Appendix A: Semi-structured interview guide

Interview Guide

1. Interviewer Name	
2. Participant ID#	
3. Interview Date (dd/mm/yyyy)	|___|___|/|___|___|/|___|___|___|___|
4. Participant agrees for interview to be digitally recorded	Yes..... ☐ No..... ☐
5. Time Interview Began (hhmm-24hr clock)	|___|___|___|___|
6. Time Interview Ended (hhmm-24hr clock)	|___|___|___|___|

Step 1: Complete Q1-3 above before the interview.
Step 2: At the beginning of the interview, introduce yourself; thank participant for taking part in the interview.
Step 3: Read Section A below to participant.
Step 4: Complete demographic questionnaire
Step 5: Ask participant permission to record interview; tick appropriate box in Q4 above.
Step 6: Turn on audio recorder if acceptable, document time interview begins in Q5 above, and conduct interview.
Step 7: 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.
Step 8: Ask if the participant is interested in being re-contacted with study results; if yes, document appropriate email. Inform participant that her/his email address will not be linked with her/his study data.
Step 9: Complete the IRB Personal Data Disclosure Form

Interviewer: Please read the following to participants at the beginning of the interview.

SECTION A: Information about this 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 Trial Transformation Initiative. Is now still a good time to talk?

- Before we begin, I'd like to tell you more about the research we're doing and what we will do with the information you tell us.

- The Clinical Trials Transformation Initiative – known as CTTI – wants to better understand site investigator experiences with conducting mobile clinical trials.

- 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 the interview at any time.

- We do not think there will be any personal risks or benefits from the interview today. However, there is a risk of loss of confidentiality as with any study of this nature.

- With your permission, I would like to audio-record the interview. The audio-recording will be stored on a secure server and destroyed after the findings of this research are published.

- If you do not want the interview audio recorded, I will take detailed notes throughout the interview instead.

- The interview will take roughly 1.5 hours. You will receive $100.00 for taking part. In order to pay you through the Duke system, we will need your Social Security number. You are not required to share your Social Security number with us to participate in this interview, but we cannot pay you for taking part without it.

- Do you have any questions for me at this point? Information about who to contact if you have questions about the study after our time today, including the Duke IRB, can be found in the informational sheet.

[If yes, answer the participant's questions then proceed with the completing the demographic form.]

[If no, proceed with the completing the demographic form.]

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: Participation in Mobile Clinical Trials (MCTs)

I would like to begin our discussion by getting a sense of your experience in mobile clinical trials.

1. Can you describe 1-2 clinical trials you participated in that used mobile devices? ***[Probe: Role, purpose of study, study design, frequency of patient visits, study population, type of device (BYOD or study provided), site investigator involvement/activities, funder: sponsor versus investigator initiated]***

2. Are these clinical trials on-going or have they been completed? [Probe: If on-going, stage of implementation).

SECTION C: Site Investigator Recruitment and Initial Reactions to MCTs

Now I'd like to talk about your experience being recruited to participate in, and your initial reactions to, clinical research that used a mobile device.

3. How were you identified to be an investigator on the mobile clinical trial(s) you mentioned earlier?
    a. When you were approached to participate, what aspects of clinical research using mobile devices were appealing to you?
    b. What hesitations or concerns did you have?
    c. Were you asked to give input into the protocol?
        i. If not, would you have preferred to give input? Why?

4. When you were approached to participate, what information about the mobile device(s) or mobile clinical trial did you want to have from the sponsor?

SECTION D: Advantages and Disadvantages of Mobile Clinical Trials

Now I'd like to talk to you about your perceptions of the advantages and disadvantages of conducting a mobile clinical trial.

5. From a PI's point of view, what are the advantages of mobile clinical trials compared to traditional clinical trials?
    a. What are the disadvantages or burdens?
        i. What do you think can be done to address these disadvantages/burdens? ***[Probe for each one]***

6. As compared to a traditional clinical trial, what are the advantages, if any, to patients who participate in a mobile clinical trial?
    a. What are disadvantages or burdens, if any, to patients who participate in a mobile clinical trial?
        i. What do you think can be done to address these disadvantages/burdens? ***[Probe for each one]***

7. ***[If not mentioned before]*** How do the advantages you mention to PIs and patients impact:
    a. Clinical care?
    b. Patient-provider relationships?
    c. The overall quality of the clinical trial?
    d. Flow of visits?
    e. Decision-making about patient care?

