman (2008)[43] Contant (2006)[27] Dickert (2014)[49] Longfield (2008)[71] Powers (2019)[72]
Existing group meetings	In-person presentation by investigator or other study team member	—Face-to-face interaction —Allows substantive description of the study —Opportunities for feedback and discussion —Increased attendance relative to town hall–style meetings —Ability for IRB to observe —Can focus on relevant groups and high-value stakeholders —Can pair with survey	—Variable attendance —Concerns about selection bias/reduced generalizability based on groups —May be difficult to schedule —Labor-intensive to summarize	Dickert (2014)[49] Dix (2004)[46] Galbraith (2014)[73] Govindarajan (2013)[74] Chin (2015)[54] Holsti (2015)[41] Kasner (2011)[34] Nelson (2008)[48] Santora (1998)[70] Tisherman (2008)[43] Vohra (2014)[40]
In-person interviews or focus groups	In-person discussion and interview with individual or small groups	—Opportunity for open discussion and dialogue —Ability to ensure greater understanding of the study among respondents than other methods —Can focus on most relevant groups and stakeholders (often with condition-relevant experience) —Higher level of recall of study information among respondents —Can pair with survey	—Small sample size —Labor-intensive and potentially expensive —Concerns about generalizability of feedback/selection bias —Can be labor-intensive to summarize	Contant (2006)[27] Dickert (2014)[49] Galbraith (2014)[73] Govindarajan (2013)[74] Holsti (2015)[41] Kasner (2011)[34] Morris (2004)[58] Raymond (2010)[59] Sims (2013)[51] Tisherman (2008)[43]
Noninteractive, survey-based consultation				
Telephone or electronic surveys	Survey administered over the phone or internet	—Large numbers are achievable —Can capture more representative population (geographically) —Can sample based on zip code or other data to reflect target population —Time-efficient	—Lack of interactivity and discussion —Heavily dependent on framing (both the study and questions) —Response bias based on method (landline, Internet access) —Expensive, requires expertise —Tends to represent general public rather than more focused communities	Beshansky (2014)[35] Bulger (2009)[32] Contant (2006)[27] Dickert (2014)[49] Henry (2017)[18] Holsti (2015)[41] Morris (2004)[58] Nelson (2008)[48] Tisherman (2008)[43]

(Continues)

TABLE 1 (Continued)

Method	Interaction	Described advantages	Described limitations	References
Surveys at community events	In-person distribution of survey at sporting event, fair, etc.	—Potential for capturing large numbers in a geographic area —Avoids expense of RDD —Avoids landline/Internet selection bias —Time-efficient; some opportunity for interaction and discussion with staff present	—Potential responder bias —Selection bias based on type of event —Relatively minimal or brief interaction —Focus on geographic community	Biros (2009)[47] Dickert (2014)[49] Eubank (2018)[53]
Surveys in hospital/clinic	In-person administration of survey in a medical setting often ED or inpatient	—More focused population —Potential for significant number of respondents —Level of interaction and discussion depends on method and personnel	—Labor-intensive —May afford little interaction and discussion depending on who does it/how it is designed	Clark (2013)[37] Eubank (2018)[53] Morris (2004)[58] O'Malley (2017)[60] Scotton (2013)[75]

Abbreviation: IRB, institutional review board.

substantive input about how enrollment would impact patients and family members.[11,25,34,37–40] The literature does not reflect consensus around these issues.

Views on public disclosure

Public disclosure was a less common focus. There has been less explicit endorsement of its value. Some authors have highlighted the potential of disclosure to facilitate transparency, avoid secrecy, and increase trust and education about research.[11,12,39] Others highlight its potential to facilitate opt-out for individuals wishing not to be included.[38,41] One theme was the need to recognize that public disclosure and community consultation serve different functions.[19,25] The conceptual distinction between these activities is clear in regulations and guidance but often blurs in implementation.[2] A second theme was uncertainty regarding the value or "return on investment" from public disclosure.[17,22,42,43] This is compounded by the absence of established metrics regarding how to assess whether disclosure is adequate.[44,45]

