

INVESTIGATOR & SPONSOR INTERVIEW GUIDE

Investigator Qualification: Identifying key learning objectives for preparing investigators and their delegates for the quality conduct of sponsored clinical trials

1. Interviewer Name	
2. Participant ID#	
3. Interview Date (dd/mm/yyyy)	_ _ _ / _ _ _ / _ _ _ _ _
4. Participant agrees for interview to be audio recorded	Yes..... <input type="checkbox"/> No..... <input type="checkbox"/>
5. Time Interview Began (hhmm-24hr clock)	_ _ _ _ _
6. Time Interview Ended (hhmm-24hr clock)	_ _ _ _ _

Step 1: Complete Q1-3 above before calling the participant.

Step 2: Once you connect with the participant, introduce yourself; thank participant for taking part in the interview.

Step 3: Read Section A below to participant.

Step 4: Ask permission to record interview; tick appropriate box in Q4 above.

Step 5: Turn on audio recorder if acceptable, document time interview begins in Q5 above, and conduct interview.

Step 6: At the end of the interview, thank the participant and ask if she/he has any further questions; document time interview ended in Q6 above.

SECTION A: Information about the study

- Hello, thank you for taking time out of your busy schedule to speak with me today. My name is [Name], and I am a _____ with the Clinical Trials Transformation Initiative. Is now still a good time to talk?

- As you know, the U.S. Food and Drug Administration regulations require that sponsors of clinical trials select qualified investigators to conduct registrational clinical trials. Investigators are typically deemed qualified to participate in such trials based on a combination of professional training and previous trial experience. Trial sponsors also generally require investigators and their delegates to complete Good Clinical Practice (GCP) training prior to participating in each clinical trial. GCP training is designed to meet regulatory expectations on investigator preparation.

While GCP training has become the industry standard for meeting the sponsors’ responsibility for ensuring investigators receive adequate training, it’s unclear as to how well GCP prepares investigators and their delegates for the quality conduct of sponsored clinical trials.

- The Clinical Trials Transformation Initiative—referred to as CTTI—is developing recommendations on how investigators and their delegates can become qualified for the quality conduct of sponsored clinical trials. We would like to learn from your opinions and experience. One of our ultimate goals is to identify key learning objectives for preparing investigators and their delegates for the quality execution of sponsored clinical trials.
- There are no right or wrong answers to the questions I will ask. We want to hear about your perspectives on training for clinical trial investigators and their delegates on the quality conduct of sponsored clinical trials. Please feel free to share your candid thoughts to the questions that I ask you. It's very helpful to hear your point of view.
- As described in the informational sheet provided to you earlier, participating in this interview is voluntary. You can choose not to answer a question or you can stop participating at any time.
- If you agree, I would like to audio record the interview because I want to make sure I don't miss any of your comments. If you don't want the interview audio recorded, I will take detailed notes during the interview instead. Members of the study team will transcribe the interview or type up the detailed notes. They will remove any personal or organizational names.
- We do not think there will be any personal benefits from the interview today. However, there is a risk of loss of confidentiality. This means that people outside the study team could learn what you said in the interview. But every effort will be made to protect your privacy and confidentiality. This includes removing names from transcripts and storing your information on secure servers accessible only to the study team.
- The interview will take roughly 1 hour. Information about who to contact if you have questions about the study, including the Duke IRB, can be found in the informational sheet.
- Do you have any questions for me so far about the interview?

[If yes, answer the participant's questions.]

Is it okay if I turn on the audio recorder now?

[If yes, begin audio recording now.]

[If no] That's okay, I'll take detailed notes as we talk.

Ok, let's get started!

Section B: Definition and Characteristics of the Quality Conduct of Sponsored Clinical Trials

The first set of questions focuses on the definition and characteristics of the quality conduct of sponsored clinical trials.

For the purposes of this interview, we are defining sponsored clinical trials as phase III clinical trials of drugs, biologics and medical devices for registrational purposes.

1. How do you define the quality conduct of a phase III clinical trial?
 - a. Probe: What are the characteristics of such trials?
2. What are your concerns, if any, about the quality of how clinical trials are conducted?

