

INTERVIEW GUIDE

INFORMATION TO BE CONVEYED TO INTERVIEWEE:

- *Thank you very much for agreeing to participate in this interview. We will keep it within the one-hour time limit.*
- *The interview will be audio-recorded so that your comments will be accurately captured during our discussion.*
- *The aim of the interview is to gather your opinions, perspective, and recommendations, not those of any organization with whom you have been or are affiliated with.*
- *The opinions of experts, like you, will help CTTI develop a deliverable of findings and recommendations that will hopefully improve the Informed Consent process.*
- *No statements or opinions expressed during your interview will be specifically attributed to you. You will have the choice to be acknowledged as a participant in the interview project or not to be acknowledged. This interview involves no benefits, risks or compensation to you.*
- *You are not required to answer all of the questions; you may pass on any question you do not wish to answer.*
- *Your participation is voluntary. You can stop the interview and your participation at any time.*

*Do you consent to participate in this interview about the Informed Consent process?
Do you consent to be audio-recorded during this interview?*

QUESTIONS IN GREEN INDICATE CORE QUESTIONS THAT MUST BE ASKED OF ALL PARTICIPANTS.

1. To begin, please briefly describe your current position and role, and your experience with Informed Consent.

The next questions will focus on Informed Consent that is regulated by the United States rules for the protection of human subjects. (NOTE TO INTERVIEWER - on the next set of questions, remind interviewee that working within US regulations and required elements of Informed Consent - instruct interviewee to think beyond the rules and regulations that cannot be changed)

2. First, what do you think are the *major* strengths of the current Informed Consent process? Please share some examples.
3. What are your *major* concerns with the current Informed Consent process? Please share some examples.

- a. Who is most affected by these concerns? Why do you say that?
4. Tell me in a couple of minutes what you think is the single biggest barrier to addressing these concerns/improving the Informed Consent process? Why do you say that?

For the next set of questions, I'd like to talk about patients and the Informed Consent process...

5. From the Informed Consent process at the beginning of a trial, how could the process be improved to help patients understand what being in the trial would be like? (*probe if time permits: How do you think this affects the success of the trial, in terms of recruitment, retention, adherence... ?*)
6. Are there aspects of the current Informed Consent process that:
- a. Encourage and enable patients to participate in clinical trials?
 - b. Discourage or impede patients from participating in clinical trials?
7. How can the current Informed Consent process be improved to help a prospective participant have a better understanding of the potential risks and benefits associated with clinical trial participation?
8. In your experience, what could be done to help prospective participants be more comfortable asking questions?

Now, I'd like to talk specifically about the typical Informed Consent document...

9. How do you think patients generally feel about the Informed Consent document? Why do you say that?
- 10.** Thinking about the most important aspects of the Informed Consent document, which generally need improvement in your opinion? Why? (*NOTE TO INTERVIEWER: Remind interviewee to think beyond the required elements of the ICD/items that cannot be changed*)
- a. Which sections or components in the Informed Consent document, if any, could be simplified or shortened? How would this benefit the patient?

- b. Do you have any thoughts on how the benefits and risks sections could be improved *(in terms of helping a patient clearly understand these sections)*?
11. What communication tools, if any, do you believe are effective alternatives to written Informed Consent documents? What experiences have you had, if any, with these type of tools? *(probe on whether true alternatives or “add-on” tools)*
 - a. What do you think about electronic consent? In what ways can supplementary materials such as videos, brochures, etc., help improve the consent process?
 12. Regarding the use of the data gathered in the trial, what are your recommendations for improving Informed Consent regarding other potential future research uses? *(probe on potential differences between genetics/biologic samples and information derived from that vs. scientific/numeric data)*

Next, I'd like to talk about your experience with IRBs and the Informed Consent process...

13. Do you currently work with a local or central IRB or both?
14. What has been your experience with these IRBs in terms of the Informed Consent process? *(probe on how IRBs enhance or impede the Informed Consent process overall)*
 - a. In what ways do specific IRB members - that you are aware of - enhance or impede the Informed Consent process? Please share examples.
 - b. In what ways do attorneys and/or compliance officers enhance or impede the Informed Consent process? *(if not mentioned in “a” above)* Please share examples.

Finally, let's talk about your overall thoughts and ideas on improving Informed Consent...

15. How would your recommendations to improve the Informed Consent process differ, if at all, for drugs versus medical devices? *(also probe on acute vs. chronic)*
16. If you could make ONE transformative change to improve the Informed Consent process, what would it be? Why? How would you accomplish this change? *(mention that must be a realizable change)*
17. As we work to improve Informed Consent to the benefit of patients and the research enterprise, what else do we need to be thinking about – what have we missed in the interview so far?

18. Thank you very much for your time and participation today. Before we close, are there any final thoughts you'd like to share? (*NOTE TO INTERVIEWER: Let interviewee know after this question that if he/she has any additional thoughts after the conclusion of the interview, he/she can email thoughts to us*)

IF TIME LEFT

19. When significant new information develops during a clinical trial, how can communications to the trial participants be improved, including the re-consent process?

20. Have you ever been involved in or know of any important efforts or initiatives to improve the Informed Consent process? If yes, please elaborate on your experience and the results of those efforts. (*probe on successful and failed initiatives/US initiatives or abroad*)

Thank you once again for your valuable feedback. Just as a reminder, we will not attribute quotes to you directly in our analysis. However, will you permit us to acknowledge you as a participant only?

Yes

No