

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

BOARD OF GOVERNORS MEETING

Tuesday,
March 16, 2021

Webinar

[Transcribed from PCORI webinar.]

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APPEARANCES:

BOARD OF GOVERNORS

Kara Ayers, PhD
Kate Berry
Tanisha Carino, PhD
Jennifer DeVoe, MD, MPhil, MCR, DPhil, FAAFP
Alicia Fernandez, MD
Christopher Friese, PhD, RN, AOCN, FAAN
Christine Goertz, DC, PhD [Chairperson]
Michael Herndon, DO
Russell Howerton, MD
James Huffman
Connie Hwang, MD, PhD
Mike Lauer, MD, Designee of the NIH Director
Sharon Levine, MD [Vice Chairperson]
Michelle McMurry-Heath, MD, PhD
Barbara J. McNeil, MD, PhD
David Meyers, MD, FAAFP
Eboni Price-Haywood, MD. MPH, FACP
James Schuster, MD, MBA
Ellen Sigal, PhD
Kathleen Troeger, MPH
Danny van Leeuwen, MPH, RN
Robert Zwolak, MD, PhD

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Consider for Approval:

Research and Dissemination & Implementation
Award Slates [continued]

Slates of Awards from Cycle 2 2020 Dissemination
and Implementation PFAs:

-Limited Competition Dissemination and
Implementation PFA

-Dissemination and Implementation Shared
Decision Making PFA

Joanna Siegel, ScD, Program Director,
Engagement, Dissemination and Implementation
(D&I)

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Consider for Approval:

Research Topics for Targeted PFAs for
Cycle 2 2021

Nakela L. Cook, MD, MPH

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Alicia Fernandez, MD, Science Oversight
Committee (SOC) Chair

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Targeted PFA for Cycle 2 2021: Improving
Postpartum Maternal Outcomes for Populations
Experiencing Disparities

Els Houtsmuller, PhD, Associate Director,
HDDR

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Targeted PFA for Cycle 2 2021: Comparative
Effectiveness of Interventions Targeting
Mental Health Conditions in Individuals with
Intellectual and Development Disabilities (IDD)

Holly Ramsawh, PhD, Senior Program
Officer, CEDS

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P R O C E E D I N G S

[1:02 p.m. EST]

OPERATOR: Dr. Goertz, the floor is yours.

CHAIRPERSON GOERTZ: Thank you so much.

Good afternoon and welcome to the March 16, 2021 meeting of the PCORI Board of Governors, I'm Christine Goertz, Chairperson. I want to welcome those of you who are joining us for today's Board meeting via teleconference and webinar. Thank you to those who have joined us virtually online and on the phone, we're very pleased to have you here.

I want to remind everyone that conflict of interest disclosures for Board members are publicly available on the PCORI's website, and are required to be updated annually and if the information changes. If the Board will deliberate or take action on a matter that presents a conflict of interest for you, please recuse yourself or inform me if you have any questions. If you have questions about disclosures or recusals relating to you or others, contact your staff representative.

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1 consideration today will be available during the
2 webinar and then after the webinar will be posted on
3 our website at www.PCORI.org. The webinar is being
4 recorded, and the archive will be posted within a
5 week or so.

6 Finally, a reminder that we are live
7 tweeting today's activities on Twitter, join the
8 conversation with @PCORI.

9 Nick, would you please call roll.

10 MS. WILSON: Certainly. Kara Ayers.

11 DR. AYERS: Present.

12 MS. WILSON: Kate Berry.

13 MS. BERRY: I'm here.

14 MS. WILSON: Tanisha Carino.

15 DR. CARINO: Present.

16 MS. WILSON: Francis Collins, or Mike
17 Lauer, Designee of the NIH Director.

18 DR. LAUER: Here, Mike Lauer.

19 MS. WILSON: Jennifer DeVoe.

20 DR. DeVOE: Present.

21 MS. WILSON: Alicia Fernandez.

22 DR. FERNANDEZ: Present.

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1 MS. WILSON: Christopher Friese.
2 DR. FRIESE: Present.
3 MS. WILSON: Christine Goertz.
4 CHAIRPERSON GOERTZ: Present.
5 MS. WILSON: Mike Herndon.
6 DR. HERNDON: Present.
7 MS. WILSON: Russell Howerton.
8 DR. HOWERTON: Present.
9 MS. WILSON: James Huffman.
10 MR. HUFFMAN: Present.
11 MS. WILSON: Connie Hwang.
12 DR. HWANG: Present.
13 MS. WILSON: Sharon Levine.
14 [No response.]
15 MS. WILSON: Michelle McMurry-Heath.
16 [No response.]
17 MS. WILSON: Barbara McNeil.
18 DR. McNEIL: Here.
19 MS. WILSON: David Meyers, or Karin Rhodes,
20 Designee of the AHRC Director.
21 DR. MEYERS: David Meyers is here.
22 MS. WILSON: Thank you. Eboni Price-

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1 Haywood

2 DR. PRICE-HAYWOOD: Present.

3 MS. WILSON: James Schuster.

4 DR. SCHUSTER: Present.

5 MS. WILSON: Ellen Sigal.

6 DR. SIGAL: Here.

7 MS. WILSON: Kathleen Troeger.

8 MS. TROEGER: Yes, here.

9 MS. WILSON: Daniel van Leeuwen.

10 MR. VAN LEEUWEN: Present.

11 MS. WILSON: Janet Woodcock.

12 [No response.]

13 MS. WILSON: And Robert Zwolak.

14 DR. ZWOLAK: Here.

15 MS. WILSON: Dr. Goertz we have a quorum.

16 CHAIRPERSON GOERTZ: All right, thank you

17 so much. All right. Can I have the next slide

18 please?

19 So our agenda today is we'll consider our
20 minutes for approval and then we have a number of
21 other approvals. We will be looking at our research
22 and dissemination implementation award slates,

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1 research topics for targeted PFAs for Cycle 2 2021.
2 And then, finally principles for the consideration
3 of the full range of outcomes data in PCORI-funded
4 research. So this is a very ambitious agenda so
5 we've asked the staff to make really condensed
6 presentations and we'll be moving through as quickly
7 as we can to make sure that we're able to have some
8 time for Board discussion, but also so that we're
9 able to get through the agenda today. So I thank
10 you for your patience and consideration as we move
11 relatively quickly through the agenda today.

12 All right. Can I have the next slide?

13 So, our first order of business has to
14 approve the minutes of the February 9, 2021 Board of
15 Governors meeting. Can I have a motion to approve?

16 DR. McNEIL: So moved.

17 CHAIRPERSON GOERTZ: Okay. Barbara. Thank
18 you. Can I have a second?

19 DR. AYERS: Second. This is Kara.

20 CHAIRPERSON GOERTZ: Thank you, Kara. All
21 right. Any further discussion?

22 [No response.]

1 CHAIRPERSON GOERTZ: All those in favor,
2 please signify by saying aye.

3 [Ayes.]

4 CHAIRPERSON GOERTZ: Opposed?

5 [None.]

6 CHAIRPERSON GOERTZ: Abstentions?

7 [None.]

8 CHAIRPERSON GOERTZ: All right, thank you.

9 I am now going to I'm asked Nakela to
10 provide an overview of our award slates, Nakela.

11 DR. COOK: Thank you so much. You may
12 recall that at our December Board meeting we
13 discussed approaches to monitor our progress against
14 what's laid out on in the Board-approved commitment
15 plan, and also provide the Board with some context
16 for the slates under consideration for approval
17 within each cycle. And so, I wanted to begin today,
18 our review of our slates that we are putting forward
19 for consideration for approval with some overarching
20 contextual remarks and I wanted to ask that we all
21 recall that the slates have been -- that are going
22 to be presented today have gone through the multi-

1 step process of merit review, staff review, and the
2 relevant selection committee. And at the Board
3 level today, the focus is really for consideration
4 of approval of the slates and to ensure that they
5 are aligned, that the slates are aligned with the
6 overall goals of the priorities of the PCORI funding
7 announcement, which are aligned, as well to PCORI
8 priorities as well as budgetary oversight.

9 So let's go ahead to our next slide.

10 So the today, the Board will consider the
11 following five award slates for approval. Three of
12 them come from Research solicitations and two from
13 Dissemination and Implementation solicitations, they
14 total \$48.5 million, all together, and from a timing
15 perspective, it may be helpful for you to know that
16 all of these were the very first cycles after
17 reauthorization and all were unfolding as well
18 during the COVID-19 pandemic. None of them come in
19 at over the set-aside budget that we had for each
20 PCORI funding announcement, there's no additional
21 request for funding at this time.

22 Let's go to the next slide.

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1 So this slide demonstrates how the funding
2 cycles for the targeted PFA award slates that you'll
3 be considering today fit into the larger context of
4 data related to Letters of Intent, applications, and
5 funding rates compared to historical average. And
6 what you can see here is that we've had a pretty
7 robust response to these announcements that you're
8 considering, with more Letters of Intent submitted
9 as compared to our historical average. And we also
10 had a higher proportion of Letters of Intent that
11 were invited to actually submit for the diabetes
12 studies. While we had a lower proportion for the
13 rare diseases studies and a high proportion of those
14 that had accepted Letters of Intent, actually did
15 submit applications to PCORI.

16 And with the Board approval today, these
17 slates represent funding rates that are at or above
18 our historical average.

19 And since these were fairly typical PFAs,
20 with better than average performance in some rounds,
21 and as you can see for the targeted PFA on the right
22 side of the slide for Cycle 3 on Suicide Prevention,

1 which is really timely given what we are seeing
2 right now with this pandemic, we'll be coming back
3 to the Board in July. And we'll again, we'll see
4 that we have a robust response in applications that
5 have come in to PCORI and they're making their way
6 through the process. So you'll see those as slates
7 in the July meeting.

8 Let's go to our next slide.

9 So this slide is to demonstrate how the
10 Cycle 1 2020 broad PFA slate fits into the larger
11 context of data related to Letters of Intent and
12 application and funding rates, and it's really to
13 help us kind of gauge whether or not a given cycle
14 is a typical cycle or departure. And this slide
15 should be familiar to you because we looked at the
16 Cycle 1 2021 broad slate in our prior Board meeting.
17 And what we have in confer consideration for the
18 Board today are two applications which were deferred
19 due to COVID-19, and during the early days of the
20 pandemic, we didn't have a Cycle 2 issue, and so
21 you'll see these as for inclusion in the Cycle 1
22 2020 slate.

