COMIRB's Involvement in Emergency Research Involving Exception from Informed Consent (EFIC) Overseen by an External IRB

Key Terms:

- *Community Consultation:* a process by which the research team holds discussions with, and solicits opinions from, the community in which the study will take place and/or from which the subjects will be recruited. Community consultation activities may include--but are not limited to—focus groups, presentations at community events, interviews with community leaders, electronic surveys, and other forms of outreach. The goal of this process is to provide the community an opportunity to ask questions, raise concerns, and provide input about the research and the plan to enroll subjects without informed consent.
- *Public Disclosure:* the dissemination of information to the community, the general public, and other researchers and medical professionals about the plan to conduct emergency research under EFIC. This may take the form of social media postings, direct mailings, advertisements (newspaper, TV, radio, online, etc.), press releases, PSAs, news stories, and other forms of mass communication. The goal of public disclosure is to inform as broad a cross-section of the community as appropriate of the research and the intent to enroll subjects without informed consent.

Guidance:

If the University agrees to cede to an external IRB for EFIC research, researchers are also required to obtain approval from COMIRB for the local plans for Community Consultation and Public Disclosure, and for assessment of those activities before the study may be opened for enrollment. COMIRB's role is not to conduct duplicate IRB review. Rather, COMIRB's role is to use our knowledge of our local community and patient population, and our previous experience with EFIC research, to contribute to the Community Consultation and Public Disclosure planning and assessment. COMIRB will do the following:

- Meet with the investigators to discuss plans for Community Consultation and Public Disclosure, and provide input into those plans
- Review and approve those plans at a convened IRB meeting, possibly asking for changes to the plans
- Possibly attend and participate in Community Consultation events
- Review and approve the results of Community Consultation and Public Disclosure activities. COMIRB must approve the results before the study may be opened for accrual.
- Be kept abreast of UAPs, withdrawals, and complaints about the research

- After the study is closed, review and approve the Public Disclosure plans and information before this information is disseminated locally

Meet with COMIRB:

Researchers planning to conduct an EFIC study under review by an external IRB should contact COMIRB as early as possible to discuss these plans. COMIRB leadership and at least one IRB Chair will be available as soon as possible to provide input and guidance. In general, plans should consider the following:

- What constitutes the "community" in the context of this research? Who are the key stakeholders, and how will the research team ensure that its outreach activities reach a sufficiently broad cross-section of the potential subject population?
- How will the research team measure the extent and success of this engagement?
- Is the set of proposed outreach activities diverse, in terms of format, level of interactivity, etc.?
- Will members of the community have an adequate opportunity to provide input/feedback to the study team with regard to the proposed conduct of the study? How will the study team solicit and incorporate that feedback into their plans?
- Will members of the community have an opportunity to "opt-out" of the research, and if so, how will that status be conferred?

In multisite EFIC research, the specific details of these plans may vary from site-to-site. Ideally, the lead site will have provided a list of acceptable activities and templates to guide local study teams. If not, COMIRB can provide advice for developing appropriate plans

This meeting prior to formal submission to COMIRB will streamline the review process.

Submit Community Consultation and Public Disclosure Plans to COMIRB

After consulting with COMIRB, the study team should submit an Initial Application through InfoEd/eRA. The submission should include a copy of the multi-center protocol, consent form, an outline of the Community Consultation and Public Disclosure plans, and any materials that will be provided to members of the community as part of these activities. Researchers do not need to complete a full COMIRB application form and may upload a blank placeholder document in the "Application Form" field.

COMIRB will review these plans at a convened full board meeting. Community Consultation and Public Disclosure activities may commence only after COMIRB and external IRB approval.

Conduct the Community Consultation and Public Disclosure Activities

Investigators are asked to notify COMIRB in advance of Community Consultation events so that COMIRB staff or IRB members may attend. If agreed in advance, COMIRB can also directly participate in events.

Assess Community Consultation and Public Disclosure Activities

After the Community Consultation and Public Disclosure phase, assess the results of the activities. For example, analyze survey or focus group data, summarize comments received form the community, tabulate attendance at events, and document all of the activities that took place. An amendment should be submitted to COMIRB to report on these assessments. The external IRB will also need to review the assessments and if the lead site or lead IRB has a preferred format for reporting the assessments, COMIRB will accept that format.

Enrollment in the research may only begin after COMIRB and external IRB approval of the assessments.

Conduct and Complete the Research

Keep COMIRB abreast Serious Adverse Events, subjects withdrawals, and complaints about the research. These can be reported to COMIRB as UAPs.

After the study is closed, submit an amendment to COMIRB for review of the final Public Disclosure plans and information before this information is disseminated locally.