Appendix 3. Interview Guide for Focus Groups

The Patient-Centered Outcomes Research Oversight Study (PCOROS)

IRB Member and Chair Focus Group Guide

13th and 14th Nov 2015

PI: Joel Weissman, PhD

A) Introduction, ground rules, informed consent (5 min, 5 min elapsed) 2
B) Icebreaker – Is PCOR/CER different? (5 min, 10 min elapsed) 4
C) Challenges for investigators applying for IRB approval for PCOR/CER studies (10 min, 20 min elapsed) 5
D) Role of patients (10 min, 30 min elapsed) 5
E) Other Challenges (15 min, 45 min elapsed) 6
F) Guidelines for the IRB reviewing PCOR/CER (10 min, 55 min elapsed) 7
G) Close (5 minutes, 60 minutes elapsed) 7

A) Introduction, ground rules, informed consent (5 min, 5 min elapsed)

Good evening everyone. Thanks for coming to speak with us today. I'd like to start by introducing myself. I'm Joel Weissman, the PI for the study and this is _____ (note-taker).

I am Chief Scientific Officer at Brigham and Women's Hospital's Center for Surgery and Public Health, affiliated with Harvard Medical School. This study 'The Patient-Centered Outcome Research Oversight Study (PCOROS)' is being sponsored by the Patient Centered Outcomes Research Institute (PCORI). It aims at identifying ethical challenges posed by Patient Centered Outcomes Research or Comparative Effectiveness Research (PCOR/CER) that are relevant to IRB oversight and human subject protections and we would like to learn about your experience in the area. When we start the official part of the group, I will define these terms for you.

- Purpose of study and why you are here **(Smile, eye contact)**
- Team
- Sponsor of study
- Your participation – how FG's work
    - Your ideas
    - Everyone's are important
    - How discussion will work
        - Only one person at a time
        - Feel free to address each other, but,
        - No side conversations
- Ground rules
    - Food
    - bathrooms
    - Time - ending
    - Payment/compensation - when you leave
- Turn off cell phones, pagers – no emailing on PDAs please!
- My role
- Ask questions and keep on schedule

We'll be on a first name basis, but no names will be used in any reports, and your responses will only be reported in summary form.

Please speak openly about your experience and ideas. The goal of this group meeting is not to reach agreement on anything, but for us to learn from you.

We should be done by ___ o'clock, but we have a lot to cover in the next 1 hour. So for the sake of time, I may have to jump ahead to the next topic, but please stop me if you want to add anything. So

that we can give each other our full attention, I ask that everyone please turn off their cell phones and pagers and minimize their use in the focus group area.

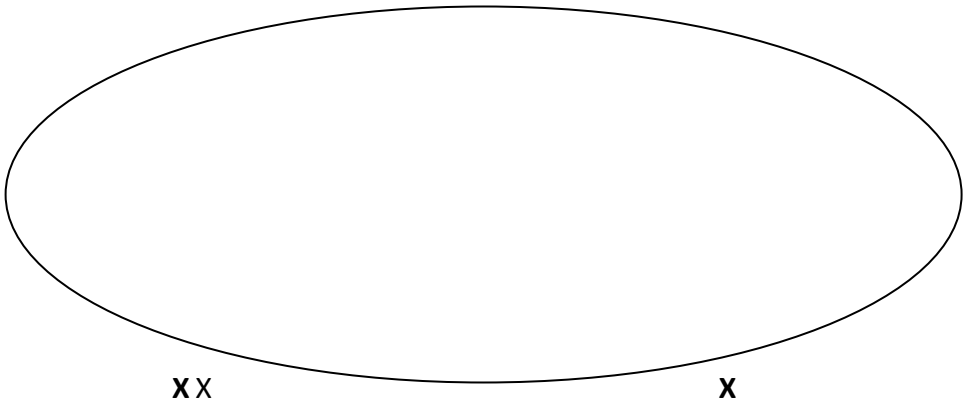
Beverage is available in the back and you should feel free to help yourselves at any time.

Very importantly, the consent script has already been shared with you in an email sent earlier. If you have any question about it, please ask now and I am also summarizing it here for your reference:

- This protocol was approved by the IRB at Partners HealthCare
- Your responses will be reported only in summary form
- All data will be kept confidential
- I want to be sure that you understand that being part of this group is voluntary and you may leave at any time you wish.
- Please do not share anything during the group that is involved in a legal case.
- You can choose not to answer a question.
- This session is being audiotape recorded so that we remember everything you say. However, your comments are confidential and will be used for research purposes only. Our discussion will only be recorded by this digital recorder which will be kept securely with the research team.
- Finally, if you do not have any question or concern now, your participation implies your informed consent to participate in this focus group

Please indicate verbally whether you consent to participate.