1 And you may recall that because of the
2 pandemic, there were a high number of deferrals in
3 the timing of the launch of this PFA. And what we
4 see with the approval of the deferrals from Cycle 1
5 2020, there are a few things that are notable. It
6 turns out that actually even though there were a lot
7 of things that were unusual about this cycle, given
8 the deferrals and the pandemic that ultimately it
9 performs similar to a typical cycle. And when you
10 look at the return of Letters of Intent and
11 applications funded, and you see the funding rate
12 overall was about 15 percent inclusive of the
13 deferrals similar to what we've seen in our
14 historical average.

15 For the deferrals we had actually 35
16 applications that requested a deferral and were
17 granted a deferral, but only 19 of those submitted
18 at the next opportunity. And so, together those
19 that submitted plus the deferral submissions yield
20 an overall submission rate of 75 percent, which is
21 very similar to historical average. And on the
22 right side of the slide you see the next broad

1 slate, which is anticipated to come through for
2 Cycle 3 2020 since the broads again we're not
3 offered in Cycle 2. And you can see that it looks
4 very similar in terms of yield.

5 Let's go the next slide.

6 So this slide is to provide some context
7 for the cycles in terms of the commitment plan in
8 2021. And here you can see that the research line,
9 the planned commitment for 2021 is \$290 million, and
10 the proposed total award for the slates with the
11 additional studies that we will discuss today is \$84
12 million, with approximately \$260 million available
13 for awards from the Cycle 3 2020.

14 So upcoming for Cycle 3 2020 are several
15 slates, including a Cycle 3 2020 broad slate with
16 two special areas of emphasis included. There's
17 also a Cycle 3 2020 phased large award slate for
18 comparative effectiveness research or the PLACER
19 announcement, remember these are those large stage
20 clinical trial awards.

21 And we also anticipate having the PFA slate
22 coming from Cycle 3 2020 on the brief interventions

1 for youth.

2 So this is really a robust group of slates
3 that will be coming to the Board, later in July for
4 review. We're also working on a COVID-19 targeted
5 PFA that's been developed in a fast-track way under
6 our previously approved plans, and that'll likely
7 launch off-cycle, so it's also included here as a
8 future announcement.

9 So given what we see that we've currently
10 made progress against with a commitment plan and
11 what we have teed up for Cycle 2 of 2020, at this
12 time we're not proposing changes to the commitment
13 plan for 2021, and we don't anticipate requesting
14 additional funding for the remaining cycles, unless
15 we have a better than anticipated batch of
16 applications from the slates, for these Cycle 3
17 announcements that will be coming to you in July.

18 Let's go to our next slide.

19 So I'm going to transition and talk about
20 the Dissemination and Implementation slates, and
21 you'll see a similar pattern for the context for the
22 slates. And this slate demonstrates how the Cycle 2

1 limited competition Dissemination and Implementation
2 slate fits into a larger context and compares it
3 against historical average. And it's important to
4 note that for this cycle, and the subsequent cycles
5 on this slide, they were also affected by the
6 pandemic given the timelines and it may have
7 affected our number of Letters of Intent and our
8 applications that came in.

9 But with the approval of the slate for
10 Cycle 2 2020, you're going to see a few things here.
11 We see that we have a greater success of the
12 conversion of the Letters of Intent that were
13 invited to applications that were submitted, and we
14 see a higher funding rate.

15 As we move out into the future cycles that
16 will come before the Board in the summer and beyond.
17 In addition to COVID-19, application numbers may be
18 affected by the throughput in the research-funding
19 pipeline. So you may recall that this is a limited
20 competition announcement, and it's limited to
21 findings from research funding that are primed for
22 Dissemination and Implementation awards, and so,

1 this comes in waves depending on historical funding
2 patterns, and we're still working to understand how
3 COVID-19 will affect that wave of funded awards that
4 may actually move into Dissemination and
5 Implementation Limited Competition awards.

6 And you'll also note here that this slate
7 includes one smaller word that was approved under
8 the authority of the Chief Engagement and
9 Dissemination Officer who delegated the authority
10 for smaller budget size.

11 Let's go to our next slide.

12 And this slide is actually -- this slide
13 tries to demonstrate how the Cycle 2 2020
14 implementation awards related to shared decision
15 making, fit into the larger context and how it
16 compares to historical average. And so, this table
17 is really also designed to kind of give you a sense
18 of if things are typical or a departure and it's
19 important to note the same things that I talked
20 about on the prior slide apply here. That the
21 number of Letters of Intent and applications were
22 likely affected by the pandemic, and given the

1 timeline.

2 And with the approval of the slate for this
3 PFA you'll see a few things. While there was only
4 one award, it was a really strong application and is
5 being proposed for funding. It does also raise an
6 important topic for us related to our strategic
7 planning. It brings to the fore the question about
8 PCORI's role and the continued opportunity. And
9 this is a really important space, and we may be at a
10 point that we've cleared some of our backlog in
11 terms of pending demand and pent-up demand for this
12 space and now we're maybe entering a more steady
13 state, but these are the sorts of things that we can
14 look forward to discussing through our strategic
15 planning activities at a future time.

16 Let's go to the next slide.

17 This is the last slide to provide some
18 context and this slide is really focused on thinking
19 about the dissemination and implementation slates in
20 terms of our commitment plan for 2021. And again
21 here you can see that the D&I align, had a plan
22 commitment for 2021 of about \$28 million, and the

1 proposed total award for the slate with the
2 additional study that's being discussed today is \$6
3 million. And that leaves approximately \$22 million
4 available for awards for Cycle 3 2020. And upcoming
5 are several slates including a Cycle 3 2020 limited
6 competition D&I PFA, as well as the Cycle 1 2021
7 limited competition PFA

8 But based on submissions to the remaining
9 cycles that are supposed to be funded in fiscal year
10 2021, that you saw on the prior slides, we
11 anticipate that the funding plan for D&I awards this
12 year would be sufficient and at this time we're not
13 proposing changes to the commitment plan, we don't
14 think we'll anticipate requesting any additional
15 funding, but in fact we do anticipate that with the
16 trends of the applications coming in, we may be
17 below our funding commitment allocation in this
18 phase.

19 So that's the context I wanted to provide
20 for the slates that you're going to be seeing today
21 in considering for approval. And I'll turn it back
22 over to Dr. Goertz for any discussion and to

1 introduce the Selection Committee chair.

2 CHAIRPERSON GOERTZ: Great, thank you so
3 much, Nakela, I really appreciate it.

4 Does, does the Board have any questions or
5 comments on this overview? I think it's really
6 helpful to have this broad overview, and so we can
7 put that in context as we're as we're moving forward
8 with consideration of the slates that we'll be
9 looking at today.

10 DR. COOK: Great.

11 CHAIRPERSON GOERTZ: Thank you. All right,
12 I'm not seeing anything in the chat or anyone
13 turning on their camera, so in that case I think
14 we'll move along. So what I'd like to do is I'd
15 like to, to turn this over to Barbara McNeil, who
16 will introduce the three research awards slates.

17 DR. McNEIL: So thank Chris, the Selection
18 Committee for PCORI met on February 3rd and
19 recommended three slates of awards for approval by
20 this board. These slates come from the broad PFAs
21 as well as the targeted PFAs in focus on Type 2
22 Diabetes and rare disease research, and the staff

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1 will present the results of our deliberations now,
2 so we can move on.

3 Kim.

4 MS. BAILEY: Thank you. Slide please.

5 I'm pleased to be presenting for the
6 Board's review and approval a slate of four awards
7 from this targeted funding announcement. The goal
8 of this announcement is to find high quality
9 observational studies that compare the effectiveness
10 of older versus newer second-line pharmacological
11 agents in Type 2 Diabetes in a patient population at
12 moderate cardiovascular risk, with a focus on
13 cardiovascular outcomes. Drug classes of interest
14 specified in the planning announcement, are the
15 newer SGLT2 inhibitors and GLP-1 receptor agonist,
16 and the older sulfonylureas and DPP-4 inhibitors.

17 As a quick reminder this funding
18 announcement was the result of more than four years
19 of work and stakeholder engagement, during which
20 PCORI explored the possibility of funding a
21 randomized trial in this space. A number of factors
22 limiting the feasibility of a randomized trial

1 resulted in our issuance of this funding call for
2 studies using robust observational designs.

3 While not a substitute for randomized
4 trials, the evidence generated by studies funded
5 through this initiative may help to inform clinical
6 decision making and the design of future trials, the
7 availability of up to \$20 million in total funds was
8 posted with direct cost limited at \$4 million per
9 study and maximum project periods of three years.

10 Next slide please.

11 The total award amount of the four studies
12 on the proposed slate is \$18.4 million. The four
13 studies proposed for funding are highly
14 complementary to one another, both in terms of the
15 methods used and sources of data proposed for
16 analysis, and each is directly responsive to the
17 priority research question, outlined in the funding
18 announcement. Together they form a robust slate of
19 studies that employ diverse approaches to answering
20 this key question of interest.

21 I am happy to answer any questions, but
22 we'll turn things back over now to Dr. Goertz to

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1 facilitate discussion and the vote.

2 CHAIRPERSON GOERTZ: Thank you so much,
3 Kim. I really appreciate it. Are there any
4 questions or comments for Kim before we move forward
5 with the vote?

6 MR. VAN LEEUWEN: No questions for me.

7 CHAIRPERSON GOERTZ: Great, thank you.

8 DR. McNEIL: I move approval.

9 CHAIRPERSON GOERTZ: All right, thank you.
10 In that case what I'm going to do is I'm
11 actually going to ask for a motion to approve the
12 Cycle 2 2020 observational analysis,

13 UNIDENTIFIED BOARD MEMBER: Motion to
14 approve.

15 CHAIRPERSON GOERTZ: All right.

16 DR. ZWOLAK: Zwolak, second.

17 CHAIRPERSON GOERTZ: Okay, thank you. Is
18 there -- so now we're going to do something a little
19 bit differently. Normally we've done a voice, or a
20 roll call vote for this. Instead we're going to be
21 doing a voice vote I do want to announce that
22 Michelle McMurry-Heath has joined the Board meeting

1 so that everyone that was engaged in the original
2 roll call at the beginning and in addition to
3 Michelle is on the call for this voice vote.

4 So, all those in favor please say aye.

5 [Ayes.]

6 CHAIRPERSON GOERTZ: Opposed?

7 [None.]

8 CHAIRPERSON GOERTZ: Abstentions?

9 DR. McNEIL: I abstain I'm in conflict.

10 MS. HENNESSEY: Christine, I think you were
11 going to note the Board members who did not intend
12 to participate --

13 CHAIRPERSON GOERTZ: Yeah. Okay, I'm
14 sorry. For the Board members that did not attend
15 for this are Janet Woodcock, I believe -- and then
16 Kathleen also?