Community consultation processes and reports

Twenty-seven articles reported results of community consultation conducted for EFIC trials; many used more than one method. Common methods included open forum/town hall meetings (11), meetings with existing groups (10), surveys in hospital or community settings (six), interviews (four) or focus groups (nine), and random-digit dialing (seven; Table 1). The most frequent population in reported community consultation activities was the general public (19); this is a broad term that includes, for example, randomly sampled individuals as well as faith-based communities and other civic organizations. This was followed by current/former patients (eight) with the condition under study, neighborhood/geographic groups (seven) patients in emergency departments (six), and support group members (two).

Participants' responses

Participants' responses were commonly assessed using surveys, which were sometimes done as stand-alone consultation activities (e.g., random-digit dialing) and sometimes administered after discussion-based meetings. Reported survey data thus span consultation methods. Qualitative summaries of discussions are often provided to IRBs, but these reports or summaries have not generally been published.

The most common survey domain (Table 2) was personal acceptance of being included in the proposed EFIC trial. Reported acceptance of personal EFIC enrollment was generally 64% to 85%, consistent with a prior systematic review (Appendix S3) and a review of the FDA docket of consultation data.[28,30] Outliers included a

TABLE 2 Assessment questions in community consultation

Content	Examples	Potential advantages/disadvantages
Personal acceptance of EFIC enrollment in proposed trial	—"My own EFIC enrollment in this study would be acceptable."[47] —"If you were having a heart attack and were to be treated by paramedics, would you object to participating in this study?"[35]	—Stronger content validity —Epistemically more valid (people can know the answer for themselves)
Willingness to enroll in proposed trial	— "If today your child had been in a coma as a result of a serious head injury, would you agree to enroll him/her in this study?"[33] —"Would you agree to participate in this study?"[74]	—Stronger content validity —Does not specifically address EFIC (attitude toward study and not EFIC)
General acceptance of EFIC for proposed trial	—"Do you object to the enrollment of someone in this research study without their individual consent before the study begins?"[71] —"Sometimes no family member can be found to make medical decisions for patients with traumatic brain injury. It is okay to include those patients in the ProTECT study without consent."[50]	—May avoid idiosyncratic preferences —Difficult to answer for others —Potential bias toward more negative response
Acceptance of EFIC in community	—"EFIC is acceptable for emergency research in our community."[47] —"Would you be willing to allow us to do this study in your community?"[35]	—Lacks content validity —Heavily dependent on phrasing
Importance of proposed trial	—"Do you feel there is potential benefit from receiving the experimental blood substitute, PolyHeme?"[71] —"The COMBAT study is an important study to do."[54]	—Straightforward —Ceiling effect —Lack of information/expertise —Does not address enrollment/EFIC
Acceptance of enrollment in proposed trial with surrogate consent	—"If you are confused or drowsy, you might not be able to make such a decision for yourself. Would you be happy for your next of kin/relative (or other representative) to take this decision for you?"[75] —"If I had a traumatic injury and a family member agreed to include me in the COMBAT study, I would be okay with being included."[54]	—Stronger content validity —Does not specifically address EFIC

Abbreviation: EFIC, exception from informed consent.

study reporting personal EFIC acceptance of 93% and another with only 51%.[46,47] Personal EFIC acceptance was the most commonly and most consistently assessed domain, but it seems to vary in response to how trial information is communicated and how questions are asked. Even among questions about personal acceptance, differences in phrasing are common and appear to drive variation in response patterns.

