CTTI Central IRB Project: Stakeholder Interview Guide

Introduction

- Interviewer(s)
  My name is [name], and I'm [title/role] in [department] at [institution].

- Research purpose
  The Clinical Trials Transformation Initiative (CTTI) is a public-private partnership seeking to increase the quality and efficiency of clinical trials. We are conducting these interviews as part of a CTTI project aimed at identifying barriers to the adoption of centralized IRB review for multicenter clinical trials, as well as potential solutions to obviate these barriers.

- What's expected from participant
  Today's interview will take about 45 minutes. Is this still a good time for you? Did you receive the study information sheet (verbal consent form) that was sent?

Review of verbal consent form

- Have you had a chance to review the verbal consent form?
  - *If yes:* Do you have any questions about the study?
  - *If hasn't received:* Would you like me to email you a copy? I can also read it to you now.
  - *If hasn't reviewed:* Let's review it together now then.
- Do you agree to participate?

- Also, have you received the document Devon sent you, entitled "Considerations in Assigning Responsibilities to a Central IRB and a Local Institution for Multicenter Clinical Trials?" It will be helpful to have that on hand for some of the questions I'll ask you in the interview.
- Is it okay if I record our conversation for transcription and analysis purposes?
  - *If no, do not record. Take notes on conversation instead.*
- Okay, let's get started then. I am going to start the recording, state your ID number and date, and then get your consent on the recording. Are there any other questions about the study or this interview that I can answer before we begin?

BEGIN RECORDING

Today is Month Day, 2012 and I am speaking with ID #s XXXXX, XXXXX, and XXXXX. Do you agree to participate in this research? Is it okay if I record our interview?

I'd like to hear your opinions about several concerns that might serve as barriers to the adoption of centralized review for multicenter clinical trials. I'll also present some potential solutions to obviate those barriers for your consideration and feedback. Your specific expertise may lend itself to certain topics over others. If you have no opinion or comments about any specific question, please just let us know. To start, I want to make it clear that when we are talking about centralized review, we are considering only the context of multicenter clinical trials. We are

defining centralized review as use of a single IRB-of-record for a given multicenter protocol. That is, the central IRB assumes all regulatory responsibility for assuring the protection of the rights and welfare of research participants from initial review to termination of the research, including review and approval of informed consent.

Before we get to that, I'd just like to note that the results of this research will be going to a pretty broad audience, so I might ask you to explain some points that may seem a bit obvious.

First, I'd like to hear about any general thoughts or concerns you might have concerning the central IRB model.

[*If interviewee mentions administrative concerns, start with the questions below. If comments more related to legal/regulatory concerns, start with that section.*]

Now I'd like to first hear your thoughts about some specific administrative concerns.

Administrative barriers	**Potential solutions to obviate the barrier**
Individuals working in institutions have expressed concerns about the feasibility of working with multiple outside IRBs, each requiring different forms and/or electronic systems to submit a protocol. Is this a concern for you or your institution? • Why/why not?	• What if an attempt was made to standardize and/or reduce the information required for these forms? • Would this help to alleviate some of the administrative obstacles associated with accepting central IRB review? • Why/why not? • Do you have any other ideas for how to address this barrier?
Many research institutions who support their own IRB have raised concern over the loss of revenue generated from fees for institutional IRB review of studies with commercial sponsors, as this revenue is often used to cover institutional costs of IRB infrastructure, sending IRB members to conferences, etc. • Is this a concern for you or your institution? • Why/why not?	• If the institution conducting the research could recover from the study sponsor a separate fee for their local institutional costs involved in assuring such things as the adequacy of facilities, the training and competency of investigators, and patient privacy related to the protocol undergoing central review, would this be sufficient to address this concern? • At your institution, do you think it would be feasible to cover fixed costs for the IRB in another way? (For example, by negotiating with the Dean to convince him/her that it is an institutional responsibility to make sure the IRB runs well.)

Now let's talk about some perceived regulatory and legal barriers to centralized review.

Legal/Regulatory barriers	Potential solutions to obviate the barrier
Local institutions may be hesitant to delegate to external IRBs because they are concerned that OHRP could still hold their institution responsible in the event of noncompliance. • Is this a concern for you or your institution? • Why/why not?	• Would clarification of OHRP policy to take action against the IRB-of-record as opposed to participating sites for noncompliance with regulations help to alleviate concerns at your institution over regulatory liability? • Why/why not?
In the event of litigation secondary to errors, omissions, or negligence of an IRB not directly affiliated with the institution conducting research, local institutions may be concerned about legal liability. • Is this a concern for your institution? • Why/why not?	• Some have suggested that local institutions can establish liability protections through a well-defined communication plan and contract with the external IRB. Would this help alleviate your or your institution's concerns over legal liability? • Why/why not? • Would a document describing considerations for the institution and the external IRB when negotiating the legal and ethical responsibilities of the two entities for a multicenter trial be useful? • Why/why not? • Consider the attached outline as an example of considerations when negotiating the legal and ethical responsibilities of the local institutions enrolling patients and the central IRB of record for the trial.

[*Only raise considerations below if interviewee expresses concern over review quality/local context.*]

Concerns over review quality/local context	**Potential solutions to obviate the barrier**
Quality of review – potential concerns • Important human subject protections issues could be missed without redundant review • Caliber of reviewers • Who assigns reviewers to the particular protocol? • How much time is spent on each review? • Is AAHRP accreditation enough?	If quality concerns are raised as issue by interviewee: • No empirical metric by which to measure/compare review quality. How would you measure review quality? • NOTE for interviewers about AAHRP accreditation. AAHRP accredits an entire human subjects protection program at an institution. For an independent IRB, this is only the IRB.
Potential loss of local context in external IRB review. • Assumption that local considerations will lead to a better quality review, and avoidance of inappropriate consent forms • Lose community representative offered by a local IRB • Conflicts of interest of institutions or investigators	• What are concrete examples of local considerations that would be lost with centralized review, since the goal of multicenter trials is to be widely generalizable? • Consent forms can have core that is same for all sites, then a customizable section for the institution that addresses any state laws or institutional concerns regarding, e.g., compensation for research related injury, institutional contact information, and costs of participation • Representing local context could be done by other entities at local institution. The evaluation of a study's social value, scientific validity, and risks and benefits, and the adequacy of the informed consent document and process generally do not require the unique perspective of a local IRB. • In well-defined relationship, local institution retains authority to participate or not and to limit investigators' involvement.

Person Responsible For Decisions re: Use of a Central IRB

- Who at your institution would make the decision regarding whether or not to use a central IRB?

Institution's IRB Serving as the Central IRB

- So far, we've been discussing your perspective as a potential site in a multicenter clinical trial using a central IRB of record. Switching gears now, what would the main considerations be if your institution's IRB were to serve as the central IRB of record for a multicenter trial?