17 MS. HENNESSEY: Yes, I believe, who did not
18 intend to participate in the vote due to conflict of
19 interest.

20 CHAIRPERSON GOERTZ: Okay, yes.

21 DR. McNEIL: No, did I Mary. I believe I'm
22 in conflict with numbers three and four, is that not

1 true?

2 CHAIRPERSON GOERTZ: Sorry. I believe that
3 myself, Barbara, and then Sharon Levine who is not
4 in present is recused from this. Does that match
5 your notes, Mary?

6 MS. HENNESSEY: Yeah, it does Christine.
7 Thanks so much. And so I think in terms of a
8 motion, let's just make sure someone moves that who
9 doesn't have a conflict, I believe Barbara --

10 DR. FERNANDEZ: So moved, Fernandez.

11 CHAIRPERSON GOERTZ: Okay, great. Thank
12 you Alicia. Can we just start over here?

13 [Laughter.]

14 CHAIRPERSON GOERTZ: So we're doing voice
15 votes. We have three people in conflict, myself,
16 Barbara, and Sharon, who is not present and so I
17 would like to ask for a motion to approve the
18 recommended slate of awards for the Cycle 2 2020
19 observational analysis of second-line
20 pharmacological agents in Type 2 Diabetes.

21 DR. FERNANDEZ: So moved, Alicia.

22 CHAIRPERSON GOERTZ: Thank you, Alicia.

1 Can I have a second?

2 DR. ZWOLAK: Zwolak, second.

3 CHAIRPERSON GOERTZ: Thank you Bob. Is
4 there any further discussion?

5 [No response.]

6 CHAIRPERSON GOERTZ: All right, I'm now
7 going to call for a voice vote.

8 All those in favor?

9 [Ayes.]

10 CHAIRPERSON GOERTZ: Opposed?

11 [None.]

12 CHAIRPERSON GOERTZ: Abstentions?

13 [No additional.]

14 CHAIRPERSON GOERTZ: Okay, I think we I
15 think we did it. Thank you. It takes a little bit
16 of getting used to this new to this new process.

17 All right, I believe that Penny Mohr, are
18 you up next?

19 MS. MOHR: I am.

20 DR. McMURRY-HEATH: Can you guys hear me?

21 Sorry, Christine, can you guys hear me? This is

22 Michelle. I voted on the minutes as well. I'm not

1 sure if it got recorded.

2 CHAIRPERSON GOERTZ: Okay thanks Michelle.
3 I appreciate it.

4 MS. MOHR: Great, thank you very much Dr.
5 Goertz I'm very pleased to be presenting four
6 applications for Board approval today on the rare
7 disease funding announcement. If you could go to
8 the next slide please.

9 So this funding announcement had two
10 objectives. The first was to answer one or more
11 important questions about the care of patients with
12 rare disease through observational cohort studies,
13 utilizing PCORnet resources. The second was to
14 enhance the capabilities for the conduct of multi-
15 site rare disease research by creating or
16 strengthening partnerships, methods, tools, and data
17 linkages for rare disease research.

18 This funding announcement set aside \$25
19 million, and allowed for studies with total direct
20 costs of up to \$3.5 million, and a maximum duration
21 of three years. It was designed to encourage more
22 large-scale studies that are national in scope

1 across PCORnet. This is fitting with the Board's
2 recently passed strategic prioritizing principles
3 for PCORnet.

4 Also, while PCORI has a mandate to have a
5 rare disease advisory panel, and this underscores
6 the importance of our authorizing legislation places
7 on rare disease research, our Rare Disease Advisory
8 Panel has urged us to use PCORnet for better use for
9 these purposes, given the scale of PCORnet.

10 The funding announcement was designed with
11 a recognition of the difficulty of conducting rare
12 disease research, and allowed for either comparative
13 effectiveness research or descriptive studies that
14 can form the basis for the comparative effectiveness
15 research question. That is describing treatments or
16 care management studies being used and outcomes,
17 importantly, we're hoping that the work done under
18 this funding announcement will lay the groundwork
19 for future randomized controlled trials or robust
20 observational studies in rare disease.

21 Next slide please.

22 The slate includes four studies that span a

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1 variety of rare diseases and conditions, focusing
2 both on pediatric conditions and those affecting
3 adults, and also spanning the critical period for
4 the transition between pediatric to adult care,
5 which often suffers due to gaps in care.

6 So I'm going to hand this off now to Dr.
7 Goertz for further questions or a vote.

8 CHAIRPERSON GOERTZ: Thank you so much
9 Penny. Before we begin any discussions the
10 following Board members have notified us of their
11 intention to recuse themselves from the deliberative
12 discussion vote on the slate of awards from the
13 conducting rare disease research using PCORnet PFA:
14 Kara Ayres, Michael Lauer, Alicia Fernandez, myself
15 and Eboni Price-Haywood.

16 If there are other Board members who
17 believe they should recuse themselves from the
18 deliberative discussion vote, then please feel free
19 to do so. All right, I'll now open it up for
20 discussion, please remember to identify yourself
21 before making a comment.

22 Any comments or questions for Penny?

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1 MR. VAN LEEUWEN: No question.

2 CHAIRPERSON GOERTZ: Great, thank you.

3 All right, in that case, I'm going to ask
4 for a motion to approve the slate of awards for the
5 Cycle 2 2020 conducting rare disease research using
6 PCORNet PFA.

7 Can I have a motion?

8 DR. McNEIL: So moved.

9 CHAIRPERSON GOERTZ: Thank you, Barbara.

10 DR. SIGAL: Ellen, second.

11 CHAIRPERSON GOERTZ: Thank you Ellen.

12 All right. Is there any further
13 discussion?

14 [No response.]

15 CHAIRPERSON GOERTZ: All right. All those
16 in favor, please say aye.

17 [Ayes.]

18 CHAIRPERSON GOERTZ: Opposed?

19 [None.]

20 CHAIRPERSON GOERTZ: Abstentions?

21 [None.]

22 CHAIRPERSON GOERTZ: All right, the motion

1 passes. Thank you.

2 I'm now going to ask Steve Clauser to
3 present our next slate for us.

4 Steve, you're on mute -- Steve, still on
5 mute. We can't hear you.

6 DR. CLAUSER: Okay -

7 CHAIRPERSON GOERTZ: There you are. Good,
8 thank you.

9 DR. CLAUSER: The organizer got me.

10 Today I'm presenting the for the Board's
11 consideration for approval the addition of two
12 projects to the slate of awards for the Cycle 1 2020
13 broad PFAs recommended by the Selection Committee.

14 Next slide.

15 These additions to the previously Board-
16 approved slate from Cycle 1 2020 broad PFA result
17 from the fact that applicants could differ
18 applications from Cycle 1 during the COVID-19
19 pandemic, and they bring the total slate to 10
20 awards. Next slide.

21 On this slide you can see the additions to
22 the slate under consideration today in red. The

1 first slate addition comes from the Addressing
2 Disparities PCORI funding announcement, and it's
3 entitled Advancing Perinatal Mental Health and
4 Wellbeing: The DC Mother-Infant Behavioral Wellness
5 Program, and the second comes from the Methods PCORI
6 funding announcement, and it's entitled Development
7 of Methods to Improve Identification of Patients
8 with Rare or Complex Diseases. We are requesting an
9 additional \$5.3 million for the slate of awards.

10 I would be happy to answer questions and
11 now turn it back to Dr. Goertz to facilitate any
12 discussion and address the motion.

13 CHAIRPERSON GOERTZ: Thank you so much,
14 Steve. Before we begin a discussion the following
15 Board members have notified us of their intent to
16 recuse themselves from the deliberative discussion
17 vote on the additions to the slate of awards from
18 the Cycle 1 2020 broad PFAS, and those are Mike
19 Lauer, Christopher Friese, and David Meyers. If
20 there are any other Board members that feel that
21 they should recuse themselves from this discussion
22 and vote, please do so.

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1 Now, I'll open it up for discussion and any
2 questions or comments for Steve.

3 [No response.]

4 CHAIRPERSON GOERTZ: All right, in that
5 case I'm going to ask for a motion to approve
6 funding for the addition of the recommended projects
7 to this slate of awards for the Cycle 1 2020 broad
8 PFAs.

9 DR. DeVOE: So moved, DeVoe.

10 CHAIRPERSON GOERTZ: Thank you, Jen.

11 DR. HERNDON: Second, Michael Herndon.

12 CHAIRPERSON GOERTZ: Was that Mike?

13 DR. HERNDON: Yes.

14 CHAIRPERSON GOERTZ: Thank you. Okay, any
15 further discussion?

16 [No response.]

17 CHAIRPERSON GOERTZ: All right, we're once
18 again going to have a voice vote. So, all those in
19 favor?

20 [Ayes.]

21 CHAIRPERSON GOERTZ: Opposed?

22 [None.]

1 CHAIRPERSON GOERTZ: Abstentions?

2 [None.]

3 CHAIRPERSON GOERTZ: All right, the motion
4 passes. Thank you.

5 Now I'm going to ask Mike Herndon, then to
6 start our discussion on our two D&I awards slates.

7 Are you here, Mike?

8 DR. HERNDON: Yes, I'm sorry. Yeah, I'm
9 excited. I think we have a good slate the EDIC
10 committee has discussed these in detail. I think
11 that it is a very interesting and I think very
12 worthy of our vote in consideration for approval so
13 I'll turn it over now to Joanna.

14 DR. SIEGEL: Thanks Mike.

15 The first proposed slate that I'd like to
16 present to you is for the D&I limited competition
17 PFA. As Nakela mentioned a bit earlier this funding
18 initiative provides the opportunity for PCORI
19 awardee teams who've completed a PCORI-funded study
20 to take the next steps in promoting uptake of the
21 evidence in the context of related work into
22 practice and lay the groundwork for broader, future

1 uptake.

2 Next slide.

3 This slate includes three projects,
4 proposing to implement findings from studies funded
5 through PCORI's CDR; communication and dissemination
6 research and addressing disparities research
7 priority areas, with the total funds requested for
8 these proposed projects at \$3.8 million.

9 Next slide.

10 The second slate that I'd like to present
11 is for our implementation of effective shared
12 decision-making approaches in practice settings
13 funding initiative. This PFA is designed to promote
14 the uptake of shared decision-making in healthcare
15 settings in line with PCORI's goal of supporting
16 patients in making informed, evidence-based
17 decisions about their care with their clinicians.

18 Next slide please.

19 The proposed project will use a learning
20 collaborative approach to support the uptake of
21 tested conversation aids to support women with
22 early-stage breast cancer in making treatment

1 decisions, the total funds requested for the
2 proposed project is \$2.1 million. And now I will
3 turn it back to you Dr. Goertz for any questions or
4 discussion.

