Appendix 6. Survey Instrument

PCORQS

Patient Centered Outcomes Research Oversight Study

S1. Before you begin, have you <u>ever</u> been a chair or alternate chair of an IRB?

☐$_1$ Yes, chair → ***PLEASE READ THE DEFINITIONS IN THE 2ND BOX BELOW.***

☐$_2$ Yes, alternate → ***PLEASE READ THE DEFINITIONS IN THE 2ND BOX BELOW.***

☐$_3$ No → ***DO NOT CONTINUE. PLEASE RETURN THE BLANK SURVEY IN THE ACCOMPANYING ENVELOPE.***

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Instructions for completing the survey:

- Please read each question carefully. Using a blue or black pen, place an "X" in the box next to the appropriate response.
- If you are asked to provide a written response to a question, please ***print*** legibly in the space provided.
- Please note that we hope that you will answer all the questions as appropriate; but you may skip over any which you choose not to answer.
- Please answer every question ***except those that you are specifically instructed to skip***. ***Be sure to follow the "GO TO" instructions carefully.***

If you have any questions about this survey, please contact Sandra Applebaum, Study Director at 1-646-654-4978 or sandra.applebaum@nielsen.com or Joel Weissman, the PI at the Brigham and Women's Hospital at 1-617-525-7300 or jweissman@partners.org.

Thank you in advance for your participation!

Please return your completed questionnaire in the enclosed postage-paid envelope.

For the purposes of this survey, please refer to these definitions

a. **Patient-centered outcomes research or PCOR** is the evaluation of questions and outcomes that are meaningful and important to patients and caregivers, and that engages patients beyond their traditional role as research subjects.

b. **Non-Traditional Role** refers to whenever patients are named as personnel in research projects as advisors, consultants, or investigators where they are involved in any aspect of research from topic development through study design, implementation, interpretation, and dissemination.

c. **Digital Health** refers to any aspect of research involving either social media such as Facebook or Twitter, or mobile devices, such as mobile phones, patient monitoring devices, wearables, like Fitbit, and other wireless devices, <u>*excluding*</u> electronic health or medical records.

SECTION A: IRB ACTIVITIES

If your institution has more than one IRB panel, please answer in reference to the panel for which you most recently served as Chair. If you are not the person who reviews the majority of minimal risk expedited reviews at your institution, please respond to the best of your ability.

A1. Are you currently an IRB chair or alternate chair?

☐$_1$ Yes → In what year did you become chair or alternate chair of your current IRB? ☐☐☐☐

☐$_2$ No → In what year did you stop serving as chair or alternate chair? ☐☐☐☐

A2. Which of the below <u>best</u> describes the setting for your most recent IRB service? *Please select only one. If more than one setting applies, please select the setting that is most relevant to PCOR.*

☐$_1$ Medical school
☐$_2$ School of Public Health
☐$_3$ Other university
☐$_4$ Hospital
☐$_5$ Commercial
☐$_6$ Other IRB (Please specify) _____

A3. In your most recent year as chair or alternate chair of an IRB, about how many <u>new</u> protocols were considered by all IRBs at your entire institution? *Please include protocols that get full review, or are expedited or exempt. If you are not sure, your best estimate will do.*

☐☐☐☐ # of <u>new</u> protocols last year

A4. In your most recent year as chair or alternate chair of an IRB, about how many <u>new</u> protocols using any aspect of digital health (as defined above) were considered by all IRBs at your entire institution? *Please include protocols that get full review, or are expedited or exempt. If you are not sure, your best estimate will do. If none, please enter "0".*

☐☐☐☐ # of <u>new</u> digital health protocols last year

SECTION B: EXPERIENCE WITH PCOR

Refer to definition of PCOR above. Even if you have little or no experience with PCOR, please answer the following questions to the best of your ability.

B1. In your most recent year as chair or alternate chair of an IRB, about how many <u>new</u> PCOR protocols were considered by all IRBs at your entire institution? *Please include protocols that get full review, or are expedited or exempt. If you are not sure, your best estimate will do.* ***If none, please enter "0" and go to B4 on the next page.***

☐☐☐☐# <u>new</u> PCOR protocols last year

B2. How much experience do you have as chair or alternate chair reviewing PCOR protocols?