8. ***[If not mentioned before]*** How do the disadvantages you mention to PIs and patients impact:
    a. Clinical care?
    b. Patient-provider relationships?
    c. The overall quality of the clinical trial?
    d. Flow of visits?

e. Decision-making about patient care

SECTION E: Comparison Between Traditional and Mobile Clinical Research

Now, I'd like to explore the conduct of mobile clinical research in comparison to traditional trials.

9. First, how easy or difficult did you find conducting mobile clinical research in comparison to traditional clinical research?
    a. What aspects were easier to do? Why?
        i. What were harder to do? Why?

10. In your mobile clinical trial, did you find that you, as the investigator, needed to spend more or less time on study activities than in a traditional trial? ***[Probe about during study set-up, during implementation]***
    a. Why was more/less time needed?
    b. What about for the rest of the study team?
        i. Why was more/less time needed?

11. How often did you or study staff have to troubleshoot issues with the mobile device(s) with trial participants?
    a. ***[If ever]*** How did this impact clinical trial activities***? [Probe: Exams, other assessments, patient care]***

12. As compared to a traditional clinical trial, what kinds of support did you need <u>as the investigator</u> to implement a trial using a mobile device? Why? Please consider all kinds of support. ***[Probe about support needs during study start up, during trial implementation]***
    a. What about <u>study staff</u>? What kinds of specific support did they need? Why?
    b. What type of support was provided <u>by the sponsor</u> to your site?
        i. Was this support sufficient or insufficient? Why?
        ii. What types of support would you suggest that sponsors provide to site investigators so they can implement mobile clinical trials?
    c. Aside from sponsor support, <u>what other types of support</u>, if any, were provided? For example, support from device manufacturers or from your institution's IT department.
        i. Who provided this other support?
        ii. How useful or not useful was this support? Why?

SECTION F: Training

Now, I'd like to discuss the training and preparation process for your trial involving a mobile device.

13. In comparison to traditional trials, what additional training was needed because the trial used a mobile technology?

14. How was the training on the mobile technology provided to study staff?
    a. Who was trained?
    b. What would you do similarly next time?
    c. What would you do differently?
    d. What suggestions do you have for how future trainings might be improved?

15. How were patients trained to use the device?
    a. Did you find the training to be sufficient or insufficient? Why?
    b. What suggestions do you have for how future patient trainings might be improved?

SECTION G: Ethics

Now I'd like to talk about your experiences throughout the ethics approval process for the mobile clinical trial(s).

16. In terms of the application process, what additional information, if any, did you need to provide to your local/central IRB that typically does not typically need to be submitted with a traditional clinical trial?

17. What concerns did the IRB raise around the use of mobile devices in the clinical trial?
    a. How were these addressed by the research team?
    b. What recommendations to you have for other PIs for when they prepare their mobile clinical trial protocol for IRB submission?

SECTION H: Costs

Now I'd like to get your thoughts on cost and payment considerations for sites to run mobile trials.

18. In your experience, what additional costs were associated with site-level responsibilities for running a trial involving mobile devices as compared to a traditional trial?

19. When you were first approached to be a site for a mobile clinical trial, did you find that you were adequately prepared to plan for a mobile clinical trial from a budgetary perspective?
    a. Why/why not?
    b. What do you know now that you wished you knew then?
    c. What about from a contract perspective? What do you know now that you wished you knew then?

20. Did you need more or less staff for the mobile trial in comparison to a traditional trial? Why was that the case?

21. Were there any hidden costs or unanticipated costs that emerged?
    a. ***[If yes]*** What were they?
    b. How could this be addressed in future budgets?

22. What else, if anything, would you do differently next time with a site budget for a mobile clinical trial?
    a. What about with the site contract?

SECTION I: Access to Trial Data

Let's turn our attention to accessing the data from the mobile device.

23. Were you, as the investigator, able to access data in real time that were collected from patients via the mobile device?
    a. [If had access] How did you access the data?
    b. What did you find to be beneficial of having this kind of data access?
        i. What was challenging?

    c. How about patients—were they able to access their data in real time?
        i. [If yes] What did you find to be beneficial of patients having this kind of data access?
            1. What was challenging?

SECTION J: Lessons Learned and Guidance

Finally, I'd like to close by asking you to reflect on lessons learned from running a trial involving mobile devices.

24. Would you participate in another trial involving mobile devices?
    a. Why or why not?

25. What three things would you do differently next time if you were asked to serve as a PI/co-PI of another mobile device trial?

26. What are three pieces of advice that you would give to sponsors when they are reaching out to site investigators to ask them serve as a PI/co-PI of a mobile device trial?

That's the end of the questions that I have for you today. Do you have any final thoughts or questions that you'd like to ask about this study?

I want to sincerely thank you for your time and for the helpful information that you provided.