Note to Facilitator and note takers - Use the space below to draw a diagram of the participants seated (Male 1, Male 2, Male 3, etc. ….)



B) Icebreaker – Is PCOR/CER different? (5 min, 10 min elapsed)

Question:

- *To start off, I would like to go around the room and ask everyone to tell us four things: 1) your first name, 2) what type of IRB you serve on, 3) your role on the IRB (or other role related to ethical oversight at your institution), and 4) how long you have been or were on an IRB.*

Question:

- *The first order of discussion is to get your views on how if at all PCOR and CER present unique challenges to you in your role on an IRB compared with other protocols that you see. Now we know that there are no precise definitions of these terms. For purposes of this discussion,*
  - *PCOR refers to "**the evaluation of questions and outcomes meaningful and important to patients and caregivers.**"*
  - *CER is defined as "**the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat and monitor a clinical condition or to improve the delivery of care".***
  - *We are especially interested in research funded by PCORI, which usually requires patients to be active partners in research and defines itself as funding "patient-centered CER,"[1]. And that deliberately involves patients in the research — this may occur at all phases, from the development of research questions to the dissemination of results*
- *(Pause to ask if there are any questions about the definition)*
- *Can a few of you give an example of a PCOR or CER protocol with which you are familiar? Just one or two sentences will be sufficient.*
- *Ok, let's open up the discussion to the group. We are interested in whether you think, from your role on an IRB, whether PCOR/CER protocols are different or unique in terms of ethical, regulatory, or logistical features; and if yes, how are they different?*

Probes

- Acknowledge that it is ok to say there is nothing unique

[1] Joe Selby, interview

- What do you think are unique features of such studies compared to other types of research from the perspective of IRB oversight? What is NOT unique about them?
- Do they deserve a special attention as far as IRB oversight is concerned?
- At a minimum establish that patients as partners/collaborators is worth discussion

C) Challenges for investigators applying for IRB approval for PCOR/CER studies (10 min, 20 min elapsed)

Question:

- *AT YOUR INSTITUTIONS DO THE INVESTIGATORS FOR PCOR/CER STUDIES HAVE PARTICULAR PROBLEMS WITH THE IRB APPLICATION? DIFFERENT FROM OTHER INVESTIGATORS / OTHER TYPES OF STUDIES?*

Write on flip chart

Probe

- What are the most common pieces of information that investigators fail to supply to the IRB in their protocols, for the IRB to have sufficient details in order to review the project? What are the most common questions that the IRB has to send to the investigators after an initial review of a submitted protocol?
- What additional information or clarifications do IRB reviewers usually seek from investigators?

D) Role of patients (10 min, 30 min elapsed)

Assume that participants have brought up role of patients. If not, ask.

Question:

- *WHAT ARE THE DIFFERENT ROLES THAT PATIENTS PLAY IN RESEARCH THESE DAYS?*

Write on flip chart

Probe

- as advisors
- as investigators
  - Might help design the research questions; design (or administer) the consent document, recruit people to participate in studies (or facilitate access to data that the investigator would not otherwise have access to); disseminate research results.
- as reporters of patient reported outcomes
- as users of digital technology
- as participants in studies seeking to empower (enhance) their involvement in care
- does the content of what you ask them to do affect their roles?

Question:

- *WHAT OVERSIGHT CHALLENGES DO THEY PRESENT FOR IRBS?*

Probe

- Have you had any concerns in studies you have reviewed where patients were partners with investigators?
- What role is appropriate, what is problematic?
- When does a patient switch from becoming a subject to an advisor to a researcher?
- What obligations does the institution have to the patient and what responsibilities does the patient have to the institution?
- ~~what added value is there in including patients in research? maximum impact on improving human health?~~

E) Other Challenges (15 min, 45 min elapsed)

Question:

- *PLEASE TELL US ABOUT OTHER CHALLENGES THAT YOU HAVE FACED IN PROVIDING REVIEW AND OVERSIGHT FOR PCOR/CER STUDIES.*

PUT IDEAS/TOPIC AREAS UP ON FLIP CHART

Probes

- Consent procedures for cluster randomized trials (vs pragmatic trials)
  - If consent is waived or modified, what are the alternatives? Do you require notice? What constitutes sufficient notice? Does it depend on the intervention (e.g., soap)?
- Tightly compressed timelines?
  - Pressure to expedite review process? Impact on quality of IRB application?
- Multi-site IRBs – variability?
- Big data
- Digital health technology/ mHealth including social media, mobile technology, patient-facing apps (communication between patients and providers), wearables.
  - When are communications between patients and their doctors part of research?
  - non-traditional partner that might cause challenges for the researcher, e.g., patient who develops software
- Investigator expertise in PCOR methods – we have heard anecdotally that some researchers engaged in PCOR lack expertise in some of the methods, e.g., qualitative research or mHealth. And this presents problems for IRB scientific review. Comment? Any different than other types of research or funder, e.g., NIH or NSF or foundations?
- Large scale recruitment, e.g., has anyone done PPRNs?

- How has your institution navigated having research conducted at multiple sites? How do you reconcile institutional policies when they differ, e.g., re: what constitutes minimal risk, what kind of ancillary review(s) is required?

F) Guidelines for the IRB reviewing PCOR/CER (10 min, 55 min elapsed)

Question:

- *WHAT ADVICE WOULD YOU GIVE (OR DO YOU GIVE) TO RESEARCHERS SUBMITTING PROTOCOLS FOR PCORI?*
- *WHAT HAVE YOU OR YOUR OWN INSTITUTION DONE TO HELP WITH THE OVERSIGHT OF PCOR/CER (GIVEN YOUR COMMENTS ABOVE)?*
- *ALTERNATIVELY, WHAT GUIDELINES OR RESOURCES WOULD YOU FIND HELPFUL TO HAVE AVAILABLE FOR REFERENCE?*

Probes

- what guidance do you use?
- educational activities? How, if at all, does the IRB ensure that patients are not just consultants but part of the team?
- guidelines/policies at your institution for ethical oversight of such research projects? (not just ethical, also regulatory as I mentioned before.... I think these are separate and distinct, worth considering how to ask about this)
  - sufficient and completely address the spectrum of challenges that these studies pose?
- Which area/topic do you think needs to be covered in more detail in such guidelines? Which area/topic has been left out but you think is important?
- Based on your experience, which area/topic in overseeing these research, is unimportant or is being given undue importance?
- What additional support do the IRBs need to be able to ensure ethical compliance of PCOR/CER research?
- What more information/guidelines should be given to the investigators conducting such studies?
- What Specific information should they provide in their protocols?

G) Close (5 minutes, 60 minutes elapsed)

Question:

- *ARE THERE ANY OTHER ISSUES THAT WE SHOULD HAVE ASKED BUT DIDN'T?*
- *WHAT IS THE MOST IMPORTANT "TAKE-AWAY" THAT OCCURRED TODAY? GO AROUND THE ROOM*

The Patient-Centered Outcomes Research Oversight Study (PCOROS)

Patients' Focus Group Discussion Guide

March 2016

PI: Joel Weissman, PhD

A) Introduction, ground rules, informed consent (5 min, 5 min elapsed) 2
B) Ice-Breaker Motivation (5 min, 10 min elapsed) 4
C) Role on study (15 min, 25 min elapsed) 4
D) Interaction with IRB, incl CITI, HIPAA, Consent/Training (15 min, 40 min elapsed) 5
E) mHealth (5 min, 45 min elapsed) 6
F) Expectations/Impact on Study/Cooptation (10 min, 55 min elapsed) 6
G) Recommendations for IRBs and investigators (5 min, 60 min elapsed) 6
H) Terms (probably omit due to time constraint) 7
I) Close (5 minutes, 65 minutes elapsed) 7

A) Introduction, ground rules, informed consent (5 min, 5 min elapsed)

Good evening everyone. Thanks for coming to speak with us today.

I'd like to start by introducing myself. I'm Joel Weissman, the PI for the study and this is Karen Spikes, who will introduce herself in a moment, will help to lead the discussion. [MENTION OBSERVERS AVNI, MARTIE, BARRY]

I am Chief Scientific Officer at Brigham and Women's Hospital's Center for Surgery and Public Health, affiliated with Harvard Medical School. Karen – can you please introduce yourself?