Section C: Critical Tasks that Lead to the Quality Conduct of Sponsored Clinical Trials

Now I'd like to learn about critical tasks that lead to the quality conduct of clinical trials.

3. What are the critical tasks that must be conducted at research sites to ensure the quality conduct of clinical trials? ***[Probe until all tasks are exhausted. Make a list of all critical tasks mentioned to refer to in subsequent questions.]***

- a. ***[Interviewer: Only use the probes below if the interviewee is having difficulty coming up with a list of critical tasks.]***

Probe: What about ***[insert example from list below]***...?

- Conducting informed consent
 - Assessing AEs and results of labs/assessments with timely follow-up and reporting
 - Reviewing CRFs for accuracy and completeness, and then signing off in a timely fashion
 - Enrolling participants and following-up per the protocol
4. Of the critical tasks that you shared with me, which do you consider to be the top three critical tasks? ***[Write down each of the top 3 critical tasks to refer to for subsequent questions]***
 - a. Why do you feel ***[insert task]*** is a critical task? ***[Probe for all three tasks. Ask for each task, no need to write down answers.]***

Section D: Knowledge and Skills Required for Performing Critical Tasks with Quality

[Interviewer: Questions in Sections D and E should be asked, in order, for each of the three top critical tasks]

All right, now let's talk about each of the top three critical tasks that you identified. Let us first start with [critical task #1]

5. What are the key knowledge and skills needed to perform ***[insert critical task]*** with quality?

- a. Why is this **[knowledge and/or skill]** important? **[Ask for each task, no need to write down answers.]**

Section E: Training on Key Knowledge and Skills

Now, let's focus on GCP training.

6. Referring to the list of 13 elements of GCP training that you were sent earlier, which, if any, adequately address **[insert critical task]**?
 - a. How does **[insert element/s of GCP training identified]** adequately address **[insert critical task]**? **[Ask for each task, no need to write down answers.]**
 - b. What, if anything, is missing from current GCP training on this **[insert critical task]**? **[Ask for each task, no need to write down answers.]**
7. What type of ongoing training do study personnel currently get on **[insert critical task]**? **[Ask for each task, no need to write down answers.]**
 - a. Probes: (If training is not provided) Is ongoing training needed?
 - i. Why or why not?
8. What other kind of training is provided to site personnel to prepare them for **[insert critical task]**? **[Ask for each task, no need to write down answers.]**
 - a. Is that training adequate?
 - i. Probe if "adequate": What makes you feel that way?
 - ii. Probe if "not adequate": What is missing from that training?
Why is training on that missing topic(s) important?
9. Are there any approaches beyond training to prepare site personnel to perform **[insert critical task]**? **[Ask for each task, no need to write down answers]**
 - a. Probes: What about mentoring? On the job training / experience?

Section F: Additional Training Questions

That is all the questions I have about your top three critical tasks. Now, I'd like to talk more broadly about GCP in general as well as other kinds of training and clinical trial preparation.

10. What types of changes, if any, do you feel need to be made to current GCP training to ensure the quality conduct of clinical trials?
 - a. Of the 13 elements of GCP training you have in hand, which are most valuable?
 - a. Why these elements?

- b. Of the 13 elements of GCP training you have in hand, which, if any, do not effectively contribute to preparing investigators and their delegates for the quality conduct of a clinical trial?
11. Of all the training that site personnel typically get to prepare for clinical trials, what topics receive a great deal of focus beyond what is required for the quality conduct of a clinical trial? Meaning, what training topics have you found to be redundant.
- a. Why?

Section G: Wrapping up

Thank you for sharing your thoughts thus far. In closing, I'd like to focus on your recommendations regarding preparing investigators and their delegates for the quality conduct of a phase III clinical trial.

12. What are your top three recommendations regarding training, including GCP training, for investigators and their delegates?
13. Finally, is there anything else that you'd like to add about preparing investigators and their delegates for the quality conduct of a phase III clinical trial or any questions that you'd like to ask about this study?

I want to thank you very much for your time and for the helpful information that you provided. Have a great day!