

**ICH E6 GCP Renovations Interview Guide**  
***Version 1.0, August 8, 2019***

1. Interviewer Name	
2. Participant ID#	
3. Interview Date (mm/dd/yyyy)	_ _ _ / _ _ _ / _ _ _ _ _
4. Participant agrees for interview to be digitally recorded	Yes..... <input type="checkbox"/> No..... <input type="checkbox"/>
5. Time Interview Began (hh:mm)	_ _ _  :  _ _ _  am/pm
6. Time Interview Ended (hh:mm)	_ _ _  :  _ _ _  am/pm

**Step 1:** Complete Q1-3 above before starting the interview.  
**Step 2:** Introduce yourself at the beginning of the interview. Thank participant for taking part in the interview.  
**Step 3:** Read “information about the study” below to participant.  
**Step 4:** Ask for the participant’s permission to record interview. Tick appropriate box in Q4 above.  
**Step 5:** Turn on audio recorder if permitted. 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.

**I. Information about the study**

The purpose of our interview today is to learn about your experiences in implementing GCP and how you believe it should be renovated.

There are no right or wrong answers to the questions I’ll ask, only opinions. Please feel free to share your candid thoughts. You are the expert here, and there is no one else we can ask to get the unique information that you can tell me about your experience.

Please know that I will share your answers, linked specifically with your name and organization, with the ICH committee. Is this acceptable to you? (Interviewer: If asked why, please explain: ICH prefers to fully understand the context of the information they receive, and having names and organizations from respondents provides that context.)

- Yes → continue
- No → end interview

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. The recording will be stored securely and eventually destroyed after we publish the study's findings.

Do you have any questions for me so far about the interview?

Are you okay with our conversation being audio recorded?

### **TURN ON AUDIO-RECORDER**

***Interviewer:** Obtain verbal confirmation from participant while audio-recording that the participant agrees to be audio-recorded and that the participant agrees for her/his name to be provided to ICH linked with her/his specific information.*

OK -- Let's get started!

### **Section 1: GCP Revision Aspirations**

***Interviewer script:** Now I'd like to focus on your aspirations for the GCP renovations.*

1. What do you hope the revision to GCP will achieve overall?

*For each aspiration mentioned:*

- a. [Ask only if response is not described in detail earlier] Why do you hope GCP will achieve this?
- b. What needs to be done to the GCP guidance document to accomplish this revision?

### **Section 2: Most helpful sections of GCP**

***Interviewer script:** I'd like to start by learning more about your perceptions of the most helpful aspects of GCP.*

2. What sections of GCP has been most helpful to you? (e.g., beneficial, useful, valuable, of assistance)

*For each section mentioned:*

- a. Why is this section helpful?
- b. How have you applied this guidance to your research? (Probe for concrete examples).

### Section 3: Least helpful sections of GCP

**Interviewer script:** Now I'd like to focus on your perceptions of the least helpful aspects of GCP.

**Interviewer:** You can also refer to survey responses for areas that should be renovated and explore those topics.

3. What sections of GCP has been least helpful to you?

*For each section mentioned:*

- a. Why is this section unhelpful? Ask participant for an example of applying the specific GCP guidance and how it was problematic.
- b. How could GCP guidance in this section be improved?
  - i. How would the conduct of trials be improved if the guidance was revised in this way?

### Section 4: Conclusion

4. Is there anything else that you could like ICH to know as they revise GCP? Remember your comments will be linked with your name and organization.

That's the end of the questions that I have for you today.

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

Thank you very much.