This study 'The Patient-Centered Outcome Research Oversight Study (PCOROS)' is being sponsored by the Patient Centered Outcomes Research Institute (PCORI). Traditionally, patients or other members of the public participate as SUBJECTS of a study. For this project, we want to understand the issues for patients like you who participate in ways ***other than as subjects***. We would like to learn about other types of experience in research you've had.

<u>Who here has been to a FG before? Great. Here's how they work.</u>

- We'll be on a first name basis, but no names will be used in any reports..
- Please try to speak one at a time, and no side conversations
- So please speak openly about your experience and ideas. The goal of this group meeting is not to reach agreement on anything, but for us to learn from you.
- My job is to ask questions and keep us on time. We have a lot to cover, so I may from time to time have to interrupt you or jump ahead to the next topic, but please stop me if you want to add anything.

- Ground rules
  - Food/ Beverages are available in the back and you should feel free to help yourselves at any time.
  - bathrooms
  - Time - ending
  - Payment/compensation – please fill out the form and you should receive payment in about six weeks
  - Turn off cell phones, pagers – no emailing on PDAs please!

Finally, by now you have had time to fill our your questionnaire and read the informed consent page. Does anyone need more time? In any case, I will summarize it now and you can ask questions. :

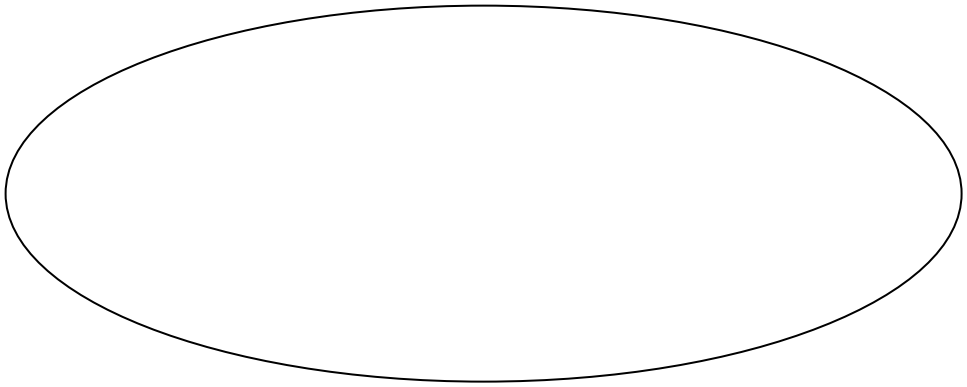
- A version of this discussion guide was approved by the committee that oversees research at Brigham & Women's Hospital, a.k.a.: the IRB.

- Your responses will be reported only in summary form.
- I want to be sure that you understand that being part of this group is voluntary and you may leave at any time you wish.
- Please do not share anything during the group that should be treated confidentially.
- You can choose not to answer a question.
- This session is being audiotape recorded so that we remember everything you say. However, your comments will be used for research purposes only. Our discussion will only be recorded by this digital recorder, which will be kept securely with the research team.

Finally, if you do not have any questions or concerns now, your participation implies your informed consent to participate in this focus group.

Consent: Just for the record, once we start the tape, please say your first name and say whether you consent to participate.

[NOTE TO FACILITATOR AND NOTE TAKERS - USE THE SPACE BELOW TO DRAW A DIAGRAM OF THE PARTICIPANTS SEATED (MALE 1, MALE 2, MALE 3, ETC. ….]



B) Ice-Breaker Motivation (5 min, 10 min elapsed)

Question:

- *AS I MENTIONED EARLIER, THIS STUDY IS ABOUT PATIENTS WHO PARTICIPATE IN RESEARCH STUDIES IN WAYS OTHER THAN AS SUBJECTS. SO TO START OFF, I WOULD LIKE TO GO AROUND THE ROOM AND ASK EVERYONE TO TELL US ABOUT THE MOST RECENT RESEARCH STUDY IN WHICH YOUR INVOLVEMENT WAS NOT LIMITED TO A ROLE AS A STUDY **SUBJECT**.*
- *WHEN YOU DO, PLEASE TELL US THE NAME OF THE STUDY AND, I KNOW YOU ALREADY ANSWERED THIS QUESTION ON THE REGISTRATION FORM, BUT CAN YOU TELL US AGAIN WHY YOU DECIDED TO GET INVOLVED IN THIS STUDY?*