☐$_1$ A lot
☐$_2$ Some
☐$_3$ A little
☐$_4$ None at all

B3. Does your IRB have staff or an IRB member with experience in PCOR to help with the review of these protocols?

☐$_1$ Yes
☐$_2$ No

B4. Please rate how challenging each of the following are for your IRB's review of PCOR protocols.

	Very Challenging	Somewhat Challenging	A Little Challenging	Not at all Challenging
a. Patients serving as study consultants	☐1	☐2	☐3	☐4
b. Patients on advisory groups	☐1	☐2	☐3	☐4
c. Patients serving as co-investigators	☐1	☐2	☐3	☐4
d. Patients recruiting study subjects	☐1	☐2	☐3	☐4
e. Patients having access to identifiable study data	☐1	☐2	☐3	☐4
f. Patients serving as <u>both</u> subjects and in non-traditional research roles	☐1	☐2	☐3	☐4

B5. Please rate how challenging each of the following are for your IRB's review of PCOR protocols.

	Very Challenging	Somewhat Challenging	A Little Challenging	Not at all Challenging	My IRB does not have experience with this
a. <u>Investigators</u> engaging in research activities for which they are not adequately trained	☐1	☐2	☐3	☐4	☐5
b. Having the research conducted at multiple research sites	☐1	☐2	☐3	☐4	☐5
c. The creation of local patient registries to serve as a source of potential subjects for other studies	☐1	☐2	☐3	☐4	☐5
d. The creation of PCORI's Patient-Powered Research Networks	☐1	☐2	☐3	☐4	☐5

B6. How much do you agree or disagree with the following statements?

On average, compared to non-PCOR protocols, PCOR protocols are…	Strongly Agree	Agree	Disagree	Strongly Disagree
a. More difficult to review	☐1	☐2	☐3	☐4
b. More difficult to oversee	☐1	☐2	☐3	☐4
c. Less scientifically sound	☐1	☐2	☐3	☐4
d. More aggressive in terms of the study timeline	☐1	☐2	☐3	☐4
e. More likely to involve protocols that are not adequately thought through with respect to human subjects protection issues	☐1	☐2	☐3	☐4
f. More likely to result in research findings that <u>make a difference</u> to patients	☐1	☐2	☐3	☐4
g. More likely to meet study recruitment goals	☐1	☐2	☐3	☐4

SECTION C: IRB POLICIES AND PRACTICES

C1. In general, how much responsibility do you feel your IRB has to <u>protect</u> patients who are serving in non-traditional roles and activities on PCOR studies? *(**Non-Traditional Role** refers to whenever patients are named as personnel in research projects as advisors, consultants, or investigators where they are involved in any aspect of research from topic development through study design, implementation, interpretation, and dissemination.)*

☐$_1$ A lot of responsibility
☐$_2$ Some responsibility
☐$_3$ A little responsibility
☐$_4$ No responsibility at all

C2. In general, how much responsibility do you feel your IRB has for on-going oversight of patients who are serving in non-traditional roles on PCOR studies?

☐$_1$ A lot of responsibility
☐$_2$ Some responsibility
☐$_3$ A little responsibility
☐$_4$ No responsibility at all

C3. Does your IRB consider patients serving in non-traditional roles to be research subjects even if they are not formally enrolled as subjects in the same study?

☐$_1$ Yes
☐$_2$ No

C4. In the last year, has your IRB reviewed one or more PCOR protocol(s) in which patients served in any of the non-traditional roles?

☐$_1$ Yes
☐$_2$ No → **GO TO C6**

C5. Please think about all of the protocols your IRB has reviewed involving patients in non-traditional roles. How often does your IRB or institution require patients serving in those roles to …?

	Never	Rarely	Sometimes	Often	Always
a. Sign informed consent for research participation	☐$_5$	☐$_4$	☐$_3$	☐$_2$	☐$_1$
b. Undergo HIPAA training	☐$_5$	☐$_4$	☐$_3$	☐$_2$	☐$_1$
c. Undergo CITI training or other formal research-ethics training	☐$_5$	☐$_4$	☐$_3$	☐$_2$	☐$_1$
d. Undergo training in research methods	☐$_5$	☐$_4$	☐$_3$	☐$_2$	☐$_1$
e. Provide COI disclosure	☐$_5$	☐$_4$	☐$_3$	☐$_2$	☐$_1$
f. Provide confidentiality agreement	☐$_5$	☐$_4$	☐$_3$	☐$_2$	☐$_1$
g. Get a TB test	☐$_5$	☐$_4$	☐$_3$	☐$_2$	☐$_1$
h. Be listed on the protocol as study staff	☐$_5$	☐$_4$	☐$_3$	☐$_2$	☐$_1$

C6. How much do you agree or disagree with the following statements?

