Appendix 4. Interview Guide for Individual Interviews

Thank you for talking with us today. As we discussed before, this interview is part of a larger project in which we, with our colleagues, are researching: what unique ethical and human subjects oversight issues arise in patient centered outcomes research and comparative effectiveness research (PCOR/CER), if any; what support IRBs may need to resolve those issues; and what guidance PCOR/CER investigators and patient advisors need to design and conduct their projects in an ethically responsible manner.

A few mechanics before we begin. I previously emailed an informed consent document to you. Have you had a chance to review it? Do you have any questions? Is it okay with you if I tape our interview? Your responses will be kept confidential. For any publications or other reports of our findings, your information will be kept anonymous. If you prefer not to answer a question, you do not need to. If you agree, I have an informed consent form for you to sign. Thank you!

1. **Please tell us about yourself.**
   1.1. Where do you currently work?
   1.2. What is your position?

2. **How do you define "patient centered outcomes research"?**
   2.1. How did you reach that definition?
   2.2. How would you characterize the relationship between PCOR and CER?
      2.2.1. Patient-centered CER
   2.3. What types of research fall within this heading?
      2.3.1. Pragmatic clinical trials
      2.3.2. Cluster randomized trials
      2.3.3. Learning healthcare systems

3. **How has your work/position brought you into contact with PCOR/CER?**
   3.1. How did you get involved?
   3.2. What kind of projects have you participated in?
   3.3. How would you describe your experiences?
   3.4. What kind of specialized training or preparation do you have, if any?

4. **Now, we would like to talk about _practical_ challenges you may have encountered while involved in PCOR/CER. What practical challenges did you perceive (directly or indirectly)?**
   4.1. Can you offer specific examples?
      4.1.1. Quick review times
      4.1.2. Patients-as-investigators
      4.1.3. Inexperienced investigators
      4.1.4. E-health and mobile health applications
      4.1.5. Enlarged scale/scope of research
      4.1.6. Questions about when to waive informed consent

4.1.7. Confidentiality (e.g., in use of health apps)
4.2. What practical challenges did you personally face?
4.3. What practical challenges did colleagues face?
4.4. How frequently do you think issues like this arise?

5. **Now, I would like to talk about <u>ethical</u> challenges you may have encountered while involved in PCOR/CER. What ethical challenges did you perceive (directly or indirectly)?**
   5.1. Can you offer specific examples?
   5.2. What ethical challenges did you personally face?
   5.3. What ethical challenges did colleagues face?
   5.4. How frequently do you think issues like this arise?

6. **Now, I would like to talk about <u>regulatory/oversight</u> challenges you may have encountered while involved in PCOR/CER. What ethical challenges did you perceive (directly or indirectly)?**
   6.1. Can you offer specific examples?
   6.2. What regulatory/oversight challenges did you personally face?
   6.3. What regulatory/oversight challenges did colleagues face?
   6.4. How frequently do you think issues like this arise?

7. **How were [the challenges you just identified] addressed?**
   7.1. Who, if anyone, did you talk with?
   7.2. What resources were available to you?
   7.3. How satisfied were you with the resolution?
   7.4. Were there resources you needed that you did not have access to?

8. **What, if any, of the ethical issues we've discussed do you think are unique to PCOR?**
   8.1. What makes you think that they are unique?
   8.2. Why don't these issues arise in other types of research?
   8.3. If they are not unique, do you think that they arise with greater frequency than in other areas of research? Why?

9. **Are there any policies, resources, or practices that you think would help [IRB members/administrators/investigators/patient advisors] address ethical challenges in PCOR/CER?**
   9.1. How would these resources help?
   9.2. What advice would you give to a friend or colleague who was engaging in PCOR/CER?

10. **Before we wrap up, are there any questions I should ask you that I have not, or is there anything you would like to talk about?**

Thank you so much for talking with us today.