[WRITE THE NAMES OF THE STUDIES NEXT TO THE NAMES OF THE PATIENTS]

Probe:

- Help others
- Learn about research
- Wanting to give back
- Improving the quality/safety of care: Do not want something wrong that happened with them to happen again.
- Monetary compensation

- *THAT'S GREAT. CAN YOU ALSO TELL US HOW YOU GOT INVOLVED IN THIS STUDY TO BE MEMBERS OF RESEARCH TEAM?*

C) Role on study (15 min, 25 min elapsed)

Question:

- *GREAT. EACH OF YOU PLEASE KEEP THIS PARTICULAR STUDY IN MIND WHEN ANSWERING OTHER QUESTIONS. NOW PLEASE TELL US WHAT YOU DO IN THE STUDY [THAT'S DIFFERENT FROM JUST BEING A SUBJECT].*

[PUT ANSWERS ON WHITE BOARD/FLIP CHART]

Probe

- Role: Investigator/Study Staff; Advisor; Consultant; stakeholder panel
- Help with subject recruitment; Help with data collection; Help with data analysis; Help with data dissemination; Have access to confidential or private information of study subjects
- What terms do they use to describe their role?
- [USING THEIR OWN WORDS TO DESCRIBE THEIR ROLES….. PROBE FOR OBLIGATIONS, BENEFITS, DRAWBACKS]

- Obligations: team meetings, review documents, recruitment,
- Benefits: reports, papers, compensation, etc.
- Drawbacks: too much time

Question:

- *THANK YOU. IN THE STUDY YOU MENTIONED, DO YOU ALSO CONSIDER YOURSELF TO BE A SUBJECT OF THE STUDY IN ADDITION TO BEING A MEMBER OF THE RESEARCH TEAM?*
- *CAN YOU DESCRIBE THE DIFFERENCE IN THESE TWO ROLES?*

[NOTE WHICH PARTICIPANTS HAVE DUAL ROLES]

D) Interaction with IRB, incl CITI, HIPAA, Consent/Training (15 min, 40 min elapsed)

Question:

- *THANK YOU FOR THAT INFORMATION. ALL STUDIES INVOLVING HUMAN SUBJECTS ARE OVERSEEN BY AN INSTITUTIONAL REVIEW BOARD, OR IRB. HOW MANY OF YOU ARE FAMILIAR WITH IRBS? [IF NOT, EXPLAIN THAT AN IRB GIVES PERMISSION[1] TO THE RESEARCHERS TO PERFORM THE STUDY AND TRIES TO LOOK OUT FOR THE PROTECTION AND INTEREST OF THE SUBJECTS OF THE STUDY AND TO MAKE SURE THAT INFORMATION ABOUT THEM IS KEPT CONFIDENTIAL]*
- *CAN YOU PLEASE TELL US ABOUT YOUR INTERACTIONS WITH THE IRB FOR YOUR STUDY?*

Probe:

- Did they sign consent forms vs have to complete CITI or other certification?
- Received training in the ethical conduct of research? How intensive? How difficult?
- How did the leaders of the research study discuss issues with YOU about their interactions with the IRB [in order to have you participate as a research team member]?
- Was IRB 'over' protective or "under" protective with you and your role?

Question:

- *FOR THOSE OF YOU IN A DUAL ROLE AS MEMBERS OF THE RESEARCH TEAM AND AS SUBJECTS, IS THERE A DIFFERENCE IN THE IRB ISSUES THAT COME UP?*

Probe

- Should there be different protections for patients as subjects vs when patients are a part of research team?
- Does it create confusion for the IRB? Have investigators struggled to delineate and clearly define your roles?
- Do you think that playing dual roles is a problem for you? Do you struggle with defining transitions from one role to the other as study progresses?

[1] Term developed in cognitive testing

E) mHealth (5 min, 45 min elapsed)

Question:

- *ARE ANY OF YOU INVOLVED WITH A STUDY THAT USES SOCIAL MEDIA (LIKE FACEBOOK), WEARABLE DEVICES (LIKE FITBITS), MOBILE APPS, OR OTHER MOBILE HEALTH TYPE DEVICES? TELL US ABOUT THAT. HAVE ANY IRB ISSUES COME UP?*

Probe:
- [differentiate role as researcher vs subject]
- Do they have access to confidential data?
- Ask about different types of data.

