Exception from Informed Consent (EFIC) Checklist: Community Consultation and Public Disclosure

Reviewer: _____ Submission ID: _____

Principal Investigator: _____ Protocol #: _____

Introduction:

Research involving an exception from informed consent (EFIC): Planned FDA-regulated emergency research in which the study intervention is administered to human subjects in a life-threatening situation and obtaining prospective informed consent is not feasible. In lieu of prospective informed consent, EFIC studies require Community Consultation and Public Notification activities before the study may be opened to accrual. These activities must be reviewed and approved by an IRB.

FDA Guidance

This checklist is to be used when COMIRB reviews the Community Consultation and Public Disclosure activities for EFIC research. If an external IRB is responsible for approving the protocol and overseeing the interventional phase of the study, this is the only checklist necessary (see COMIRB Guidance). In that context, COMIRB's role is limited to using our knowledge of our local community and patient population, as well as our previous experience with EFIC research, to ensure that the Community Consultation and Public Disclosure plans and results are adequate and appropriate for this particular study and population.

If COMIRB is also responsible for approving the protocol and overseeing the interventional phase of the study, COMIRB's other standard checklists will also be needed.

Initial Review:

COMIRB's initial review will focus on the specific plans prior to their implementation. COMIRB staff and an IRB Chair should have discussed these plans with the study team prior to the IRB meeting. The IRB may vote to approve the plans as written, request minor modifications, or, if necessary, defer the review of the plans to a subsequent meeting.

1. **Eligible Population:**
   a. Have the communities that are likely to be enrolled in or affected by the research been adequately identified? ☐ Yes ☐ No
      i. If not, what specific information should be provided?

2. **Community Consultation plan:**
   a. Will this plan adequately reach members of the communities that are likely to be enrolled in or affected by the research? Consider underserved or marginalized communities and communities that are likely to object to the research (e.g., non-English speakers, individuals with limited internet access, religious groups, ethnic minority groups, people experiencing homelessness, etc.). ☐ Yes ☐ No
      i. If not, what additional communities, organizations, or outreach should be included?

b. Does the plan include a variety of mechanisms for disseminating information about the research to the communities that are likely to be enrolled in or affected by the research (e.g., focus groups, town halls, online forums, surveys, etc.)? ☐ Yes ☐ No

   i. If not, what additional mechanisms might be suggested?

c. Does the plan include adequate mechanisms to solicit and record feedback from members of the communities that are likely to be enrolled in or affected by the research (e.g., surveys, recordings, meeting minutes, etc.)? In particular, are there means to collect any concerns and objections voiced by the community? ☐ Yes ☐ No

   i. If not, what additional mechanisms might be suggested?

d. Does the plan describe the specific content that will be presented during the Community Consultation activities? ☐ Yes ☐ No

   i. If so, has the study team adequately conveyed the purpose of the research, the rationale for not being able to obtain prospective informed consent, as well as the risks and benefits of the research? ☐ Yes ☐ No

      1. If not, what changes should be suggested?

   ii. If specific content is not yet available, but the general plan is acceptable, the committee can vote to approve the plan and review specific content later as an amendment.

e. Does the plan provide an opportunity for members of the community to opt out of the research (e.g., wrist bands)? ☐ Yes ☐ No

   i. If not, is this acceptable, or should an opt-out mechanism be devised? (Note that it may not be possible to opt-out.) ☐ Yes ☐ No

3. **Public Disclosure plan:**

   a. Will this plan reach a reasonable cross-section of the communities that might be enrolled in or affected by the research? ☐ Yes ☐ No

i. If not, suggest ways in which the study team can broaden public disclosure activities.

b. Does the plan include a variety of strategies for disseminating information about the research to the communities that are likely to be enrolled in or affected by the research (e.g., targeted mailings, newspaper/TV/social media advertisements, PSAs, etc.)? ☐ Yes ☐ No

i. If not, what additional mechanisms might be suggested?

c. Does the plan describe the specific content that will be used for the Public Disclosure activities? ☐ Yes ☐ No

i. If so, has the study team adequately conveyed the purpose of the research, the rationale for not being able to obtain prospective informed consent, as well as the risks and benefits of the research? ☐ Yes ☐ No

1. If not, what changes should be suggested?

ii. If specific content is not yet available, but the general plan is acceptable, the committee can vote to approve the plan and review specific content later as an amendment.

Amendment Review: Reviewing the report of results of Community Consultation and Public Disclosure activities:
COMIRB's review of results focuses on whether the Community Consultation and Public Disclosure activities were implemented as planned, and whether the reported results from the community are sufficient to allow the study to open for accrual. The IRB may vote to accept the results, request minor modifications to the activities, or, if necessary, defer the review of the results to a subsequent meeting. If COMIRB approves this Amendment, the research team may will begin conducting the study in the community.

1. Did the study team conduct the Community Consultation and Public Disclosure activities in accordance with the plan that COMIRB previously approved? ☐ Yes ☐ No

a. If not, did the study team provide an explanation as to why it deviated from the approved plans, and are these deviations acceptable? ☐ Yes ☐ No

i. If not, defer the submission and require that the study team resume these activities, following the plans as approved.

2. Is the report of the community's feedback acceptable? For example, was feedback reported from all targeted communities? Did the community seem generally accepting of the research? ☐ Yes ☐ No

a. If no, identify any concerns. Some level of discomfort or objection to EFIC research is to be expected, so consider the nature and preponderance of objections.

End of Study: Post-intervention Public Disclosure plan:

COMIRB's review of post-intervention Public Disclosure plans focuses on communicating the study results back to the communities affected by or enrolled in the research. If COMIRB agrees that this plan is adequate, the study team may proceed with disseminating this information to the public.

1. Does the Public Disclosure plan adequately reach the communities that were enrolled in or affected by the research? ☐ Yes ☐ No
   a. If not, suggest ways in which the study team can broaden public disclosures.

2. Does the Public Disclosure plan include an adequate variety of mechanisms for disseminating the results of the study? ☐ Yes ☐ No
   a. If not, what additional strategies might be suggested?

3. Does the plan describe the specific content that will be used? ☐ Yes ☐ No
   a. If not, what changes should be suggested?

The Review Recommendation is:

☐ Approved

☐ Approved with Administrative Changes

☐ Minor Modifications Required

☐ Deferred to Full Board

Additional comments (if needed): ☐ See Comments in InfoEd

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Reviewer Signature Date