5 CHAIRPERSON GOERTZ: Thank you, Joanna.
6 Are there any -- before we begin any discussions,
7 the following Board members have notified us of
8 their intention to recuse themselves from the
9 deliberative discussion vote on the slate of awards
10 from the Cycle 2 2020 limited competition D&I PFA
11 and shared decision-making PFA. And those are
12 Jennifer DeVoe and Alicia Fernandez; if any other
13 board members believe that they should recuse
14 themselves from this deliberative discussion vote,
15 please feel free to do so.

16 All right, I'm now going to open it up for
17 discussion, just a reminder to identify yourself,
18 Danny, I see you. Oh yes, I'm sorry -- what?

19 MS. HENNESSEY: This is Mary. I'm sorry.
20 I had on my notes that also Ellen Sigal had been
21 identified, do you have that?

22 CHAIRPERSON GOERTZ: I do not have that.

1 DR. SIGAL: That was a mistake, it was a
2 disclosure that was old and I reversed. That was
3 two years old. So no, I don't have a conflict.

4 MS. HENNESSEY: Thanks for clarifying
5 Ellen. Sorry to interrupt.

6 CHAIRPERSON GOERTZ: That's okay, Mary.
7 Thanks for checking. Okay, Danny I see you on
8 camera so I'm going to assume you have a question or
9 comment so please proceed.

10 MR. VAN LEEUWEN: I do. I just want to be
11 sure that we're paying attention to dissemination
12 and implementation to regular people outside of
13 academic and specialty channels and implementation
14 in life flow of regular people.

15 I think the slate is fine; I don't have any
16 questions about the slate. I just want to make sure
17 that we're paying attention to regular people.

18 CHAIRPERSON GOERTZ: Thank you, thank you
19 for that Danny.

20 Joanna, do you have any comments on that?

21 DR. SIEGEL: Sure. I know we don't have
22 time for a really full response on to your point

1 there Danny but, I do want to point out just -- that
2 even just with this particular slate, one of these
3 projects is taking basically information on
4 effective contraceptives to adolescent girls with a
5 reach of more than 16,000. You know, bringing very
6 relevant, very timely information to people at the
7 point of decisions, which is where we like to be.

8 So, I'm very happy to present more examples
9 about at a later time, but I know we're quite
10 pressed for time today.

11 CHAIRPERSON GOERTZ: Thank you.

12 MR. VAN LEEUWEN: Thank you.

13 CHAIRPERSON GOERTZ: Any other additional
14 comments or questions?

15 DR. HOWERTON: No thank you.

16 CHAIRPERSON GOERTZ: All right, thank you.

17 In that case I'm going to ask for a motion
18 to approve the slate of awards from the Cycle 2 2020
19 limited competition D&I PFA as well as the shared
20 decision-making PFA.

21 DR. HOWERTON: Howerton, motion.

22 CHAIRPERSON GOERTZ: Thank you. Thank you,

1 Russ. Can I get a second?

2 DR. McNEIL: Barbara seconds.

3 MS. TROEGER: Second.

4 CHAIRPERSON GOERTZ: I'm sorry I have to do
5 that again I couldn't tell who it was.

6 MS. TROEGER: Troeger, seconds.

7 CHAIRPERSON GOERTZ: Okay, thank you.

8 Thank you Kathleen.

9 All right. Any further discussion?

10 [No response.]

11 CHAIRPERSON GOERTZ: All those in favor?

12 [Ayes.]

13 CHAIRPERSON GOERTZ: Opposed?

14 [None.]

15 CHAIRPERSON GOERTZ: Abstentions?

16 [None.]

17 CHAIRPERSON GOERTZ: All right, the motion
18 passes and I just want to congratulate all of our
19 awardees today. We really are very grateful for the
20 huge amount of time and effort that you put into
21 preparing your applications and we look very forward
22 to working with you as you progress on your research

1 and to seeing the results when you're done. So,
2 again, congratulations.

3 All right, I'm now going to turn the turn
4 the agenda over to Nakela so that she could provide
5 us with an overview of our targeted PFAs.

6 DR. COOK: Thank you. And again,
7 congratulations to all of the awardees.

8 We're going to shift gears now and talk
9 about developing targeting targeted PFA is in the
10 short-term while strategic planning is underway.

11 Let's go to our next slide.

12 So this discussion really picks up from our
13 discussion at our last meeting, when the Board
14 discussed our expedited and enhanced approach to
15 developing targeted PFAs. And you may remember
16 that, under that expedited and enhanced process that
17 we were working on some perspective planning for our
18 upcoming cycles. And so today, the Board will
19 consider three targeted PFAs that were recommended
20 by our Science Oversight Committee for Cycle 2 of
21 2021, and the three topics for Cycle 2 were really
22 thought to be important and feasible in the

1 timeframe to maintain pace against meeting our
2 commitment plan, and the Board also may recall that
3 we will need about three PFAs for the next several
4 cycles to meet our commitment plan goals.

5 So next month we will be coming back to the
6 Board to consider a set of topics that we would like
7 to continue for development for future cycles, and
8 simultaneously as we talked about before, we'll also
9 be developing that fast tracked targeted PFA for
10 COVID-19.

11 Let's go to our next slide.

12 So all three of the topics that you're
13 going to see today under consideration are part of
14 that expedited and enhanced process that we
15 discussed at our last Board meeting and they
16 leverage our prior and ongoing work, and have a high
17 likelihood to converge with our national priorities
18 and research agenda and help to fill that gap until
19 we have that research agenda in place. They meet
20 several criteria that you see here, including having
21 high burden conditions and issues, or being
22 responsive to mandates or express interest from

1 stakeholders and the Board in terms of scenarios.
2 They also relate to emerging themes from some of our
3 strategic planning discussions. And even though
4 these PFAs are expedited, the development of the
5 PFAs included literature review with a focus on
6 systematic reviews, which we'll hear a little bit
7 about, as well as clinical guidelines. And the
8 development also focused on outreach to relevant
9 patient groups and stakeholders and a review of
10 PCORI's funded portfolio as well as consultation
11 with other funders, including the NIH, AHRQ, and
12 other relevant entities.

13 We can go ahead to our next slide.

14 So what you're going to see in terms of the
15 main differences in the targeted PFAs that are
16 stemming from this expedited and enhanced approach
17 include several things. Number one, that these PFAs
18 are designed to be more open for the research and
19 stakeholder community to develop and propose
20 relevant studies that are within the PCORI-
21 identified focus area. And so, you're going to note
22 that study parameters are highly specified when

1 appropriate for a topic, including, for example,
2 populations or interventions or outcomes. And these
3 PFAs are open to a wider range of study duration and
4 funding level to allow for a range of study designs
5 as well as study sizes.

6 And in an effort to try to increase the
7 likelihood of accomplishing the objective of the
8 PFA, we're going to propose to offer more than one
9 cycle as warranted and allow for deferrals and
10 submissions as needed as well.

11 We can go ahead to our next slide.

12 So just wanted to give you a brief summary
13 of the topics that you're considering today for
14 approval for Cycle 2 2021. So you'll be hearing
15 about two topics that were developed within priority
16 research areas that are in our reauthorizing
17 legislation: maternal morbidity and mortality as
18 well as intellectual and developmental disabilities.
19 And you may recall, these are 10-year priorities,
20 and so we're really just getting started.

21 It's important to note that there's a
22 multi-year planning effort that's underway for both

1 of these topics, and we anticipate that there'll be
2 many future topics and opportunities in these areas
3 as well. And previously, just to jog your memory,
4 PCORI posted special areas of emphasis in our broad
5 PFA back in 2020 with set aside funding, and we had
6 a robust response from the community for that. And
7 those applications are now currently under review.
8 And we anticipate that the areas of focus around
9 maternal care coordination and health care
10 transitions for individuals with intellectual and
11 developmental disabilities will be important areas
12 that you'll see in the slates coming forward in
13 future board meetings.

14 But today the PFAs that we're going to
15 present in these two areas of our Congressional
16 mandates are going to focus on the postpartum space
17 for maternal morbidity and mortality, and for
18 individuals with developmental and intellectual
19 disabilities, also with mental health conditions.
20 The PFA will focus on interventions in that space.

21 The third topic that is up for
22 consideration for approval today is related to

1 urinary incontinence in women. And this is focused
2 on an issue that PCORI's been working on for a
3 while, it just stalled during the period leading up
4 to reauthorization, and so we're really excited to
5 pick it back up because it's still highly relevant.
6 And this works stems from systematic evidence review
7 that PCORI funded with the intention of trying to
8 identify clinical comparative effective research
9 gaps. And so, that you'll also see that coming
10 forward.

11 So here you see the list of the three
12 topics that we'll be talking about and the funding
13 profiles, and for a total of up to \$130 million for
14 this upcoming cycle.

15 So if time allows, I think, Dr. Goertz I'll
16 turn it back to you for some discussion and then we
17 could turn it over to Dr. Fernandez for the
18 presentation of the actual PFAs.

19 CHAIRPERSON GOERTZ: Thank you. Thank you
20 Dr. Cook, I appreciate it. So does anyone have any
21 questions or comments about this, our proposed
22 targeted PFA strategy?

1 DR. SCHUSTER: It's clear I think. This is
2 James.

3 CHAIRPERSON GOERTZ: Thank you James.

4 All right, Mike. Did you have a question?

5 DR. HERNDON: Just a question of clarity.
6 When we talk non-surgical interventions for women
7 that urinary incontinence that would include the
8 non-surgical intervention -- the surgical
9 intervention would be like the sacral stimulators
10 right? I mean -- can you kind of give me an idea of
11 what we're trying to get at for surgical versus non-
12 surgical? And what all is in that surgical bucket?

13 DR. COOK: I think I'm actually going to
14 allow a little bit of deferral of the question if
15 that's okay with you, because Nora McGhee is
16 actually going to present that topic and talk about
17 the interventions that we're interested in. And so,
18 if you still have questions after that I'd be happy
19 to come back but I think your question will be
20 answered in that frame.

21 DR. HERNDON: That's fine. I wasn't quite
22 sure when to ask it.

1 DR. COOK: No problem.

2 DR. HERNDON: As a payer-policymaker, I'd
3 be supremely interested in kind of the steps leading
4 up to those sacral stimulators that are quite
5 expensive and oftentimes ineffective. Thank you.

6 DR. COOK: Certainly.

7 CHAIRPERSON GOERTZ: Thanks Mike.

8 Great. Any other sort of big picture
9 questions then for Nakela before we move on?

10 DR. HOWERTON: No, thank you.

11 DR. McMURRY-HEATH: Christine?

12 CHAIRPERSON GOERTZ: Michelle.

13 DR. McMURRY-HEATH: So my understanding is
14 this is really supposed to be for quickly emerging
15 issues that we're trying to make sure we also fund.