F) Expectations/Impact on Study/Cooptation (10 min, 55 min elapsed)

Question:

- *WE WOULD LIKE TO KNOW MORE ABOUT YOUR EXPERIENCE ON THE RESEARCH TEAM. DO YOU THINK THAT YOUR PARTICIPATION HAS MADE A DIFFERENCE IN HOW THE STUDY WAS DESIGNED OR CONDUCTED? TELL US HOW?*

- *DO YOU THINK YOUR PARTICIPATION AS A RESEARCH PROJECT TEAM MEMBER HAS MADE THE RESEARCH MORE PATIENT-CENTERED?*

[NOTE IF PARTICIPANTS DO NOT UNDERSTAND THE TERM 'PATIENT-CENTERED'.]

Probe
- Were your expectations met?
- Would you have wanted a deeper involvement? What has limited your contribution?

Question: Cooptation

- *SOMETIMES WE HEAR THAT PATIENTS WHO BECOME RESEARCHERS START TO LOSE THEIR IDENTITY AS PATIENTS AND BECOME MORE LIKE THE RESEARCHERS. WHAT DO YOU ALL THINK ABOUT THAT?*

G) Recommendations for IRBs and investigators (5 min, 60 min elapsed)

Question:

- *WHAT RECOMMENDATIONS WOULD YOU LIKE TO GIVE TO IRBS THAT OVERSEE THE STUDIES IN WHICH YOU PARTICIPATE AS MEMBERS OF A RESEARCH TEAM?*

- *WHAT RECOMMENDATIONS WOULD YOU LIKE TO GIVE TO THE INVESTIGATORS OR LEADERS OF THE STUDIES THAT INCLUDE PATIENTS AS MEMBERS OF A RESEARCH TEAM?*

probe

- Modifying consent?
- Recruitment?
- Defining roles of patients as investigators
- Involving in research vs as advisors

H) Terms (probably omit due to time constraint)

Question:

- *BEFORE WE END, WE WOULD LIKE TO KNOW YOUR UNDERSTANDING OF CERTAIN TERMS. CAN YOU TELL US WHAT PATIENT-CENTERED OUTCOMES RESEARCH MEANS TO YOU?*
- *CAN A FEW OF YOU GIVE AN EXAMPLE OF A PCOR OR CER RESEARCH STUDY THAT YOU HAVE PARTICIPATED IN OR ARE CURRENTLY A PARTICIPANT IN? JUST ONE OR TWO SENTENCES WILL BE SUFFICIENT.*

I) Close (5 minutes, 65 minutes elapsed)

Questions:

- *ARE THERE ANY OTHER ISSUES THAT WE SHOULD HAVE ASKED ABOUT BUT DIDN'T?*
- *WHAT IN YOUR OPINION WAS THE MOST IMPORTANT THING THAT WE TALKED ABOUT TODAY?*

[Go around the room]

The Patient-Centered Outcomes Research Oversight Study (PCOROS)

Investigators' Focus Group Guide

April 2016

PI: Joel Weissman, PhD

A) Introduction, ground rules, informed consent (5 min, 5 min elapsed) 1
B) How the IRB handles multiple patient roles 3
C) Other IRB challenges 5
D) Practical/Administrative IRB challenges 6
E) Guidance and advice for investigators 7
F) Close 8

A) Introduction, ground rules, informed consent (5 min, 5 min elapsed)

Good evening everyone. Thanks for coming to speak with us today on this online FG forum. Please indicate now if you are having trouble hearing me or seeing the text boxes or all the participants on your screen.

(If there are no technical issues, continue..)

I'd like to start by introducing myself. I'm Joel Weissman, the PI for the study

I am Chief Scientific Officer at Brigham and Women's Hospital's Center for Surgery and Public Health, affiliated with Harvard Medical School. Other people on the call include Eric Campbell, who will serve as my co-moderator, Avni Gupta, the project director, and xxx??

This study 'The Patient-Centered Outcome Research Oversight Study (PCOROS)' is being sponsored by the Patient Centered Outcomes Research Institute (PCORI). It aims at identifying challenges posed by Patient Centered Outcomes Research or Comparative Effectiveness Research (PCOR/CER) that are relevant to IRB oversight and human subject protections. We would like to learn about your experience in this area.

