E&R

An Approach to Reviewing Local Context for Exception from Informed Consent Trials Using a Single IRB

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Appendix 1.
Designing a Plan for
Community Consultation and Public Disclosure in EFIC Studies

Background and Objectives

The purpose of this guidance is to provide an outline for drafting a community consultation and public disclosure plan for multi-site studies that include an exception from informed consent (EFIC). Requirements for EFIC are described in 21 CFR 50.24 (FDA-regulated studies) and Federal Register, Vol. 61, pp. 51531-51533 (non-FDA-regulated studies). This guidance does not provide a full accounting of the requirements of community consultation and public disclosure.

Investigators must review the FDA's community consultation and public disclosure guidance for complete information: FDA Guidance, April 2013: Exception from Informed Consent Requirements for Emergency Research.

Investigators at each research site are required to complete community consultation and public disclosure activities prior to enrolling participants into the study. The goals of community consultation are as follows:

- Ensure that all relevant communities have opportunity for input into the IRB's decision-making process before initiation of the study.
- Present information so that community members understand the proposed investigation, understand its risks and benefits.
- Ensure community members understand that the investigation will take place without informed consent.

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, 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.

Requirements for the Lead Study Team

It is the responsibility of the lead study team to design a protocol-level community consultation and public disclosure plan that can be used at each of the participating study locations. The plan must take into account the nature of the participant population overall as well as primary differences in the community and resources at the participating locations. Though the lead study team is not responsible for executing the community consultation and public disclosure plan at each participating location, the protocol-level plan provides an organized framework that participating locations can apply.

The protocol-level study plan must include a variety of passive and interactive consultation and disclosure methods and study-specific supporting materials. The plan must include specific justification for how each method can appropriately notify and solicit feedback from the participant population and the community. Study-specific supporting materials should be made available to the participating locations.

Interactive methods may include the following:

- Standing meetings, such as local civic public forums, may be better attended because such meetings are already on community members' calendars.
- Public community meetings or other special meetings specifically organized to discuss the research. Such meetings may be valuable in attracting participation from individuals with strong interest in the research, e.g., patient support groups, clinicians, IRB members, etc.
- Local radio and/or television talk shows. Such programs allow viewers to "call in" to express their views and concerns.
- Interactive websites, social media, focus groups, and surveys.

Passive methods may include the following:

- Targeted mailings to households in the communities, with information about how to obtain further details.
- Advertisements and articles in the English language, and if appropriate, foreign language, newspapers. (Public outreach documents should be translated into languages that are common in the area served by the facility where the investigation is being conducted and in the communities from which subjects will be drawn).
- Clearly marked links and information on the sponsor's and participating hospitals' Internet websites.
- Summary materials that are accessible to non-English speaking or homeless populations who reside in the community from which research subjects are likely to be drawn.
- Presentation or distribution of information at meetings of community, local government, civic, or patient advocacy groups.
- Letters to local and regional community leaders and first responders (e.g., police, paramedics).
- Announcements to local/regional hospital staff(s).
- Public service announcements and interviews or discussions on "talk" radio or television programs.
- Press conferences and briefings.
- Meetings or activities provided by hospitals' and institutions' existing community outreach programs.

The plan must also describe the general content that will be presented during the community consultation activities. Study-specific materials developed for community consultation should reflect this general content as well. General content should include the following information:

- A summary of the research protocol, study design, and a description of the procedures to be followed, including the identification of any procedures which are experimental.
- A summary of other available treatment options and what is known about their risks and benefits.
- An estimate of how long the study will last and expected duration of the subject's participation.
- How potential study subjects will be identified.
- Information about the test article's use, including a balanced description of the risks and expected benefits and any relevant information that is known about adverse events.
- A clear statement that prospective informed consent will not be obtained for most research subjects.
- The rationale as to why the study must be conducted using an exception from informed consent.
- A copy of the informed consent document.

- Relevant information that would be part of the informed consent process (21 CFR 50.25(a) and (b), as applicable), e.g., available treatments for the condition under study; risks/potential benefits of participating in the research; possibility that FDA might inspect the subject's records.
- A description of the therapeutic window, during which the test article must administered, and the portion of that window that will be used to contact the subject's LAR.
- A description of the attempts that will be made to contact the subject's LAR to obtain consent, or, if no LAR is available, a family member to provide an opportunity to object to the subject's enrollment in the study, both before and after the test article is administered.
- A description of the way(s) in which an individual may express his/her desire not to participate and avoid involvement as a subject in the research (e.g., opt-out mechanisms), if any will be made available.
- Reasons why community input is important.
- Known community perceptions/concerns associated with the study, product, and/or standard of care.
- Identification of individuals to contact for more information about the study.