16 Am I understanding that premise correctly?

17 DR. COOK: One of the things that we are
18 going to talk about, just briefly, after we go
19 through these three PFAs is the concept around
20 setting up some topics that we will be talking about
21 for the next four or five cycles. And what we're
22 trying to do there is think about things that are

1 high priority and feasible but also leave the space,
2 if there are emerging, high priority topics that we
3 need to bring into play. And I think that's what
4 you may be asking about Michelle, is the latter
5 point and if there are high priority topics that the
6 Board feels we need to think about how we select
7 them into our programming. Then we certainly want
8 to hear about that.

9 DR. McMURRY-HEATH: Okay.

10 DR. COOK: Thank you.

11 CHAIRPERSON GOERTZ: Any other questions?

12 [No response.]

13 CHAIRPERSON GOERTZ: All right, in that
14 case, Nakela, did you have anything else that you
15 wanted to add before we turn it over to Alicia?

16 DR. COOK: I think we can go ahead. Thank
17 you.

18 CHAIRPERSON GOERTZ: Thank you. Alicia.

19 DR. FERNANDEZ: Thank you Christine. So,
20 the Science Oversight, we want -- we're moving now
21 toward consideration for approval of improving
22 postpartum maternal outcomes of populations

1 experiencing disparity and comparative effectiveness
2 of interventions targeting mental health conditions
3 in individuals with IBD, and the non-surgical
4 interventions for women with urinary incontinence.
5 And I am pleased to tell you that the Science
6 Oversight Committee met on February 26th, and we
7 recommended that all three of these be approved, be
8 turned over to the Board for approval. And we are
9 pleased to present these to you today and I will
10 turn it over to Dr. Elisabeth Houtsmuller to
11 describe the first PFA.

12 DR. HOUTSMULLER: And thank you, Alicia.

13 This proposal for a targeted funding
14 announcement is part of our ongoing work in maternal
15 mortality, which as you know is one of the two new
16 research priorities that were included in our
17 reauthorizing language. There's been a lot of
18 attention in the press and on social media, on the
19 United States ranking lowest among high income
20 countries in parameters for maternal health, and
21 especially the significant disparities in maternal
22 mortality and morbidity outcomes.

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1 Now maternal mortality occurs not just
2 during the pregnancy, but in fact 40 percent of
3 maternal mortality in the United States occurs
4 during the first six weeks following delivery. This
5 is a time period that has until fairly recently been
6 overlooked in terms of care. And so, for this
7 targeted funding announcement we have focused on
8 improving postpartum maternal outcomes for
9 populations that experience disparities in those
10 outcomes.

11 Next slide please.

12 In the targeted funding announcement we
13 would ask for comparative effectiveness on
14 multicomponent interventions to improve early
15 detection and timely care for complications during
16 the first six weeks postpartum and for their risk
17 factors of those complications. We're focusing on
18 the populations that experienced the worst
19 disparities.

20 Next slide, please.

21 And so, the populations that experienced
22 the worst disparities include Black, American

1 Indian, Alaskan Native, and Hispanic women, women
2 that live in rural areas, and women of lower socio-
3 economic status.

4 We're interested in comparisons of
5 multicomponent interventions that really increase
6 both awareness and detection of both the risk
7 factors and the complications. Outcomes should
8 include health-related measures as well as patient
9 experience of care, and importantly patient
10 engagement in care, as well as follow up until one
11 year.

12 The total we request for this announcement
13 is up to \$50 million in total costs, we're planning
14 to fund four-to-six studies over two-to-three cycles
15 with a maximum project duration of five years.

16 Next slide please.

17 I will now turn this over to Dr. Goertz for
18 a vote, but I am happy to answer any questions as
19 well.

20 CHAIRPERSON GOERTZ: Thank you Els, I
21 really appreciate it. I'm going to open it up for
22 discussion, just a reminder to identify yourself if

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1 you're making a comment and not on video.

2 [No response.]

3 CHAIRPERSON GOERTZ: Right, not hearing any
4 questions or comments; I'd like to ask for a motion
5 to approve the targeted PFA for Cycle 2 2021,
6 improving postpartum maternal outcomes for
7 populations experiencing disparities. Can I have a
8 motion for approval, please?

9 DR. SCHUSTER: This is James. I make a
10 motion.

11 CHAIRPERSON GOERTZ: Thank you James.

12 DR. FRIESE: This is Christopher, second.

13 CHAIRPERSON GOERTZ: Thank you Chris. All
14 right. Any further discussion?

15 [No response.]

16 CHAIRPERSON GOERTZ: Just a note that no
17 Board members have left or joined, so we still have
18 a quorum for our voice votes.

19 So I'm going to ask for all those in favor,
20 to please say aye.

21 [Ayes.]

22 CHAIRPERSON GOERTZ: Opposed?

1 [None.]

2 CHAIRPERSON GOERTZ: Abstentions?

3 [None.]

4 CHAIRPERSON GOERTZ: All right, the motion
5 passes, then now I turn the meeting over to Dr.
6 Holly Ramsawh, to present us with our next PFA.

7 DR. RAMSAWH: Thank you. Good afternoon
8 everyone.

9 I'm here to present an overview of the
10 first targeted PCORI funding announcement proposal
11 for a new intellectual and developmental
12 disabilities research priority.

13 Next slide please.

14 For this funding announcement, we've been
15 able to leverage feedback from stakeholder groups,
16 and they've called out a variety of issues relevant
17 to mental health in individuals with IDD. Although
18 those with IDD are at increased risk of mental
19 health conditions, there are broad, wide-ranging
20 evidence gaps in this area, stressing the need for
21 future studies of both pharmacologic and non-
22 pharmacologic interventions that target co-occurring

1 mental health conditions. And so, the research
2 question that you see here, addresses these broad
3 evidence gaps.

4 Next slide please.

5 And here you can see the specifications for
6 this request. And as you can see we're keeping the
7 parameters, fairly broad to allow for a wide variety
8 of submissions. A funding allocation of up to \$40
9 million is requested to fund what we're estimating
10 to be 10-to-12 studies over two-to-three funding
11 cycles. Each would be three years in duration.

12 Next slide please.

13 And that concludes my presentation, I'll
14 hand it back to Dr. Goertz for any questions and
15 discussion.

16 CHAIRPERSON GOERTZ: Thank you so much
17 Holly. Danny, did you have a comment or question?

18 MR. VAN LEEUWEN: Yes. I'm just seeing --
19 this does not include comparative effectiveness of
20 health systems related to evidence-based approaches
21 to addressing mental health conditions, is that
22 purposeful?

1 DR. RAMSAWH: Sure, I can address that
2 question. So we didn't specify that here, but we
3 would be allowing for proposals that address sort of
4 healthcare systems questions. So that wasn't
5 intentional. That was we were just trying to be as
6 broad as possible in this initial description.

7 MR. VAN LEEUWEN: Thank you.

8 CHAIRPERSON GOERTZ: All right. Thank you.
9 Any other comments or questions?

10 DR. HOWERTON: No, thanks.

11 CHAIRPERSON GOERTZ: All right, in that
12 case, I am going to ask for a motion to approve the
13 targeted PFA for Cycle 2 2021, comparative
14 effectiveness of interventions targeting mental
15 health conditions and individuals with IDD with
16 funding up to \$40 million in total costs.

17 DR. HOWERTON: Howerton, approved.

18 DR. McNEIL: So moved.

19 CHAIRPERSON GOERTZ: Thank you. Thank you,
20 Russ and Barbara, are you willing to be a second?

21 DR. McNEIL: Sure.

22 CHAIRPERSON GOERTZ: Thank you. Any

1 further discussion?

2 [No response.]

3 CHAIRPERSON GOERTZ: All right, well once
4 more, we'll do a voice vote. So all those in favor,
5 please say aye.

6 [Ayes.]

7 CHAIRPERSON GOERTZ: Opposed?

8 [None.]

9 CHAIRPERSON GOERTZ: Abstentions?

10 [None.]

11 CHAIRPERSON GOERTZ: All right, the motion
12 passes. Thank you. Now I'd like to introduce Dr.
13 Nora McGhee, to present on our final targeted PFA.

14 Hi Nora.

15 DR. MCGHEE: Hi, good afternoon.

16 So extensive stakeholder interest and
17 evidence gaps led PCORI to undertake an update to
18 our 2012 Agency for Healthcare Research and Quality
19 Systematic Review on Non-Surgical Treatments for
20 Urinary Incontinence, or UI, in women.

21 The update funded through our research
22 partnership with AHRQ was completed in 2018. The

1 updated review found good evidence for the efficacy
2 of many non-surgical interventions for UI. However,
3 important evidence gaps remain, particularly related
4 to direct comparisons of the options. Building on
5 this and other prior work and in recognition of the
6 high prevalence and burden of UI to U.S. women, we
7 bring forward this request for your approval to
8 develop this targeted PFA.

9 Next slide please.

10 We propose that the PFA focus broadly on
11 the comparative effectiveness of non-surgical
12 options for women with UI.

13 Next slide please.

14 I'll run through the basic requirements
15 we're proposing. Participants can have either of
16 the three main types of UI: stress, urge, or mixed
17 UI. Applicants can propose to compare two or more
18 of the non-surgical treatment options; alternative
19 systems approaches will also be welcomed.

20 Investigators should include at a minimum,
21 both functional outcomes and adverse events.

22 We're requesting a total of \$40 million be

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1 allocated to this PFA, which could fund up to eight
2 studies. We anticipate posting this announcement
3 for two cycles, but this will depend on the number
4 and type of applications received. We will allow
5 studies of up to five years in duration. As always,
6 study duration should be appropriate for the design
7 as justified in the application.

8 And now I will turn it back over to our
9 Board chairperson for any questions, and to call for
10 the vote. Thank you.

11 CHAIRPERSON GOERTZ: Thank you so much,
12 Nora.

13 Can we start out with -- I know Mike, if
14 you want to ask your question again.

15 DR. HERNDON: Yeah. So, can you just
16 explain what your understanding is when we talk
17 about surgical interventions? Obviously there's
18 urethra slings and all sorts of, you know,
19 periurethral-type procedures.

20 Would we intend or expect to get some
21 potential, you know, applications that would include
22 sacral nerve stimulators?

1 DR. MCGHEE: Sure. So I can address that.

2 So the first items you mentioned, those are
3 clearly surgical treatments, but the implementation
4 of the nerve stimulators, we would consider those
5 non-surgical, and they were considered in the
6 updated systematic review as such. So those would
7 be allowed.