- Your participation – how FG's work
    - First name basis
    - Your ideas
    - Everyone's contribution is important
    - How discussion will work
        - Only one person at a time
        - Feel free to address each other, but No side conversations
        - The goal is not to reach agreement on anything, and in fact it's perfectly ok to disagree with each other in a respectful way. Our main goal is to learn from you.
- Ground rules
    - Time - ending

- Payment/compensation
- Turn off their cell phones /pagers and minimize their use while on the call.
- Please -- no emailing! We want your full attention
- My role -- Ask questions and keep on schedule

Finally, the consent script has already been shared with you in an email sent earlier. **The Tech (Corey) will run through this briefly**. If you have any question about it, please ask now

- This protocol was approved and determined to be exempt by the IRB at Partners HealthCare
- Your responses will be reported only in summary form
- All data will be kept confidential and will not be shared outside of the study team.
- Participation is voluntary and you may leave at any time you wish.
- Please do not share anything during the group that is involved in a legal case.
- You can choose not to answer a question.
- This session is being videotape recorded so that we remember everything you say. However, your comments are confidential and will be used for research purposes only. Our discussion will be kept securely with the research team.
- Finally, if you do not have any questions or concerns now, your participation implies your informed consent to participate in this focus group.

B) Icebreaker and, Defining PCOR/CER (5 min, 10 min elapsed)

Q: To start off, I would like to go around and ask everyone to tell us your name, a short name of your PCOR/CER study, the funder, and primary objective of the PCOR/CER studies with which you are involved.

[ADD THESE TO A VIRTUAL FLIP CHART; REFER TO PRE-FOCUS GROUP QNAIRE]

Q: Now can some of you tell me what makes these studies "patient centered outcomes research" or PCOR?

Probes

- Study Design
- Pragmatic clinical trials
- Cluster randomized trials
- Learning healthcare systems
- CBPR
- CDRNs
- PPRNs
- In general, would you say that PCOR is generally like other studies you've done in the past, or does it have unique qualities?

B) How the IRB handles multiple patient roles

Q: How many of you have patients or patient families involved in different roles in your research —that is, not just in their traditional role as subjects? What are the different roles that patients play in your research?

Probe roles

- as advisors/consultants
- as co-investigators / research staff
  - Design the research questions; design (or administer) consent, recruit (or facilitate access to data that the investigator would not otherwise have access to); co-authoring papers, reports; disseminate research results.
- Reporting on their own outcomes experiences
- as users of digital technology
- as participants in studies seeking to empower (enhance) their involvement in care
- *{do not spend much time (if any) on this point as it is tangential to study purpose}*How meaningful is the patient involvement? For example, would you say that the study is substantially different that it would otherwise have been due to patient involvement?

- If not, why not? What were the barriers to having patients make a more meaningful contribution?

Q: Drawing lines and defining their roles. When does a patient switch from becoming a subject to an advisor to a researcher?

Q. What are the IRB issues that you faced in involving patients in these roles within your PCOR/CER research? How have the issues been handled by you and your IRB?

Probes

One idea of the following probes is to get at variation in practices, to see if requirements are applied unevenly regardless of the role of the patient advisor; another is to identify various solutions

- IRB- or Institution-required training
  - CITI certification
  - HIPAA
  - Training in research methods
- Informed consent — is this necessary if they aren't subjects but collaborators?
- TB testing – for whom in what role?
- Data sharing
  - Does IRB weigh in on payment/compensation for them?
- Patients who are resistant to or resent the IRB as a barrier to conducting the research they think is important or conducting that research as quickly as possible.
  - E.g., we've been told anecdotally that some advocacy organizations have information that they want to hand over to the researcher, but the researcher cannot take it because the IRB won't allow it.

Q: Thank you for raising these issues. In light of this discussion, do you feel that the IRB review has helped you to protect the interests of patients and to align your research with relevant ethics and oversight regulations? Why or why not?

Probe:

- Do the issues change depending on what role the patient is playing? Are some roles as patients more challenging from an IRB perspective than others?

Q: Did anyone here conduct sessions with patients in preparation of their proposal? Did you seek IRB approval? Was IRB approval required? Please explain why or why not?

Q: If your patient advisors come from industry-funded patient advocacy groups, were they vetted somehow? Conflict of interest?

C) Other IRB challenges

Q: Are there other ethical issues in getting IRB approval for PCOR/CER protocols? Think about research design, mult--site nature, methods of recruitment, modes of data collection, scale. If yes, how are they different? How was the issue handled by the IRB? Please explain.