Requirements for the Participating Study Teams

It is the responsibility of the participating study teams to use the protocol-level community consultation and public disclosure plan to design and implement a site-specific plan. The site must use methods prepared in the protocol-level plan; however, a subset of the methods can be used, as all methods may not be appropriate for the site. The participating study teams must select the passive and interactive consultation and disclosure methods that are most appropriate and feasible for implementation at the site. The site-specific plan must describe how the selected methods will be executed and justification for how each method can appropriately notify and solicit feedback from the participant population and the community.

The site-specific plan must address the needs of the site's participant population and community, which many include the following:

- Cultural, demographic, geographic, and economic considerations
- Languages and local educational and/or literacy concerns
- Religious, social, and political considerations

In addition to the site-specific written plan, the participating study teams must complete the Participating Site Community Snapshot Worksheet, which will help the study teams identify and describe the composition of the community.

In preparing to execute the site-specific plan, the participating study teams must also be prepared to collect data regarding the results and feedback provided through community consultation and disclosure methods. The plan must include a description of how the participating study team will collect and report on this data. For more information, participating study teams should consult the guidance for **Community Consultation and Disclosure Data Collection Expectations**.

Appendix 2.
Participating Site Community Profile Worksheet

***Instructions to Participating Site**: Please complete the information below and return this form to the study Lead PI. Provide information about your local community as it may relate to a research study where an exception from informed consent (EFIC) waiver for emergency research would be used.*

Title of Study	
Name of Participating Site	
Participating Site Contact	

A. Cultural, demographic, geographic, and economic considerations:

- What is the anticipated geographic area that participants may be recruited from at your site?
  - What is the ratio of rural to suburban to urban populations in this geographic area?
- Do you have any minority populations that should be considered?
- Do you have any particular populations of affluence or poverty that may require special methods of outreach in order to inform them about the research?
- How would you describe your community's access to healthcare and awareness of existing clinical research efforts in the area?

B. Languages and local educational and/or literacy concerns:

- Does your site have a large non-English speaking population?
  - If yes, what languages?

C. Religious, social, and political considerations:

- What are the predominant religions in your area? Do they have any beliefs that may affect their willingness to participate in research or to accept an EFIC model?
- Has your community experienced any major events (i.e. local/national tragedies, heated social or political issues, etc.) that may require added sensitivity when considering an appropriate community consultation plan for this study?
- What are the dominant political inclinations of your community?

D. Are there populations being targeted by this study that may be more likely to be enrolled than others?

- Are there specific patient populations affected by this research that should be specifically consulted?
- Are recruitment procedures designed to ensure a representative sample of participants?
- Will certain disadvantaged or vulnerable groups be over or under represented?
- Will potential risks and benefits be reasonably distributed across the community as a whole?

E. Other considerations:

- Overall, is this research appropriate for your community?
- Do you have additional information to provide the IRB?

Appendix 3.
Community Consultation and Disclosure
Data Collection Expectations for EFIC Studies

Background and Instructions

When determining whether the community consultation and disclosure process is adequate for an EFIC study, the IRB must consider the community's opinions and concerns, assess the adequacy of the consultation and disclosure process, and incorporate the results of community consultation and discussion into its decision-making.

The IRB may wish to directly hear the community discussions and concerns expressed in those discussions, and not rely solely on summary documentation by the clinical investigator or feedback reported by others, so it is recommended that community discussions be recorded in some way, and that community members be informed that the minutes and/or audio/video recordings of discussions may be reviewed by the IRB.

The lead and participating study teams conducting consultation and disclosure procedures must provide the IRB with the results of the process in a Community Consultation and Disclosure Report. Quantitative results are helpful, but qualitative information is also requested. The lead study team must compile the results reports from each participating study team and add an executive summary for submission to the IRB.

Data Collection Expectations

Interactive Consultation Methods
For example, live events, standing meetings such as local civic public forums, public community meetings or other special meetings specifically organized to discuss the research, focus groups and surveys, and local radio and/or television talk shows: ☐ Date, time, and location of event, if applicable ☐ Information presented by the study team and the length of the presentation ☐ Number of community members in attendance ☐ Responses to survey/focus group questions, if applicable ☐ Amount of time allotted for community questions and feedback ☐ Questions or concerns raised by community members (grouped by common themes), if applicable o How were questions or concerns from the audience collected? How were questions or concerns from the audience addressed? What were the outcomes of these discussions?