8 DR. HERNDON: As non-surgical?

9 DR. MCGHEE: As non-surgical. Correct.

10 DR. HERNDON: Okay. Thank you.

11 DR. McMURRY-HEATH: Sorry this is Michelle.
12 Was there a reason that you guys settled on only
13 non-surgical?

14 DR. MCGHEE: The bulk of the prior work
15 that PCORI has done was in that area, so we felt
16 that was appropriate area to start with, we might
17 want to address the surgical treatment in a later
18 announcement once we do further background work in
19 that area.

20 The existing systematic review by AHRQ was
21 on non-surgical treatments, so that's what was
22 updated a few years ago, and there were clear gaps

1 that were found. So we wanted to issue the
2 announcement and start research in that area first.

3 DR. McMURRY-HEATH: Okay, just note that
4 the surgical interventions have really progressed
5 since 2012. So it's a different kind of landscape
6 in terms of treatment choice.

7 DR. MCGHEE: Yeah, so that may point to us
8 needing to do some background work in that area to
9 look and see where the gaps are, it sounds like
10 maybe new areas to explore there. Thanks.

11 CHAIRPERSON GOERTZ: Thank you. Any other
12 comments or questions at this point for Nora?

13 DR. HWANG: Christine, I have a question.
14 This is Connie.

15 Thanks. Hi. Nora, in the Board materials,
16 there's a lot of mention of collaboration with AHRQ
17 on this, and I think there's mention of a concurrent
18 funding announcement by AHRQ. So I just wanted to
19 get a sense when it notes here that there will be
20 coordination between PCORI and AHRQ. If you could
21 give a little more detail or insight on that I think
22 that'd be helpful.

1 DR. MCGHEE: Okay, sure. When we mentioned
2 that previously, it was really to indicate there's
3 been a lot of prior collaboration with AHRQ in this
4 area, and there is the announcement out from them
5 right now for dissemination and implementation work
6 in this area.

7 And really it was just the intent that as
8 we develop this PFA to ensure that our announcement
9 clarifies the research areas that we'd like there to
10 be focused in, and how those are distinct from the
11 AHRQ announcement. That's really what we were
12 referring to.

13 DR. HWANG: Great, thank you that's
14 helpful. It seems like it's going to be important
15 not to, you know, have unnecessary overlap, and try
16 to be as synergistic as possible. So I appreciate
17 it.

18 DR. MCGHEE: Yeah, certainly. Yeah, we
19 view them as complimentary and we want to just make
20 sure that's clear in our messaging.

21 CHAIRPERSON GOERTZ: Thank you. Any other
22 comments or questions?

1 [No response.]

2 CHAIRPERSON GOERTZ: All right, well thank
3 you very much, Nora.

4 DR. MCGHEE: Sure. Thank you.

5 CHAIRPERSON GOERTZ: All right. I am going
6 to then ask for a motion to approve the targeted PFA
7 on non-surgical interventions for women with urinary
8 incontinence with funding up to \$40 million in
9 direct costs.

10 DR. HERNDON: Motion to approve.

11 CHAIRPERSON GOERTZ: Is that Mike?

12 DR. HERNDON: Yes.

13 CHAIRPERSON GOERTZ: Okay, thank you.

14 And can I get a second?

15 DR. McNEIL: I second, Barbara.

16 CHAIRPERSON GOERTZ: Thank you, Barbara.

17 All right. Any further discussion?

18 [No response.]

19 CHAIRPERSON GOERTZ: All right, I'm going
20 to ask for a voice vote.

21 All those in favor, please say aye.

22 [Ayes.]

1 CHAIRPERSON GOERTZ: Opposed?

2 [None.]

3 CHAIRPERSON GOERTZ: Abstentions?

4 [None.]

5 CHAIRPERSON GOERTZ: All right, the motion
6 passes. Thank you.

7 DR. MEYERS: Dr. Goertz, this is David
8 Meyers. I was just hoping you would let Karin
9 Rhodes take my place, as I need to leave for a bit.

10 CHAIRPERSON GOERTZ: Absolutely. Thanks
11 for letting us know and welcome Karin.

12 DR. RHODES: Thank you.

13 DR. MEYERS: Thank you all.

14 CHAIRPERSON GOERTZ: All right. I just
15 want to also thank the staff and the SOC, I
16 recognize the tremendous amount of work that has
17 gone into putting together these PFAs and I'm, you
18 know, very excited to see them turned into
19 applications that we can look forward to finding, so
20 thanks. Thanks to everyone for your hard work on
21 this.

22 Now I'd like to turn the agenda over to

1 Nakela, to talk about candidate topics for PFA
2 development.

3 DR. COOK: Thank you Christine. So, next
4 Board meeting, we're going to be talking about a set
5 of candidate topics for targeted PFA development for
6 our future cycles that will take us through 2022.
7 And so, I just wanted to kind of tee that up for our
8 future discussions,

9 Let's go to the next slide.

10 So under this expedited and enhanced
11 process that we're undertaking to identify areas for
12 targeted PFA development while our strategic
13 planning is underway, we anticipate bringing to the
14 Board at our next meeting a set of topics for PFA
15 development for future cycles. And we know that in
16 bringing the full set to you early on, that they're
17 going to be at the idea stage. And so, we're going
18 to come back to the Board with each targeted PFA
19 with a recommendation from the SOC for consideration
20 of approval, after they've gone through further
21 development.

22 And the set you'll be looking at would be

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1 in addition to things such as targeted areas for
2 COVID-19 or maternal morbidity and mortality or
3 intellectual and developmental disabilities topics.
4 So we have work going on and those kind of three
5 high priority spaces, alongside the development of a
6 larger set of topics.

7 We also anticipate that these topics will
8 be really developed for that full range of options
9 of different types of PCORI funding announcements,
10 and that we want to make sure that we're still
11 responsive even though we'd be thinking about a set
12 in a prospective way. We want to be responsive to
13 development.

14 For example, if there's a development with
15 in a topic area that's proposed that we would still
16 be able to incorporate it in the time that that
17 topic is ready for solicitation announcement. We
18 also want to still be responsive to emerging topics
19 that may arise, and I believe this is what Michelle
20 McMurry-Heath was raising.

21 We also want to make sure that we're
22 thinking about the learnings from each of our PFAs,

1 as we're going through a process, it's a little bit
2 different in terms of developing PFAs.

3 And I think all of these things were raised
4 at a prior board meeting in terms of allowing some
5 of that nimbleness and responsiveness to the
6 emerging needs.

7 Let's go to our next slide.

8 So some of the things that we see as
9 potential advantages and additional benefits of the
10 Board approving a set of topics for development for
11 PFAs for several cycles, versus looking at them one
12 at a time. Instead it's going to allow for some
13 longer-range perspective planning, both by PCORI as
14 well as by the research and stakeholder community
15 with advanced notice the community could even
16 generate a greater number of applications in
17 response to our PCORI funding announcements and more
18 fully develop applications. And within the PCORI,
19 we have an opportunity with lead time to really
20 enhance what's needed for merit review. It also
21 could facilitate more rapid development by focusing
22 our concentration area and our focus at PCORI on a

1 fewer topics over a certain period of time.

2 The approval of the set will still allow
3 for us to accommodate those emerging and critical,
4 time critical areas into any of the cycles that is
5 warranted. And we really do look forward to further
6 discussion with you in April, when we bring that
7 full set to the Board for consideration.

8 So this is just to kind of whet your
9 appetite for what's to come and follow up from what
10 you're seeing now for our Cycle 2 2021 topics and
11 what we're thinking about for that set that will
12 take us through 2021 and into 2022 while our
13 strategic planning efforts are underway.

14 So I'll turn it back to you Dr. Goertz in
15 case there's any questions or discussion that people
16 would like for me to chime in on before we move to
17 our final agenda item.

18 CHAIRPERSON GOERTZ: Thank you so much.

19 Any comments?

20 DR. SIGAL: Christine -- this is Ellen.
21 I'm sorry I'm not on video.

22 So I think this is really important but,

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1 you know, with the urgency that we're seeing, and
2 the opportunities in COVID. I just hope that we can
3 be a little bit more explicit about where we can fit
4 in and what we can do in outreach to, whether it's
5 the NIH, FDA, or other -- CDC, to see where our role
6 could be in there where we can enhance some of the
7 work that is going on. We have PCORnet, and we
8 certainly have a distribution of sites all over the
9 country, and it would be interesting for us to bring
10 back some very specific proposals.

11 Because, you know, we are not understanding
12 post-COVID. There are huge opportunities in vaccine
13 hesitancy, in diagnostics and, you know, all sorts
14 of things.

15 Yeah, and I know we are working a little
16 bit on coagulopathy and some other things but I
17 would hope that we could come back with some
18 specific proposals that we could act on that would
19 be enhancing the value of what others are doing or
20 complimentary.

21 DR. COOK: And I was just going add,
22 Christine, we certainly can come back and have a

1 more robust descriptor of all things that are going
2 on and things that are being planned related to
3 COVID-19.

4 CHAIRPERSON GOERTZ: Thank you. I think
5 that that would be helpful to have an overview of
6 everything that we're doing in that space.

7 DR. McMURRY-HEATH: So Nakela to that --

8 DR. SIGAL: Or can do. There are things
9 that we may need -- there may be new opportunities
10 now.

11 DR. COOK: Absolutely.

12 CHAIRPERSON GOERTZ: Thank you.

13 I've got Michelle and then Alicia

14 DR. McMURRY-HEATH: So to that point, you
15 know, all of the PFAs that we just approved are very
16 sound and they make a lot of sense, but I just kind
17 of wonder if the scale of our response to what is
18 staring us in the face has really been broad enough
19 and I know there are a lot of different efforts
20 going, but there's some key questions that have to
21 be answered in a very tight turnaround like, how the
22 vaccine is behaving in the populations that are

1 getting it and how the variants are interacting.

2 There are just so many huge health
3 questions up here that I just wonder if we couldn't
4 be using the vast resources that PCORI has at their
5 disposal, to really shine a new light on those in a
6 very proactive way.

7 Alicia, I'll turn it over to you.

8 DR. FERNANDEZ: Thank you, it's really good
9 to hear people's thoughts on this.

10 I think one of the challenges for the staff
11 and ultimately for the Board will be figuring out
12 PCORI's contribution in this space. The NIH has
13 several extraordinarily large, well-funded RFAs out
14 on long COVID, for example. And both NIH and CDC
15 are also working very hard in the vaccine uptake
16 space. [Inaudible] just to say that I think that
17 we, PCORI, shouldn't be doing a great deal of work
18 in here, but just think, I just think -- I just
19 think it'll be important for us to think through
20 where -- where the PCORI niche is, in terms of -- so
21 that we can deploy our resources in an additive --
22 in an additive way.