Probes

- Multi-site study– coordinating IRBs at different institutions?
    - Was there disagreement between IRBs?
    - Did this affect your ability to meet PCORI deadlines?
- Big data –
- Digital health technology/ mHealth / and social media including mobile technology, patient-facing apps (communication between patients and providers), wearables, twitter, etc?
    - Does your IRB have policies re: social media? Or mHealth? If yes, what are they like?
    - Has your IRB been receptive to this?
- Large scale recruitment, e.g., has anyone done PPRNs? CDRNs?
    - How many people are you trying to recruit, and how many do you have?
    - Have you tried to utilize any innovative recruitment (e.g., advertising, website design) methods to get your target numbers? If so, please describe.
        - What concerns did the IRB have?
        - How has the IRB response affected your ability to meet your recruitment goals?
    - Getting patient consent to participation

Q: What do you think are unique features of such studies compared to other types of research that you have to struggle to explain to the IRB? What are the main issues that your IRB finds specifically concerning about these studies?

- What is NOT unique about them?

- Do you think that those concerns are valid? Does the IRB need to be extra careful about some aspects of PCOR/CER?

D) Practical/Administrative IRB challenges

Q: Now, we would like to talk about <u>practical</u> challenges you may have encountered when seeking IRB approval for PCOR/CER, that is, administrative issues. What practical challenges have you encountered (directly or indirectly) in getting IRB approval?

<u>Probes</u>

- Tightly compressed PCORI timelines?
  - Did this impact the quality of your IRB application?
  - Did you miss deadlines because of IRB review?
- Requirements to submit things for approval that you don't think were necessary
- review times
- IRBs not familiar with methods used in PCOR
- Enlarged scale/scope of research
- Questions about when to waive informed consent
- Confidentiality (e.g., in use of health apps)

Q: Can any of you talk about the practical challenges you may have encountered <u>after</u> IRB approval has been granted for your PCOR/CER research.

- What additional information or clarifications do IRB reviewers usually seek from investigators?
  - Are these different from non-PCOR/CER studies?
- Lengthy delays due to???
- Problems adding study staff or sites
- Getting approval for changes to the protocol
- Which of these has been the most challenging and why?

Q: Thank you for raising these issues. In light of this discussion, do you feel that the IRB review has helped you to protect the interests of patients and to align your research with relevant ethics and oversight regulations? Why or why not?

Q: How much time is spent on IRB issues in PCOR? Does it seem excessive, too little, or just about right? Please explain.

- How much time did you (or your study staff) spending on getting initial IRB approval?
- How much time are you (or your study staff) spending on IRB-related work now that your study is underway?

- How does this compare to other studies you've worked on? If there is a difference, which direction and why?
- Would you say the IRB has done a good job at managing the process efficiently and effectively?

E) Guidance and advice for investigators

Q: Are there any existing written policies at your institution to guide investigators conducting PCOR/CER?

- If yes, what are they? How much do you know about these policies?
- Are they similar across institutions? (judge from responses of people from different institutions)
- Sufficient and completely address the spectrum of challenges that these studies pose?
- Were you trained by your institution/IRB to conduct these studies best ethical manner?

Q: Are there any unwritten rules-of-thumb at your institution to guide investigators conducting PCOR/CER?

- If yes, what are they?
- Are they similar across institutions? (judge from responses of people from different institutions)
- How did you learn about these?
- For example, we've heard of institutions that advise investigators with PCORI grants to talk amongst themselves about best practices.

Q: Does the IRB offer any additional support to PCORI investigators?

- Meetings in preparation for grant submission?
- Meetings after funding is awarded but before the study starts?
- More frequent meetings during the study period?
- Dedicated person who reviews PCORI research (e.g., as part of their research portfolio)?

Q: What type of guidance or support do you think will be helpful for investigators when preparing protocols for IRB approval?

- Educational activities?
- Institutional guidelines?
- Which area/topic do you think needs to be covered in more detail in such guidelines?
- Which area/topic has been left out but you think is important?
- Based on your experience, which area/topic in overseeing these research, is unimportant or is being given undue importance?
- Do you think additional support is needed at all? Okay to say no.

Q: If you were to give a new investigator advice about how to interact with the IRB in an efficient and effective manner regarding PCOR/CER research what would that be?

F) Close

Q: Thinking about all of the challenges you have faced regarding IRB oversight of your PCOR/CER research, which have proved the most challenging and why?

Q: Are there any other issues that we should have asked but didn't?