Other domains (Table 2) utilized even more variable wording, complicating cross-report comparisons, and some questions lack clear validity.[28] For example, answers about willingness to be enrolled in a trial without reference to EFIC are challenging to interpret, because respondents may not understand that enrollment would occur without consent. Similarly, small variations in wording related to acceptance of a trial's conduct within a "community" appear to drive discordant answers, and it is not always clear what respondents mean when answering a question such as "EFIC is acceptable for emergency research in our community." [27,47]

No consistent patterns were reported regarding predictors of acceptance by participant characteristics (Appendix S3). Some studies observed slightly increased support among respondents who were younger[32,47]; others reported the reverse.[48,49] Several studies reported decreased acceptance among minority groups.[27,48,50] In some reports, there was increased acceptance among respondents with personal connections to the condition under study (such as a patient or family member of a patient with the condition).[50] One report found the reverse association,[51] and another suggested this relationship was modulated by race, with African-American respondents' views not demonstrating this relationship.[52]

Impact of consultation method

Meeting-based and other more interactive methods have been reported to be associated with higher rates of personal acceptance than survey-based or other less interactive methods.[27,28,35,48,50] Opportunities for dialogue in more interactive activities may deepen understanding or promote trust, contributing to buy-in. It has been commonly reported that open public meetings or "town hall" meetings have low attendance, whereas attendance was reported as more predictable at consultations involving meetings of existing groups.[22,48,49]

Efficiency and resources

There were relatively few reports including assessments of effort and resources for conducting community consultation.[32,42,53,54] Where reported, costs ranged widely ($1,500 to >$80,000 per site).[41,54] The yield of town hall meetings, relative to study team effort, was often reported as low.[41,48,49] Some reports cited the rapidity with which strategies such as random-digit dialing could be conducted as an advantage; this method also involves appreciable expense.[32,35] More interactive efforts were reported to require more time from research teams, but large community events such as state fairs and athletic events have been described as highly efficient.[38,42,47,53] Although social media has been mostly described as a method of public disclosure as noted below, it has been used for consultation as well.

Public disclosure processes and reports

A range of public disclosure methods was reported (Table 3). Traditional approaches include press releases, public service announcements, media appearances (not purchased), paid print advertisements, broadcast media, in-hospital posters, flyers, study websites, brochures, and personal letters and emails. Less common methods (though increasing) included social media ads and posts using platforms such as Facebook and Twitter. Importantly, some methods were described as serving both consultative and disclosure functions. For example, social media posts allow for feedback, but interaction with ads or pages is primarily "one way."[19,55,56]

Defining populations

Intended populations were typically geographically defined; efforts were directed toward the general public in the area where the proposed study would take place. There were attempts at notifying more focused populations; some utilized in-hospital methods (e.g., posters or flyers), for example, to reach patients or notifications directed to disease-related support groups whose members were familiar with the condition being studied.[57–60] There are also reports of focusing on high-incidence zip codes or other tools to notify individuals more likely to be enrolled.[38,55,56,61,62]

Measures of disclosure

There were no uniform methods for reporting or assessing effectiveness of public disclosure, and actual "penetration" is extremely difficult to estimate. Some reported metrics included number of activities or venues and audience diversity. Other measures included numbers of people exposed to a message based on readership or listenership, as is typically used in advertising, numbers of surveyed individuals, and patients/families who were aware of the study. Web-based or social media disclosures allow hit rate and click reports and time spent on a site. In general, reported time spent was often low, making meaningful exposure difficult to assess.[55,56] Published estimates of awareness, both within communities in which research was conducted and among individuals enrolled in a study after a disclosure effort, were low (with the exception of focused notifications within a hospital unit).[59] Rates of opt-out requests in response to disclosure efforts were invariably low, but this may reflect acceptability of research rather than poor penetration of disclosure.[42,59,61,63,64] In general, the impact of public disclosure remains largely unknown.

DISCUSSION

Acute and emergency researchers and IRBs have developed approaches to implementation and evaluation of unique regulatory requirements for community consultation and public disclosure in EFIC research. They have accumulated substantial experience, and there is a body of literature demonstrating areas of consensus and significant residual questions.

Areas of consensus

The reviewed literature suggests a growing consensus regarding community consultation in several respects. There has been an evolution away from open public forums/town halls. These efforts, used in many early EFIC studies, appear to have been characterized by low attendance and viewed as inefficient by many teams.[49] Attendance at existing groups' meetings, conduct of focus groups, and having a presence at large community activities (e.g., state fairs) have received greater enthusiasm.[47,49,53] There appears to be a functional consensus that effective consultation involves multiple methods for a particular project.[22] This is not often explicitly articulated but is reflected in many reports and matches our impression as EFIC researchers. It also seems appropriate; different consultation methods serve different goals, reach different populations, engage people differently, and require different resources.