Passive Methods
For example, mailings, websites, fliers, letters, announcements, press conference briefings, advertisements, newsletters, etc.: ☐ Date information was made public ☐ Location(s) the information was posted or sent ☐ Questions or concerns raised by community members (grouped by common themes), if applicable o How were questions or concerns from the audience collected? How were questions or concerns from the audience addressed? What were the outcomes of these discussions?

Appendix 4.
Who Can Be an HRPP Reviewer?

Background

As part of the process for an IRB to consider an exception from informed consent (EFIC) for a research study, the IRB must review and approve a community consultation (CC) plan for each site engaging in the research.

When the <<name of sIRB>> is the single IRB (sIRB) for a study that plans to employ EFIC, we employ the human research protection (HRP) program or office to help us determine whether the site investigator's CC plan is appropriate for your local population. We provide the HRP Reviewer with a copy of the CC plan, the study protocol, and we ask the HRP Reviewer to provide feedback and recommendations to the sIRB regarding the plan for their community.

Selecting an HRP Reviewer for Your Site

We rely on the HRP representative(s) at each site to select an appropriate HRP Reviewer for the EFIC CC Plan. Your HRP Reviewer should be someone very familiar with the FDA requirements relating to EFIC and community consultation. In addition, the HRP Reviewer can be someone who:

- Is very familiar with the local community under study
- Is willing to provide prompt and detailed feedback on whether or not the CC plan is appropriate for your site, including suggestions/recommendations for improvements/enhancements to the plan
- Works for or has significant experience working with the IRB at the site
- Has experience serving as an advocate for research participants
- Has served on an IRB as a scientist or non-scientist representative, preferably one familiar with the state laws and requirements of the participating site
- Feels comfortable representing/advocating for the interests of the participating community

Points to Consider

There are several things we will ask the HRP Reviewer to provide feedback on relating to the EFIC protocol. Some of the items to consider include:

1. Does the CC plan appropriately provide information to the majority of the community under study? Are there other or better ways to reach the subject pool?
2. Have all appropriate groups/populations been considered for outreach?
3. Are there conversational methods of consultation included that will allow the investigator(s) to hear and respond to the community?
4. If applicable, is there an appropriate method employed in which individuals who wish to be excluded from the research may do so (e.g. opt-out mechanisms)?
5. Will the consultation methods planned be adequate and effective for reaching the target community?
6. Are the consultation methods feasible at your institution or in your community? Can they be effectively deployed as described in the CC plan?
7. Will the proposed plan satisfy the requirements for community consultation as described in FDA guidance?

What about Public Disclosure?

In most cases, a robust and appropriate CC plan will provide the SIRB with enough insight into how to engage the site community that a Public Disclosure (PD) plan can be assessed without detailed input from sources outside the study team. However, if the HRP Reviewer has suggestions or recommendations regarding the PD plan for their local community, please feel free to send those along with your CC plan review.

References

"Exception from Informed Consent Requirements for Emergency Research, Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors," April 2013 version, accessed November 18, 2019, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/exception-informed-consent-requirements-emergency-research.

Exception from Informed Consent (EFIC) & Planned Emergency Research, https://irb.utah.edu/guidelines/efic/index.php

Informed Consent Requirements in Emergency Research, accessed November 18, 2019, https://www.hhs.gov/ohrp/regulations-and-policy/guidance/emergency-research-informed-consent-requirements/index.html.

21 C.F.R. 50.24, Exception from Informed Consent Requirements for Emergency Research, accessed November 18, 2019, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.24.

Appendix 5.
EFIC HRP Reviewer Worksheet

Section 1 of 8

Background

The purpose of this worksheet is to provide the SIRB with insight into your local community and to provide recommendations to help the SIRB make an informed decision regarding the community consultation plan for your local site.

You should have received a copy of your site investigator's proposed community consultation plan for a study that would like an Exception from Informed Consent (EFIC) for emergency research. In preparation for this review, we recommend you read the FDA's guidance on this topic at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/exception-informed-consent-requirements-emergency-research.

All final determinations relevant to the approval of this study will be made by the SIRB, so the role of the HRP Reviewer is to provide site-specific recommendations for the community consultation period of this study.

HRP Reviewers must not have a conflict of interest (personal, financial, academic or other interest) in reviewing this community consultation plan that would prevent them from providing fair and objective recommendations.