Having patients serve in non-traditional roles…	Strongly Agree	Agree	Disagree	Strongly Disagree
a. Does not add value to data quality	☐1	☐2	☐3	☐4
b. Improves the quality of the research process	☐1	☐2	☐3	☐4
c. Fails to lead to better research outcomes	☐1	☐2	☐3	☐4
d. Improves the quality of research at your institution	☐1	☐2	☐3	☐4
e. Is meaningful and important to patients and caregivers	☐1	☐2	☐3	☐4
f. Adds value to research	☐1	☐2	☐3	☐4
g. Is beneficial to advancing science	☐1	☐2	☐3	☐4

C7. In general, how much responsibility do you feel your IRB has to protect your institution from problems created by patients serving in non-traditional roles on PCOR studies?

☐1 A lot of responsibility
☐2 Some responsibility
☐3 A little responsibility
☐4 No responsibility at all

C8. Please indicate how much responsibility each of the following groups have for <u>ensuring</u> that patients who are serving in non-traditional research roles on PCOR studies are adequately trained regarding human subjects research ethics.

	A Lot of Responsibility	Some Responsibility	A Little Responsibility	No Responsibility at all
a. The PI	☐1	☐2	☐3	☐4
b. The IRB	☐1	☐2	☐3	☐4
c. The research funder	☐1	☐2	☐3	☐4
d. The patients themselves	☐1	☐2	☐3	☐4
e. The institutions that the IRBs serve	☐1	☐2	☐3	☐4

SECTION D: INFORMATION TECHNOLOGY, DIGITAL HEALTH, AND ELECTRONIC HEALTH RECORDS (EHRs)

D1. Thinking about the protocols considered by your IRB in the last year, are each of the following more or less frequent in PCOR protocols compared to non-PCOR protocols?

	More Frequent	Less Frequent	About the Same	Don't Know
a. Social media to recruit potential study subjects	☐1	☐2	☐3	☐8
b. Electronic platforms (e.g., study websites) to conduct informed consent	☐1	☐2	☐3	☐8
c. Wearable devices (e.g., Fitbit) to collect study data	☐1	☐2	☐3	☐8
d. Electronic health records to identify potential study subjects	☐1	☐2	☐3	☐8
e. Computerized apps on smart phones, tablets, to collect study data	☐1	☐2	☐3	☐8

D2. Please rate how challenging the use of each of the following are to your IRB's review of PCOR protocols.

	Very Challenging	Somewhat Challenging	A Little Challenging	Not at all Challenging	My IRB does not have experience with this
a. Social media to recruit potential study subjects	☐1	☐2	☐3	☐4	☐5
b. Electronic platforms (e.g., study websites) to conduct informed consent	☐1	☐2	☐3	☐4	☐5
c. Wearable devices (e.g., Fitbit) to collect study data	☐1	☐2	☐3	☐4	☐5
d. Electronic health records to identify potential study subjects	☐1	☐2	☐3	☐4	☐5
e. Computerized apps on smart phones, tablets, to collect study data	☐1	☐2	☐3	☐4	☐5

D3. Does your IRB <u>or your institution</u> have any written policies regarding the use of each of the following technologies?

	Yes	No	Don't Know
a. Social media to recruit potential study subjects	☐1	☐2	☐8
b. Electronic platforms (e.g., study websites) to conduct informed consent	☐1	☐2	☐8
c. Wearable devices (e.g., Fitbit) to collect study data	☐1	☐2	☐8
d. Electronic health records to identify potential study subjects	☐1	☐2	☐8
e. Computerized apps on smart phones, tablets, to collect study data	☐1	☐2	☐8

D4. In general, how would you rate the level of <u>information technology (IT) expertise</u> (e.g., digital health, electronic health records, web surveys) among members and staff of your IRB, relevant to PCOR protocols?