This review suggests general recognition that community consultation should be a two-way exchange and not viewed as a referendum. Despite varying acceptance rates in the literature, we identified only one report of a planned EFIC study not being conducted due to community consultation results. In this case, consultation revealed a high number of Jehovah's Witnesses with objections to a trial of a blood substitute.[6] There have been questions raised regarding what threshold of acceptance should be met, as asking for input should imply willingness to heed to strong objections.[65] However, there is an emphasis on substance of input over frequency of acceptance, and community consultation advocates emphasize its ability to demonstrate respect, demonstrate trustworthiness, and promote transparency.[5] It has been less fully reported whether consultation has affected concrete aspects of studies beyond approval

TABLE 3 Public disclosure methods

Method	Described advantages	Described limitations	References
Print media (newspapers, press releases)	—Can reach large audiences —Can approximate reach	—Expensive —Passive approach —People do not always read them —Often not targeted to specific communities	Salzman (2007)[69] Jacoby (2008)[61] Galbraith (2014)[73] Chin (2015)[54] Matchett (2018)[38]
Broadcast media (radio, TV, public service announcements)	—Can reach large audiences —Can approximate reach	—Expensive —Often not targeted to specific communities	Sazlman (2007)[69] Jacoby (2008)[61] Galbraith (2014)[73] Chin (2015)[54] Holsti (2015)[41]
Social media ads	—Geographic targeting (Facebook ads) —Cheaper than traditional advertising, can increase website traffic	—May only reach certain demographics (younger) —Very little engagement (time spent on websites)	Stephens (2013)[55] Galbraith (2014)[73] Chin (2015)[54] Stephens (2016)[56] Matchett (2018)[38] Harvin (2019)[62]
Websites	—Can measure hit rates —Can facilitate opt-outs —Can provide more detail, multimedia options	—Often short interactions with people who land on sites —Must drive traffic to sites —Limited to individuals with Internet access	Jacoby (2008)[61] Raymond (2010)[59] Galbraith (2014)[73] Chin (2015)[54] Holsti (2015)[41] Matchett (2018)[38]
Individual communication (letters, emails, phone calls)	—Can target specific communities and/or community leaders —Better opportunities to opt out	—Calls and postage are expensive/labor intensive	Morris (2004)[58] Raymond (2010)[59] Galbraith (2014)[73] Chin (2015)[54] Holsti (2015)[41] Matchett (2018)[38]
In-person disclosure	—Can target specific communities (parents for peds studies) —Better opportunities to opt out	—Smaller scale	Raymond (2010)[59] Holsti (2015)[41]
In-hospital materials—posters, brochures	—Can target specific communities (i.e., patients with a specific disease) —Reaches people in the health care system	—Passive method —People often do not notice posters or read brochures	Kremers (1999)[57] Morris (2004)[58] Raymond (2010)[59] Chin (2015)[54] Holsti (2015)[41] O'Malley (2017)[60]
Meetings (presentations or focus groups with hospital staff)	—Inform staff members likely to be involved	—Personnel time and cost	Morris (2004)[58] Raymond (2010)[59]

or protocol design, although one study did explicitly report its use in development of public disclosure plans, and we are aware of an instance in which an additional opt out option was developed in response to community consultation input.[38] These examples, we believe, demonstrate productive ways to harness community input that may be underrecognized.

Areas of debate about community consultation

It remains actively debated whether community consultation efforts should focus primarily on individuals with connections to or at risk for the study condition and the relative importance of involving the general public. Empirical literature frequently reports geographically focused efforts involving the general public. However, there is a theme in conceptual and policy-focused literature that feedback from individuals with connections to conditions under study may be more meaningful and limited evidence that patients enrolled in trials find talking to "people like them" more meaningful.[66] Regarding the "type" of community to be consulted, there can be a false dichotomy between geographic versus condition-related communities; EFIC regulations and guidance recognize that they need not be separate.[2] Moreover, a mixed approach is common.