Click "Continue" →

Section 2 of 8

EFIC HRP Reviewer and Site Information Worksheet

First Name*
Short answer text

Last Name*
Short answer text

Title*
Short answer text

Institutional Affiliation*
Short answer text

Email Address*
Short answer text

Telephone Number*
Short answer text

May the SIRB contact you to follow up if additional information is needed relating to your review of this Community Consultation Plan?
[Yes/No]

Click "Continue" →

Section 3 of 8

EFIC HRP Reviewer Statement of Assurance

I understand that my role is to provide the SIRB with insight into my local community and to provide recommendations to help the SIRB make an informed decision regarding the community consultation plan for my local site.

I understand that all final determinations relevant to the approval of this study will be made by the University of Utah IRB, and that I am serving as an ad hoc consultant to provide site-specific recommendations for the community consultation period of this study.

I do not have a conflict of interest (personal, financial, academic or other interest) in reviewing this community consultation plan that would prevent me from providing fair and objective recommendations.

If you agree with the above statement, please select "Yes" below and continue.
[Yes, I agree/No]

Click "Continue" →

Section 4 of 8

Cultural, Demographic, Geographic, and Economic Considerations

Please provide information about your local community as it may relate to a research study where an Exception from Informed Consent (EFIC) for emergency research may occur.

4.1 What is the anticipated geographic area that participants may be recruited from at your site?
Short answer text

4.2 What is the ratio of rural to suburban to urban populations in this geographic area?
Short answer text

4.3 Do you have any minority or underserved populations that should be considered?
Yes/No

4.4 Do you have any particular populations of affluence or poverty that may require special methods of outreach in order to inform them about the research?

Yes/No

4.5 How would you describe your community's access to healthcare and awareness of existing clinical research efforts in the area?

Long answer text

4.6 Please provide more information about your responses above, if needed.

Long answer text

Click "Continue" →

Section 5 of 8

Languages and Local Educational and/or Literary Concerns

Please provide information about your local community as it may relate to a research study where an Exception from Informed Consent (EFIC) for emergency research may occur.

5.1 Does your site have a significant non-English speaking population?
Yes/No

5.2 If yes, what languages?

Long answer text

5.3 Please provide more information about your responses above, if needed.

Long answer text

Click "Continue" →

Section 6 of 8

Religious, Social, and Political Considerations

Please provide information about your local community as it may relate to a research study where an Exception from Informed Consent (EFIC) for emergency research may occur.

6.1 What are the predominant religions in your area? Do they have any beliefs that may affect their willingness to participate in research or to accept an EFIC model?

Short answer text

6.2 Has your community experienced any major events (i.e. local/national tragedies, heated social or political issues, etc.) that may require added sensitivity when considering an appropriate community consultation plan for this study?
Yes/No

6.3 What are the dominant political inclinations of your community?

Short answer text

6.4 Please provide more information about your responses above, if needed.

Long answer text

Click "Continue" →

Section 7 of 8

Subject Selection

Please provide information about your local community as it may relate to a research study where an Exception from Informed Consent (EFIC) for emergency research may occur.

7.1 Are there populations being targeted by this study that may be more likely to be enrolled than others?
Yes/No

7.2 Are recruitment procedures designed to ensure a representative sample of participants?
Yes/No

7.3 Will certain disadvantaged or vulnerable groups be over or under represented?
Yes/No

7.4 Please provide more information about your responses above, if needed.

Long answer text

Click "Continue" →

Section 8 of 8

Community Consultation Plan Criteria

Please answer each question with respect to the proposed Community Consultation and Public Disclosure activities proposed at your local site.

8.1 Please provide a brief description of your understanding of your site's community consultation plan, as well as any thoughts, questions, or concerns your may have relating to the proposed plan.

Long answer text

8.2 Are the proposed community consultation methods based on appropriate factors such as the size of the communities, the languages spoken within those communities, and the targeted research population and the heterogeneity of the population?
Yes/No/N/A

8.3 Do the proposed Community Consultation materials include an accurate representation of the risks and benefits of the project, as well as a clear indication that the study procedures will take place without initial direct informed consent from individual participants and/or Legally Authorized Representatives?
Yes/No/N/A

8.4 Does the proposed Community Consultation Plan include adequate methods for participants to exclude themselves from participation?
Yes/No/N/A

8.5 Does the proposed Community Consultation Plan include methods for receiving and incorporating feedback from the community into the research protocol?
Yes/No/N/A

8.6 Does the proposed Public Disclosure plan include adequate methods for dissemination of information after the investigation is completed so that communities and scientific researchers are aware of the study results?
Yes/No/N/A

8.7 Overall, is this research appropriate for this community?
Yes/No/N/A

8.8 Please provide more information about your responses above, or any additional information to provide to the IRB, if needed.
Long answer text

Click "Continue" →