☐1 Excellent
☐2 Very good
☐3 Good
☐4 Fair
☐5 Poor

D5. In general, how often do you feel that your IRB needs to seek advice from experts outside of your IRB on IT relevant to PCOR protocols?

☐1 Always
☐2 Often
☐3 Sometimes
☐4 Rarely
☐5 Never → **GO TO E1**

D6. How often is your IRB <u>able</u> to obtain advice from experts outside of your IRB on IT relevant to PCOR protocols?

☐1 Always
☐2 Often
☐3 Sometimes
☐4 Rarely
☐5 Never

SECTION E: GUIDANCE

E1. Below is a list of potential topics related to PCOR research. *For each, please rate how helpful it would be for the federal government to provide additional guidance for IRBs.*

Additional guidance for:	Very Helpful	Somewhat Helpful	A Little Helpful	Not at all Helpful
a. Informed consent for patients serving in non-traditional roles	☐1	☐2	☐3	☐4
b. Training for patients serving in non-traditional roles	☐1	☐2	☐3	☐4
c. Training for PIs regarding IRB issues specific to PCOR research	☐1	☐2	☐3	☐4
d. Training for IRB members regarding PCOR related research in general	☐1	☐2	☐3	☐4
e. Policies related to the participation of patients in grant development activities	☐1	☐2	☐3	☐4
f. Standardization across IRBs in policies/practices related to PCOR research in general	☐1	☐2	☐3	☐4
g. Policies related to the use of social media to recruit subjects in PCOR research	☐1	☐2	☐3	☐4
h. Policies related to the use of EHRs in PCOR research	☐1	☐2	☐3	☐4
i. Policies regarding conflicts of interest among individuals serving as both subjects and in non-traditional roles in PCOR	☐1	☐2	☐3	☐4
j. Other (Please specify)				

SECTION F: DEMOGRAPHICS

F1. Do you identify as…? *Please select only one.*

☐1 Male
☐2 Female
☐6 Other

F2. Please indicate your race/ethnicity. *Please select all that apply.*

☐1 American Indian or Alaskan Native
☐2 Asian
☐3 Black or African-American
☐4 Hispanic or Latino
☐5 Native Hawaiian or Other Pacific Islander
☐6 White
☐7 Other (Please specify)_____

F3. In what year were you born? ☐☐☐☐

F4. At the start of your most recent year as chair or alternate chair of an IRB, about how many years of experience did you have conducting …? *If none, please enter "0".*

	Years
a. Clinical research involving living humans as research subjects	☐☐
b. PCOR related research	☐☐

F5. At the start of your most recent year as chair or alternate chair of an IRB, which of the following graduate degrees had you earned? *Please select all that apply.*

☐$_1$ Master's degree
☐$_2$ MD
☐$_3$ PhD
☐$_6$ Other (Please specify) _____

F6. Other than as IRB chair or alternate chair, do you hold another administrative position at your institution?

☐$_1$ No
☐$_2$ Yes (Please specify your primary title or position, city and state)

Primary title or position	City	State

F7. In your most recent year as chair or alternate chair of an IRB, what was your academic rank?

☐$_1$ None
☐$_2$ Instructor, Lecturer, etc.
☐$_3$ Assistant professor
☐$_4$ Associate professor
☐$_5$ Professor
☐$_6$ Other (Please specify) _____

F8. Would you be willing to be contacted in the future, if necessary, to gain information regarding your perspective on your IRB? *Remember that your information is confidential and we will only contact you if you select yes.*

☐$_1$ Yes
☐$_2$ No → **GO TO F10**

F9. Please provide the following information. *Please indicate your preferred method of contact.*

Preferred method of contact			
	First name:	**Last name:**	
☐$_1$	**Telephone:**		
☐$_2$	**Email:**		
☐$_3$	**Address 1:**	**Address 2:**	
	City:	**State:**	**Zip code:**

F10. Is there something you would like to comment on that we did not ask about related to PCOR research? *If so, please add your comments in the box below.*

THANK YOU FOR TAKING THE TIME TO COMPLETE THIS SURVEY. PLEASE RETURN YOUR COMPLETED QUESTIONNAIRE IN THE ENCLOSED ENVELOPE.

[UNIQUE ID]-1