A related area of debate is whether community consultation should be primarily a quantitatively driven, survey-based process designed to ensure numeric representation or a qualitative, interactive process between researchers and community members.[5,8,10,22,25,28] This debate is primarily about depth versus breadth of engagement and which functions of consultation are most important. If the goal is principally to demonstrate population-level approval, quantitative efforts may

BOX 1 Regulatory Requirements and Federal Guidance Regarding Community Consultation and Public Disclosure

Community Consultation	Regulatory requirement—"Consultation (including, where appropriate, consultation carried out by the IRB) with representatives of the communities in which the clinical investigation will be conducted and from which the subjects will be drawn."[1] Guidance—"Community consultation means providing the opportunity for discussions with, and soliciting opinions from, the community in which the study will take place and the community from which the study subjects will be drawn. These communities may not always be the same; when they are not the same, both communities should be consulted."[2]
Public Disclosure	Regulatory requirement—"Public disclosure to the communities in which the clinical investigation will be conducted and from which the subjects will be drawn, prior to initiation of the clinical investigation, of plans for the investigation and its risks and expected benefits;" *and* "Public disclosure of sufficient information following completion of the clinical investigation to apprise the community and researchers of the study, including the demographic characteristics of the research population, and its results"[1] Guidance—"FDA interprets the term 'public disclosure' to mean dissemination of information (i.e., one-way communication) to the community(ies), the public, and researchers about the emergency research. The goal of public disclosure *prior to initiation of the study* is to provide sufficient information to allow a reasonable assumption that the broader community is aware of the plans for the investigation, its risks and expected benefits (see 21 CFR 50.24(a)(7)(ii)), and the fact that the study will be conducted without obtaining informed consent from most study subjects. The goal of public disclosure *after the study is completed* is to ensure that the communities, the public, and scientific researchers are aware of the study's results."[2]

be viewed more favorably; if the goal is to generate more substantive input on other aspects of a study or to improve understanding of how enrollment may impact potential enrollees, more in-depth approaches are important. The fact that both sets of goals are widely viewed as important is one reason for adoption of multipronged efforts.

Salient for both the choice of method and the population of focus are concerns about underrepresentation of minorities in consultation and considerations of public trust in researchers.[7,30,67] Ensuring representation of minority voices in geographic-based events requires equitable and representative sampling. In more interactive approaches, it means seeking out and consulting with discrete minority groups, especially those who have been traditionally underrepresented, who are socially vulnerable, or who have been targets of past research misconduct. It is, of course, difficult to measure the impact of any particular strategy or set of strategies on public trust, and attitudes likely do not trace to engagement around a single study but rather to longer-term relationships between institutions and communities.

Specific challenges with survey data for community consultation

Survey data are overrepresented in the literature, likely because they are seen as more publishable and easier to synthesize than qualitative data. There are important insights that can be drawn from survey data. One finding is that there appears to be consistency in acceptance across geographic areas and trials.[28,35] This raises questions regarding the incremental value of further large, population-based efforts, particularly given their expense, when baseline attitudes are well understood and methods do not allow for substantial dialogue or interaction. Especially when a site has conducted multiple EFIC trials (testing different interventions) and received similar responses, the yield of repeating similar efforts may be low.

It has also been demonstrated that different phrasing of questions about acceptance yields different results.[27,47,50] The most common and consistent focus has been personal acceptance of EFIC enrollment. There may be reasons to solicit feedback on other domains, but prioritizing personal acceptance facilitates comparison with other studies, is straightforward for participants, and is a question that participants may feel comfortable answering. Questions about attitudes toward a study being conducted within a community, in contrast, are difficult to interpret. In general, greater uniformity in phrasing and focus would facilitate cross-site comparisons of data. This may be valuable for central IRBs in the context of multisite trials and for individual sites in understanding whether new trials raise distinct concerns.

