



Where the world comes for answers

Effective 1/1/2023  
Next Review 1/1/2026

Owner Susan Kornetsky:  
Manager  
Department Research  
Applicability Boston Children's  
Hospital- Policies  
& Procedures

# Community Consultation and Public Disclosure for Exception from Informed Consent Research (EFIC) Policy/ Procedure

## Internal Approval

SVP, Research

EVP & Chief Scientific Officer, Research

## Scope

The purpose of this policy is to provide guidance, ethical principles, definitions, objectives and institutional requirements concerning community consultation and public disclosure for studies that include an Exception From Informed Consent (EFIC) at Boston Children's Hospital.

## Definitions

	Description	Objectives
<b>Community Consultation</b>	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. *Note <u>community</u> as defined below.	Inform the community in advance of the study and allow the community to provide meaningful feedback to the IRB before to consider during IRB review Respectfully acknowledge community representatives to identify community-level concerns and potential consequences.
<b>Public Disclosure</b>	Dissemination of information to community(ies), the public, hospital care	<b>Prior to study initiation:</b> Provide sufficient information so that the broader

	providers and researchers.	community is aware of the study plans, risks and benefits, and that informed consent will not occur with most study participants. <b>Post-study completion:</b> Ensure communities, researchers, and public are aware of study results Provide a mechanism for potential subjects in the communities to opt out of the research.
--	----------------------------	--

Per [U.S. Food & Drug Administration \(FDA\) guidance](#), **community** can be defined in two ways:

1. **Community from which subjects are drawn:** The group of patients who share a particular medical or other characteristic that increases the likelihood that they (or a family member) may be enrolled in the study.
2. **Community in which the research is conducted:** Geographic area (i.e., hospital or other facility, city, region), where the hospital or clinical investigator study site is located.

These communities may not always be the same; when they are not the same, both communities should be consulted. In defining community consideration should be given to consideration of demographics such as age, race, ethnicity, gender, economic status, cultural values, religious beliefs, customs and identity.

## Policy Statements

Boston Children's Hospital will follow all regulatory requirements described in 21 CFR 50.24 for 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. For expanded guidance see: the [FDA's Exception from Informed Consent Requirements for Emergency Research](#).

In addition, Institutional leadership will be informed about any studies requiring community consultation and public disclosure and have the opportunity to add requirements above and beyond those approved by the Institutional Review Board (IRB).

## Procedures

### How do Community Consultation and Public Disclosure differ?

**Community consultation** occurs before the IRB has made a decision about approval and includes discussions/dialogues with a community group and representative(s).

**Public Disclosure** occurs before study initiation, during the research and upon completion, and is the process which information is provided to the community(ies).

# Ethical Principles and Expectations of Community Consultation and Public Disclosure

The Belmont reports provides a basis for the ethical principles that need to be considered for all research. The consideration of justice/equitable selection is one of the ethical requirements. In addition, for the purposes of EFIC we describe other requirements to consider that include representation, accessibility and resources as they apply to community consultation and public disclosure. Investigators must consider possible biases and disparate impacts and address these in plans for community consultation and public disclosure.

## EFIC-specific expectations:

1. Justice/Equitable selection
  - a. Consideration needs to be given to who ought to receive the benefits of research and bear its burdens.
  - b. There are moral requirements that there be fair procedures and outcomes in the selection of research subjects.
  - c. An injustice occurs when some benefit (such as potential inclusion in research) to which a person is entitled is denied without good reason.
2. Representation
  - a. Potential patient population must be clearly understood in order to define the community and establish appropriate mechanisms for consultation and awareness
  - b. Representation includes an understanding about cultural, demographic, geographic, economic, language, and local educational and/or literacy, religious, social, and political considerations including any concerns. Once defined, representatives may be approached about the community consultation and informed during public disclosure.
3. Accessibility
  - a. Efforts and plans to obtain community consultation and provide public disclosure must consider population-specific needs, issues, and challenges, including those related to access to information and barriers to research participation.
  - b. Methods of community consultation and public disclosure should be appropriately matched to the community involved. Communities may access information by different means. For example, postings about the research in a community location may be more appropriate than the hospital social media outlets depending on the community. The IRB will require plans for community consultation and public disclosure that include:
    - i. Interactive methods that may include public community meetings, focus groups, local television, interactive websites, etc. **AND**
    - ii. Passive methods include targeted mailings, advertisements, announcements, postings etc.

#### 4. Resources

- a. Investigators seeking to conduct research under EFIC must plan for the resources, expertise and staffing needed to successfully complete community consultation and public disclosure.
- b. The IRB will require the investigator develop a plan for translation of materials used during community consultation and public disclosure as applicable for the population under study.
- c. While availability of resources and time commitment may be a consideration, they must not be a limiting factor in assuring that the plans meet all ethical requirements and are performed in accordance with these principles.
- d. Investigators should also utilize the expertise and resources within the Boston Children's Hospital community for assistance

## Development of Community Consultation and Public Disclosure Plan

The demographic representation of the potential patient populations must be clearly understood so that representatives for the populations may be approached for community consultation and informed during public disclosure. Community consultation efforts and public disclosure plans must be responsive to specific community values and concerns and ensure that materials are culturally and linguistically appropriate for the populations. The following describes the responsibilities of the investigator and IRB in upholding all ethical and regulatory requirements.