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1 And I for one really appreciate hearing
2 what different Board members are thinking about. I
3 think it's -- it's really important. Thank you.

4 DR. SIGAL: Yeah, Alicia, I'll add one more
5 thing and then I promise I will be quiet. The COVID
6 accelerator, which is where we're aggregating
7 information on drugs, diagnostics, treatments, and
8 now vaccines; is a place that we can play well with
9 it because you're right, there's a lot going on and
10 there's a lot of money allocated to the NIH, CDC,
11 and FDA, but there are spots where our database in
12 our population could be very helpful so we should
13 try to work with them and see where the gaps are,
14 that could be very important.

15 DR. FERNANDEZ: I couldn't agree with you
16 more. For example, PCORnet could be used in COVID
17 research in a very fundamental way that could be
18 very different, both in terms of diseases, and also
19 in terms of getting estimates on a local prevalence
20 and also in terms of the vaccine, and at the same
21 time, the PCORI is really special focused on
22 patient-centeredness.

1 I think that is truly important here. So,
2 I think, our long-standing focus on impact on
3 caregivers and families, and so on is very, very
4 important.

5 So I think we have a lot to do, and I'm
6 very happy to hear this, to hear how aligned we all
7 are in trying to support the staff to do this, this
8 really difficult work in a very rapidly moving
9 funding environment.

10 CHAIRPERSON GOERTZ: Great. Thank you,
11 Alicia. Kathleen.

12 MS. TROEGER: Yeah, just a quick comment
13 and I want to underscore Ellen's interest, and at
14 Alicia's support for the utilization of PCORnet.
15 It's similar to look for ways, for synergies and
16 ongoing opportunities within the networks to support
17 both mission, a little bit broader outside of COVID.
18 And then certainly, direct to COVID, and perhaps
19 continue the work that accelerator project has done.
20 It really does utilize PCORnet as part of the
21 mechanism of machinery to conduct research.

22 CHAIRPERSON GOERTZ: Good comment. Thank

1 you Kathleen.

2 Chris Friese, I believe you had a question
3 or comment.

4 DR. FRIESE: Sure, I don't want to take a
5 lot of time. I think we're all sort of, I'm hearing
6 a lot of consensus here and I think the sweet spot
7 is to find how we can be helpful and additive. And
8 to that point, I guess I don't understand. Do we
9 have senior program staff or a program official who
10 is sort of heading up the COVID-related portfolio?
11 And if so, is that person sort of regularly
12 corresponding the appropriate other agencies? Or
13 how are we, I guess, structuring that response?
14 Because I agree with Michelle. I mean I think we
15 have to really kind of, you know, and I said this at
16 the SOC last week, I think we need to be very bold
17 but we also need to be in a lane that's helpful.

18 DR. COOK: Yes. Maybe -- it may be helpful
19 for me just to comment on a couple of things which
20 is -- one is that we have been having pretty robust
21 discussions with NIH, CDC, and FDA on a regular
22 basis and have several collaborative efforts that

1 are underway. And so we will -- that's why I was
2 saying it'd be great for us, I think, to come back
3 and give you a sense of the breadth of some of those
4 activities. And internally we have organized, what
5 we've been calling our COVID Connect Team. It's
6 basically a team that's co-led by some of our
7 leadership from PCORnet as well as from our Research
8 and Engagement teams, related to COVID-19.

9 And so, we've started to focus on the
10 efforts that we're trying to move forward across all
11 the spaces that PCORI covers, and I believe we were
12 going to make sure that you also have -- just
13 available to you, our fact sheet around several of
14 the things that we have going on in the space
15 related to COVID-19. Many of them have been
16 presented at different times at a Board meeting and
17 so I feel like bringing it all together in a more of
18 a comprehensive presentation and discussion could be
19 quite beneficial for the Board based off of what I'm
20 hearing here.

21 And some things, you know, are still ahead
22 of primetime for announcement but we definitely

1 think that when those are ready that they would be
2 great to bring to the Board as well.

3 DR. McMURRY-HEATH: Just one last
4 suggestion, given the prominence of this issue and
5 the health disparities that it's really
6 highlighting, Perhaps it could have a standing item
7 on COVID at our Board meetings, so we could have a
8 sense of the progress and where we all can plug in
9 and help, because I have researchers who reach out
10 to me trying to get a sense of the comparative
11 effectiveness of various vaccines or therapies or
12 what happens on secondary infections and I know a
13 lot of these things aren't being covered by either
14 FDA or NIH.

15 DR. COOK: Okay.

16 CHAIRPERSON GOERTZ: Thank you. Any other
17 comments or questions?

18 [No response.]

19 CHAIRPERSON GOERTZ: All right, this was a
20 good discussion. There were definitely some things,
21 Nakela, to take back and think about a little bit
22 and bring back to the Board I think.

1 DR. COOK: We'd be happy to. Thank you.
2 Thanks for all the input.

3 CHAIRPERSON GOERTZ: Thanks. All right, I
4 think we're going to go into our final agenda item
5 then. So, Nakela if you could continue on.

6 DR. COOK: Certainly, and so we're pleased
7 to transition to talk about approving the principles
8 for the consideration of the full range of outcomes
9 data in PCORI-funded research, and we can go to our
10 next slide. I'm sorry we can go back.

11 So the principles that we're bringing
12 forward for consideration of approval today have
13 been discussed with the Board and Board committees
14 on an iterative basis, and so now we're at that
15 stage of considering them for Board approval. And
16 we first reviewed the principles with the Board when
17 they were draft back in September of last year ahead
18 of posting them for public comment, and we've
19 engaged in substantial efforts to seek stakeholder
20 and public input.

21 And following this input at the February
22 board meeting, the Board reviewed high level themes

1 from the input that we've received in its December
2 meeting and then more detailed synthesis of the
3 input, some of which was really relevant to reflect
4 on the principles and some that we thought was
5 really relevant for upcoming implementation plans.
6 And so the proposed principles reflect a lot of
7 careful consideration of the stakeholder and public
8 input as well as the comments of committees and the
9 Board and are now presented for a Board motion to
10 approve.

11 At this point the Board's focus is really
12 on the proposed principles, which capture the key
13 substantive issues that PCORI applicants and
14 stakeholders would need to be addressed to move
15 forward. And if we have potential edits to the
16 principles and issues that require change to the
17 principles because they're so substantive in nature,
18 we're going to need to make sure we capture that
19 exact language in an amended motion, so I just
20 wanted to alert the Board to that.

21 And we also wanted to remind the Board that
22 while we're discussing principles today, the

1 principles do lead to the formulation of guidance
2 for applicants as well as other products as part of
3 our implementation plan. And those products are
4 where we're going to be able to reflect a deeper
5 level of specificity, guided by some of our next
6 steps in our processes including our ongoing
7 engagement with the Methodology Committee and our
8 Stakeholder Advisory Committee.

9 Comments that you may have related to the
10 details that may be helpful for those implementation
11 plans, we're going to note those today and will
12 inform our implementation planning, but we'll also
13 some have additional insights that we think will
14 emanate from our implementation activities
15 themselves, and we'll look forward to continually
16 revising our approaches.

17 So I'm going to ask that Dr. Andrew Hu, our
18 Director of Public Policy and Government Relations
19 presents the principles for consideration for your
20 approval. Andrew, do you want to go ahead?

21 MR. HU: Yep. Very good. Thanks Dr. Cook
22 and good afternoon everybody. So for this session,

1 as Dr. Cook mentioned, we will be presenting for
2 approval, the principles for the full range of
3 outcomes data and PCORI-funded research.

4 Next slide.

5 As a reminder, here is an overview of the
6 PCORI's implementation proposal and the three
7 pillars of activity. Pillar one is where most of
8 the activity has taken place, and is nearly
9 complete. This includes the development and
10 finalizing of the principles that describes how the
11 PCORI interprets the law. The inclusion of initial
12 set of guidance and FAQs as part of Cycle 1 2021,
13 and the potential development of additional guidance
14 as needed for future funding cycles.

15 Pillar two is focused on updating methods
16 and standards, as we are staying coordinated with
17 the Methodology Committee on this effort.

18 And pillar three, will be a more public
19 policy-focused activity, looking at opportunities
20 where PCORI can advance and support discussions
21 related to a patient-centered approach to addressing
22 healthcare value and rising healthcare costs.

1 Next slide.

2 As part of our transparent and deliberative
3 approach, we have laid out a robust plan to collect
4 public input on the principles. This included a 60-
5 day public comment period, two PCORI-hosted
6 webinars, and numerous discussions and meetings with
7 individual stakeholders that informed the initial
8 development of an input on the principles. We also
9 sought input from PCORI's advisory panels, the
10 Methodology Committee, as well as from the Board
11 during presentations in December and February.

12 Next slide.

13 We shared this slide with the Board at last
14 month's meeting so we won't go through it in too
15 much detail again. But it shows the overarching
16 themes and potential considerations we received from
17 our analysis of the public comments. And as Dr.
18 Cook mentioned, you know, the important thing to
19 note here is that through the broad input that we
20 received, the implications for PCORI fall under two
21 categories: considerations that inform the revision
22 of the principles and considerations for additional

1 activities or additional implementation activities
2 and goals.

3 So the next few slides will showcase what
4 we heard from the comments, and how we revise the
5 principles, and what we may consider for additional
6 implementation activities.

7 Next slide.

8 Principle one focuses on identifying
9 outcomes important to patients and caregivers. From
10 the comments we heard support for maintaining
11 principle one is central to PCORI's work, and that
12 the PCORI should ensure patient and caregiver
13 engagement in our research studies and that we
14 prioritize cost burden and economic impact measures
15 that are important to them. And also to consider
16 ways to monitor unintended consequences from the use
17 of this data,

18 Based off the input, the principles further
19 emphasize the importance of patient-centeredness in
20 our funded research, we note that the importance of
21 engagement when identifying outcomes, and we
22 clarified that when we referenced the full range of

1 outcomes when we're talking about relevant health
2 outcomes, patient reported outcomes, in addition to
3 the burden economic impact outcomes.

4 Next slide.

5 Principle two focuses on identifying
6 outcomes important to stakeholders. Here, we heard
7 the need to facilitate continuous engagement of a
8 diverse set of stakeholders and provide
9 opportunities for them to engage at individual
10 project levels. Based on the input, we did not need
11 to make significant changes to the principle itself,
12 but we did clarify certain examples of outcomes that
13 may be important to patients, caregivers, and
14 stakeholders that were identified from the public
15 comments.

