

Emergency Exception from Informed Consent (EFIC) Protocol Preparation Guide

EFIC Protocol Preparation

In your EFIC protocol, be prepared to provide detailed information about each of the additional human protections. These are the minimum requirements outlined in federal guidance.

- EFIC Eligibility
- A Community Consultation Plan
- A Pre-Trial Public Disclosure Plan
 - Including a plan for participants to opt-out of the research, if appropriate
- A Post-Trial Public Disclosure Plan
- A Data and Safety Monitoring Plan

EFIC Eligibility

The investigator must provide rationale for the following requirements:

1. The human subjects are in a life-threatening situation,
 - a. available treatments are unproven or unsatisfactory, and
 - b. the collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions.
2. Obtaining informed consent is not feasible because:
 - a. the subjects will not be able to give their informed consent as a result of their medical condition;
 - b. the intervention involved in the research must be administered before consent from the subjects' legally authorized representatives is feasible; and
 - c. there is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the research.
3. Participation in the research holds out the prospect of direct benefit to the subjects because:
 - a. subjects are facing a life-threatening situation that necessitates intervention;
 - b. appropriate animal and other preclinical studies have been conducted, and the information derived from those studies and related evidence support the potential for the intervention to provide a direct benefit to the individual subjects; and
 - c. risks associated with the research are reasonable in relation to what is known about the medical condition of the potential class of subjects, the risks and benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity.

4. The research could not practicably be carried out without the waiver.
5. The proposed research protocol defines the length of the potential therapeutic window, which is supported by scientific evidence.
6. The investigator must describe prospective informed consent procedures that detail a plan to attempt contact with a legally authorized representative for each subject within the potential therapeutic window; and
 - a. If feasible, obtain consent from the contacted legally authorized representative within that window rather than proceeding without consent.
 - b. Detail a plan to summarize efforts made to contact representatives and make this information available to the IRB at the time of continuing review.
 - c. Provide an informed consent document to be used:
 - i. With subjects or their legally authorized representatives in situations where use of such procedures and documents is feasible.
 - ii. When providing an opportunity for a family member to object to a subject's participation.
7. The investigator must describe informed consent procedures to inform:
 - a. At the earliest feasible opportunity: each participant (or if the participant remains incapacitated, a legally authorized representative of the participant, or if such a representative is not reasonably available, a family member) of:
 - i. the participant's inclusion in the research,
 - ii. the details of the research and
 - iii. other information contained in the informed consent document.
8. The investigator must describe informed consent procedures to inform:
 - a. The participant (or if the participant remains incapacitated, a legally authorized representative of the participant, or if such a representative is not reasonably available, a family member) that he or she may discontinue the participant's participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.
 - i. If a legally authorized representative or family member is told about the research and the participant's condition improves, confirm the participant is also to be informed as soon as feasible.
 - ii. If a participant is entered into research with waived consent and the participant dies before a legally authorized representative or family member can be contacted, confirm information about the research is to be provided to the participant's legally authorized representative or family member, if feasible.

Community Consultation Plan

A community consultation plan should be provided which details plans for consultation with representatives of the communities in which the research will be conducted and from which the subjects will be drawn. This plan should cover:

Targeted Community

1. How the study team plans to provide information to the majority of the community under study, including those with limited English proficiency if they are likely to be included in the research;
2. How the study team plans to identify community groups whose geographic location, illness condition, or other characteristics increase their susceptibility or risk for being involved in the research;
3. How the study team plans to identify group ‘leaders’ who are willing to function as intermediaries for continued communication

Methods

4. Methods of consulting to hear and respond to the community. Acceptable methods may include interactive community meetings, surveys, focus groups, study specific websites, social media, community education sessions, etc.

Opt-Out

5. How the community will be given the opportunity to comment on opt-out mechanisms

If the protocol includes children, the Community Consultation plan should detail plans for outreach to parents of children who would potentially be included and, if appropriate, the children themselves.

Pre-Trial Public Disclosure Plan

Prior to initiation of the research, the community must be informed of the plans for the research and its risks and expected benefits. A pre-trial public disclosure plan should include:

- Strategies for public disclosure to the communities in which the research will be conducted and from which the participants will be drawn;
- Materials (including flyers, ads, etc.) to be used;
- If determined appropriate based on community consultation, details on the mechanism for opting out of the research.

If the protocol includes children, the Public Disclosure plan should detail plans for disclosure to parents of children who would potentially be included and, if appropriate, the children themselves.

Post- Trial Public Disclosure Plan

After the completion of the trial, the community and researchers must be apprised of sufficient information. This should include the demographic characteristics of the research population and the study results. A post-trial public disclosure plan should describe:

- Information to be disclosed
- Strategies for public disclosure;

- Materials (e.g., website to be used;

Data and Safety Monitoring

The study team should submit a data and safety monitoring plan that includes the establishment of an independent data monitoring committee to exercise oversight of the research. Guidance on Data and Safety Monitoring is online here:

<https://irb.upenn.edu/homepage/how-to-submit/initial-submission/submission-completion-guidance/data-and-safety-monitoring/>

References

U.S. Office of Human Research Protections (1996). *Informed Consent Requirements in Emergency Research*. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/emergency-research-informed-consent-requirements/index.html>

Food and Drug Administration (FDA) (2013). *Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research*. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/exception-informed-consent-requirements-emergency-research>