### Principal Investigators

1. The Principal Investigator is responsible for developing a protocol specific community consultation and public disclosure plan.
2. The plan must address the principles and expectations noted above.
3. The plan must include specific justification for how each method can appropriately notify and solicit feedback from the community.
4. The written plan for community consultation and public disclosure should be summarized in the protocol and the EFIC Supplemental form.
5. In addition to developing the written plan, the Principal Investigator must complete the Community Snapshot Worksheet. This form is designed to provide detailed information on the community from which the subjects will be drawn and where the study will be implemented. The form requires the investigator document how the plan meets the principles and expectations noted above.
6. When the protocol will be conducted at multiple sites, the Lead Principal Investigator must develop the protocol-level community consultation and public disclosure plan that can be used at each of the participating study locations. The Relying Site PI will be responsible for developing the site-specific plan.
7. The Community Consultation and Public Disclosure Plan must include a variety of passive and

interactive methods. Refer to [Appendix A: Possible Community Consultation and Public Disclosure Methods.](#)

8. All materials used during Community Consultation and Public Disclosure must be submitted to the IRB. This includes but is not limited to printed material, PowerPoint presentations, interview/focus guides, presentation and other informational material developed for social media.
9. The Principal Investigator is expected to review [FDA Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors on EFIC,](#) specifically, section VIII Community Consultation and Section IX Public Disclosure.
10. The IRB requires that for all interactive methods the Principal Investigator collect demographic data on the individuals who attended or participated. Refer to [Appendix B: Data Collection Expectation.](#)

## IRB Review of Community Consultation and Public Disclosure Plan

1. The community consultation and public disclosure plan must be reviewed and approved by the full board before implementation.
2. In addition to ensuring the plan meets all regulatory requirements ((21 CFR 50.24), the IRB will require documentation that the plan meets the principles and expectations noted above.
3. The Principal Investigator must prepare a written report of the results of community consultation.
4. The plan will be evaluated on its ability to reach a reasonable sample from the target communities as outlined in the Community Snapshot Worksheet.
5. In order to find and document that community consultation has occurred, as required in 21 CFR 50.24(a)(7)(i), the IRB must determine whether meaningful feedback was secured from the community.
6. The IRB must also consider the community concerns and incorporate the feedback, as appropriate, into its review of the protocol and informed consent document with documentation in the minutes.
7. The IRB may request changes to the protocol and/or informed consent in response to community consultation, determine additional community consultation is needed or, if the community raises strenuous objections and concerns, the IRB may decide that the study should not be performed in that community.
8. Ultimately when the community consultation and public disclosure has been completed, the IRB must approve that community consultation/public disclosure has been 'adequate.' 'Adequacy' generally means that an acceptable number of individuals from the communities will directly participate in consultation activities and be made aware through public disclosure. The results of the community consultation will be taken into consideration as a basis for approving the research. The IRB must be confident that the community consulted values the importance of the research and supports it being allowed to proceed.

All community consultation and public disclosure efforts are subject to additional approval and oversight

by institutional leadership as deemed necessary. Institutional leadership may add additional requirements but cannot eliminate or lessen what the IRB approved as necessary.

## Appendix A & B

### Appendix A: Possible Community Consultation and Public Disclosure Methods

Interactive methods may include the following:

1. Standing meetings, such as local civic public forums, may be better attended because such meetings are already on community members' calendars.
2. 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).
3. Local radio and/or television talk shows. Such programs allow viewers to "call in" to express their views and concerns.
4. Interactive websites and social media
5. Focus groups and in-depth interviews
6. Surveys, questionnaires

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.

# Appendix B: Data Collection Expectation

## Interactive Consultation Methods

1. Demographic information of attendees
2. Date, time, and location of event, if applicable
3. Information presented by the study team and the length of the presentation Number of community members in attendance
4. Responses to survey/focus group questions, if applicable
5. Amount of time allotted for community questions and feedback
6. Questions or concerns raised by community members (grouped by common themes), if applicable
  - a. How were questions or concerns from the audience collected?
  - b. How were questions or concerns from the audience addressed?
  - c. What were the outcomes of these discussions?

## Passive Consultation Methods

1. Date information was made public
2. Location(s) the information was posted or sent
3. Questions or concerns raised by community members (grouped by common themes), if applicable:
  - a. How were questions or concerns from the audience collected?
  - b. How were questions or concerns from the audience addressed?
  - c. What were the outcomes of these discussions?

## Related Content

- U.S. Food & Drug Administration CFR – Code of Federal Regulations Title 21
  - 21 CFR 50.24: Exception from informed consent requirements for emergency research
- U.S. Food & Drug Administration Guidance
  - [\*\*FDA's Exception from Informed Consent Requirements for Emergency Research\*\*](#)

## Approval Signatures

Step Description

Approver

Date

---

## Applicability

Boston Children's Hospital- Policies & Procedures

COPY