**Local Context IRB Project: Stakeholder and Key Informant Interview Guide**

Thank you for agreeing to talk with me today.

I am a part of a team of researchers at the University of Michigan. We are interested in understanding the goals and values of Institutional Review Boards (IRB) as they relate to questions of consideration of local context review in multicenter clinical trials, both in general, and especially in Exception from Informed Consent (EFIC) trials. Our goal is to find ways to compare local context review performed by individual site IRBs to the local context review that might be performed by central (single) IRBs. We are talking to you so that your experience and opinion can help inform how we make such comparisons.

1. **Can you tell me your title, role and responsibilities?**
2. **How long have you been in that role?**

**Sensitivity of Local Context Assessment**

**READ:** First I’d like to discuss local review of multicenter clinical trials in general:

1. **What does the requirement for consideration of local context in IRB reviews mean to you?**

**How and when does the IRB look for and consider community input or concerns?**

1. **What values or virtues of the IRB review process are most relevant to why review of local context by an IRB may be important?**
	1. Some examples may be trustworthiness, diligence, transparency, efficiency, prudence, autonomy, acceptability, beneficence, non-maleficence, fidelity, fiduciary, respectfulness. Which, if any, resonates?

**Local context review in Exception from Informed Consent (EFIC) trials**

**READ:** Now, I’d like to talk about a particular type of local context review. Specifically, Exception from Informed Consent for Emergency Research and how Community Consultation is considered by the IRB.

1. **Have you had any experience with trials using Exception from Informed Consent for emergency research (EFIC)?**
	1. If yes, tell me about your experiences with EFIC trials?
2. **What difficulties, if any, have your IRB faced when reviewing EFIC proposals?**
3. **In EFIC trials, what IRB practices influence planning and performing community consultation?**
	1. Tell me about IRB practices that contribute to more effective community consultation.
	2. Tell me about less effective IRB practices related to community consultation.
	3. How does the IRB decide how many events or participants should be planned?
	4. How does the IRB determine whether the plan is sufficiently diverse in outreach?
	5. Does your IRB routinely consult a community advisory board or similar pre-existing community engagement forums with regard to EFIC applications?
	6. Do staff or members of the IRB routinely attend community consultation events themselves?
	7. Does the IRB tend to emphasize quantitative measures of CC or narrative comments and concerns?

**Review and interpretation of community consultation data in EFIC**

1. **How is the community consultation data used during the IRB review?**
	1. How have you observed the community consultation data affect the approval of a trial?
	2. Is community consultation generally helpful? How is it helpful (Improves relationships? Alters decisions? Protects against criticism?)
	3. How do you determine whether data from the community consultation process was sufficiently vetted during the IRB review?
2. **How do you determine whether the focus or breadth of the community consulted was appropriate? (did it sufficiently reach the most relevant community, or a sufficient diversity of community?)**
3. **Is it helpful to know how your local community consultation compares to that performed in other communities (from other research sites)?**
	1. Would it be useful to use others’ results as a kind of benchmark?
	2. Do you think that other communities are basically irrelevant? (If so? Because they are so different? Because focus should only be local?)
	3. Would it be helpful to know how other IRBs have reviewed community consultation elsewhere?

**Closing Questions**

1. **Have you had any specific experiences in which the review of local context was very important to protecting human subjects?**
2. **Have you had any specific experiences in which your local IRB review of local context could clearly not have been performed by a central (single) IRB?**
3. **Is there anything else that you want to share about these issues? Are there other relevant questions that you think we should have asked?**
4. **Based on your experience and insights, who else should we interview?**

**Thank you!**