Lingering uncertainty about public disclosure

Public disclosure has been less a focus of scholarly work but raises important ethical and practical challenges. The clearest themes within the literature are that there are many ways to conduct it and that awareness of EFIC studies is low despite extensive disclosure campaigns. [42,61,63] Unfortunately, the literature reflects an underdeveloped sense of key goals, and there are no standards or benchmarks by which investigators or IRBs assess adequacy. It seems appropriate to treat the requirement as requiring a "good faith effort" to be transparent. This avoids secrecy, displays respect, may

facilitate trust, and may educate the community about research. It also may serve as a sort of mirror for research teams by forcing them to consider how their trials may be perceived. However, greater clarification is needed regarding what constitutes a "good-faith effort" and how best to convey respect and promote trust.

Practical steps and future directions

As part of our work within the SIREN Network, we have created peer-to-peer guidance in the form of a set of EFIC model operating procedures (MOP) informed by the results of this review and input from a broad group of experts and stakeholders.[68] This publicly available MOP may be used by investigators and IRBs in developing approaches for future studies. It includes an example EFIC implementation plan and advice regarding community consultation and public disclosure, including advantages and limitations of different types of activities in varying settings. We encourage other networks and investigators to share experiences and processes as well.

Several areas of community consultation and public disclosure are ripe for future studies. First, defining what type of community input is most meaningful in different contexts may help investigators and IRBs make determinations of when consultation efforts are sufficient and how to elicit feedback. Second, there is growing use of social media for both consultation and disclosure, and there is a need for data regarding the most meaningful use of evolving platforms. Use of these methods has grown in the context of the COVID-19 pandemic, and it is important to learn from this experience. Third, studying the role of community consultation in addressing issues beyond acceptability is important. It may, for example, facilitate development of disclosure strategies or identify ways to improve communication with patients and families after enrollment. Finally, studying the impact of engagement efforts within populations over time is important.

Specific implications for central IRBs

A change in recent years has been the growing role of central IRBs. Community consultation and public disclosure are aspects of local context, and optimal strategies for central review of local context are emerging. The presence of varied interpretations of these requirements and methods of meeting them suggest that coordination between central IRBs and local sites may be important and potentially challenging. On the other hand, central IRB review may promote growth of shared norms and comparisons of approaches and feedback, attenuating differences across sites.

LIMITATIONS

This review is limited to published literature. Community consultation feedback is often only reported to IRBs and not published. Related, this review likely over-represents survey data, because quantitative reports are more often submitted for publication, and publication bias may exist. Similarly, the impact of consultation feedback on trials may be under-reported or narrowly reported. Data from public disclosure efforts are even more limited. We encourage reporting of experiences with both community consultation and public disclosure. The platform of central IRB review, in which single boards will see consultation and disclosure data from multiple sites, may provide a meaningful way to facilitate important comparative assessments.

CONCLUSIONS

Accumulated experience with and reflection on community consultation and public disclosure for EFIC research offer guidance moving forward. Neither requirement poses an insurmountable barrier to EFIC trials. There are multiple ways to accomplish both activities, and both serve multiple purposes. Investigators and IRBs must continue to consider each protocol and setting in order to assess the most suitable approaches to engagement. However, clarifying norms could be helpful in two areas. First, there are no settled norms regarding assessments of adequacy and extensiveness of public disclosure. Second, there is a lingering debate about needed breadth, depth, and focus of community consultation. Clarity on these issues will be important for, and may be facilitated by, central IRB review.

ACKNOWLEDGMENTS

The authors thank Hannah Rogers for assistance developing and executing the search and participants in a sponsored workshop of experts related to EFIC for their insights on these topics.

CONFLICT OF INTEREST

The authors' institutions receive funding from NIH. ND reports research funding from AHRQ and the Greenwall Foundation. The other authors have no potential conflicts to disclose.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

How to cite this article: Dickert NW, Metz K, Fetters MD, et al. Meeting unique requirements: Community consultation and public disclosure for research in emergency setting using exception from informed consent. *Acad Emerg Med*. 2021;28:1183–1194. https://doi.org/10.1111/acem.14264