



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:

- To ensure that all relevant communities have opportunity for input into the IRB's decision-making process before initiation of the study
- To present information so that community members understand the proposed investigation, understand its risks and benefits.
- To be sure 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 web sites.
- 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 including 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.



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- 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

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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 University of Utah's guidance for **Community Consultation and Disclosure Data Collection Expectations**.

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