16 Next slide.

17 Principle three focuses on the collection
18 of data as appropriate and relevant. Commenters
19 across the board agreed that the collection of
20 burden and economic data is important, but also that
21 it should not be a requirement across all PCORI
22 studies. We also heard that it'd be helpful for

1 PCORI to identify outcomes we may want prioritized
2 research, noting that any of those outcomes should
3 be appropriate and relevant, and that PCORI factor
4 in social risk factors when considering costs and
5 economic impacts. So in the principles we clarify
6 that PCORI encourages the collection of this data,
7 but will not require it.

8 We also provided some examples of where the
9 collection of data is appropriate and relevant and
10 further emphasized the importance of engagement,
11 when identifying outcomes. And we specifically
12 highlight social risk factors and social
13 determinants of health as an area of particular
14 interests for PCORI when considering costs and
15 economic impacts.

16 Next slide.

17 Principle four focuses on the conduct of
18 certain types of economic analysis, similar to the
19 request for additional clarity on what are
20 appropriate and relevant outcomes. We also heard
21 the need for clarity on the types of analyses for
22 PCORI will support. And even with broad support for

1 the collection of burden and economic impact data,
2 the commenters still noted strong support for the
3 prohibitions from PCORI authorizing law that
4 prevented PCORI from developing and employing a
5 dollars-per-quality adjusted life year threshold,
6 and maintaining PCORI's policy for not funding cost
7 effectiveness analysis.

8 So in the principles we clarify that
9 certain analysis will be allowable, either in the
10 course of a PCORI-funded research study, or
11 independent of one if appropriate. But note that
12 the limitations from our authorizing a law that
13 prohibited PCORI from developing or employing a
14 dollars-per-quality adjusted life year threshold or
15 from conducting cost-effectiveness analysis still
16 remain. But we do clarify that those limitations
17 stop at PCORI-funded research, and that researchers
18 can seek additional funding outside of the PCORI, if
19 they choose to conduct further analysis.

20 Next slide.

21 Beyond the principles, we are considering
22 additional implementation activities that were

1 identified from the public comments. These include
2 undertaking additional steps to further ensure
3 patient-centeredness across PCORI's work, including
4 and looking for opportunities to advance and support
5 discussions related to a patient-centered approach
6 to rising healthcare costs and value, to support
7 ongoing patient and stakeholder engagement. We will
8 also build on our existing engagement work, and
9 perhaps consider additional convenings to directly
10 connect stakeholders with researchers to help
11 identify appropriate and relevant outcomes.

12 And to further support future applicants
13 and our investigators, PCORI may develop additional
14 guidance as needed, and will work with the
15 Methodology Committee to develop and update the
16 methodology standards related to the collection of
17 cost burden and economic impact data.

18 Next slide.

19 So to bring us back full circle. Here
20 again, are the four principles for the consideration
21 of the full range of outcomes in PCORI-funded
22 research, then address the goals of identifying

1 outcomes important to patients and caregivers,
2 identify outcomes important to stakeholders,
3 providing criteria for the collection of this data,
4 and considering the conduct of certain types of
5 economic analyses.

6 Next slide.

7 So with that I'll turn it back to Dr.
8 Goertz to facilitate any discussion and are happy to
9 answer any questions. Thank you.

10 CHAIRPERSON GOERTZ: Thank you so much,
11 Andrew and, and I want to thank you for the
12 tremendous amount of work that's gone into putting
13 these principles together and also thank you for the
14 many times you -- the way that you've kept the Board
15 informed, you know, throughout this this process. I
16 think that's been incredibly helpful as we consider
17 the motion before us today, to have seen this evolve
18 over time, you know, based on the information that
19 you've presented to the Board as you worked through,
20 to get us to this particular point.

21 So does anyone have any questions or
22 comments for either Andrew or Nakela? Mike.

1 DR. HERNDON: Yeah. So Andrew through all
2 of the conversations and meetings and all. What,
3 what do we really feel like will be the research
4 community uptake for this, you know, elaborate
5 allowance that kind of gives this broader range of
6 outcomes, including the burdens and the economic
7 impact?

8 Now, I don't know if I asked it very
9 eloquently but if you got it, can you answer it? If
10 you didn't get it, I can clarify.

11 MR. HU: Yeah and I want to let Penny and
12 Joanna, and Bill, the rest of the team who really
13 worked with me on this effort jump in as well.

14 But, you know, I think the comments that we
15 got, you know that this is a huge addition and --

16 DR. HERNDON: Right.

17 MR. HU: -- for PCORI here, which is really
18 helpful for the community. I think we're already
19 hearing from a lot of investigators who want to do
20 this work and we're getting questions on, you know,
21 what's allowable and what's not. So those are the
22 things that we are already trying to consider in the

1 current cycle, Cycle 1 2021.

2 And I think for the most part of the
3 comments that we got from the stakeholder committees
4 is really positivity and willingness and interest in
5 how we're going to work on methods, standards, and
6 guidance.

7 And as the Nakela mentioned, and as we're
8 already trying to think about, how can we move
9 toward that phase? That really stem from the
10 principles themselves. And I think that's where
11 most of the interest is aligned, especially around
12 identifying what are some of the patient-centered
13 costs, you know the indirect costs that aren't
14 traditionally measured or not as frequently captured
15 in research or in practice. Those are some areas
16 where we heard, saw support for PCORI to kind of
17 jump in and play a leadership role.

18 DR. HERNDON: And I know at the EDIC, to
19 follow up if you don't mind. We had some discussion
20 about potentially doing a kind of toolkit for
21 researchers who want to include this type of work,
22 can you just kind of give the Board a bit of an idea

1 of what we're thinking there and when that might be
2 implemented?

3 MR. HU: Yeah, and if Kristin Carman is on
4 the line, our Director for Public and Patient
5 Engagement, she can definitely chime in too, but one
6 of the things that we considered based on the
7 comments we heard was, you know, we really -- the
8 stakeholders, both from the patient, caregiver, and
9 stakeholder communities all wanted to be engaged in
10 this work, both at the system level and institution
11 level, but also at the project level.

12 So one of the things that we've already
13 done in our work, I know Kristin has done a lot of
14 work leading this effort is building together these
15 toolkits to support researchers, and to engage with
16 the community. So I think this is an area where we
17 can do more of that, I know a little work has
18 already been underway on some of these proposals.

19 I'm not sure Kristin is here but we can
20 definitely provide more input in background on that
21 information.

22 DR. HERNDON: I was kind of asking just as

1 a way to kind of make sure that the Board understood
2 that, you know that was, and I'm not sure what all
3 committees have heard the presentation, we heard it,
4 EDIC, a couple of weeks ago so I just wanted to
5 clarify that, I do think that's important. And I do
6 think that it will be helpful to the research
7 community, as we go forward with this addition.
8 Thanks.

9 CHAIRPERSON GOERTZ: Thanks, Mike. All
10 right. Sharon welcome. Good to see you. You're
11 on mute.

12 DR. LEVONE: Sorry. I'm sorry to miss the
13 first part of the Board meeting.

14 Andrew, could you go to the previous slide,
15 can you go back to the previous slide?

16 Yeah. This is offered -- sorry about the
17 lateness of my observation but in principle three as
18 a friendly amendment, whether we could expand
19 potential burdens and economic impacts of treatment
20 options and interventions that must be appropriate
21 and relevant to the clinical aims of the study. And
22 I add that only because some of the interventions

1 that we study are not just clinical interventions,
2 they are environmental and system interventions, and
3 so just expanding the language to signal that we're
4 not limiting this to drug versus drug research.

5 MR. HU: Thanks Sharon. That's definitely
6 helpful. That's definitely not the intent to limit
7 it to just drug versus drug -- we are trying to take
8 a holistic view of this, and I may have to defer a
9 little bit. Nakela, I see you jumped on because I
10 know we, if we have to make tweaks to the language
11 itself; it takes a little bit more effort.

12 DR. COOK: Yeah, one of the things I was
13 just going to ask for may be a bit of clarification,
14 is it treatment options and interventions or just
15 intervention Sharon that you --?

16 DR. LEVONE: And.

17 DR. COOK: And. One of the things we're
18 trying to also think about is making sure if we want
19 to make an amendment to the principle that we're
20 capturing the exact language so we wouldn't have to
21 amend the motion. So I wanted to make sure I was
22 understanding.

1 And that to me is kind of as -- it was
2 intended but maybe me is a substantive comment if
3 it's not signaling that and so maybe one of the
4 things we'd have to consider for an amendment to the
5 motion.

6 DR. LEVINE: Sorry to gum up the works.

7 DR. COOK: No, we're capturing it.

8 CHAIRPERSON GOERTZ: Good. So, one option
9 that we have is to -- for that to be a friendly
10 amendment at the time that we make the motion.

11 All right. Bob.

12 DR. ZWOLAK: Yes, thank you Andrew. That's
13 a very nice presentation and these are excellent
14 principles but they are principles and I want to not
15 only emphasize what Mike said about the toolkit, but
16 the details of the toolkit and examples of what
17 works and what's out of bounds. Examples of
18 offerings of the Methodology Committee are really
19 important.

20 And finally, this is so new and so
21 important; I would hope that it would be a recurring
22 an agenda item for updates at the Board level

1 because this really is groundbreaking. And I think
2 that we all want to understand this as it rolls out.

3 So congratulations and please come back to
4 us frequently with updates and any new information.

5 MR. HU: Yeah, thank you and I definitely
6 heard the comments and we are happy to provide
7 ongoing updates to inform the Board as you continue
8 with the implementation activities, including the
9 development of guidance and working with the
10 Methodology Committee and updates on the progress
11 there.

12 DR. LEVINE: Thank you.

13 CHAIRPERSON GOERTZ: Eboni.

14 DR. PRICE-HAYWOOD: Just to follow up on
15 the inquiry about Methodology Committee. My
16 question is, you know, Board members have expressed
17 concerns about the research method background of
18 staff and things that we need to do to become more
19 rigorous in the representation of that, and
20 especially as it relates to cost measures and
21 economic analysis. I guess my -- I don't know if
22 this is a premature question, but was wondering, is

1 part of the strategy, not only to engage those
2 stakeholders who may use certain types of
3 information but in building your toolkit and working
4 with the Methodology Committee, are we looking to
5 bring in experts in certain areas representing those
6 perspectives who have done research in a certain
7 area?

8 And I'm asking that question because I
9 worry from the researcher's perspective about seeing
10 a list of things that you could measure, but not
11 necessarily using them in the way we are or
12 analyzing them in a way that really is meaningful
13 say to a healthcare system or provider or whomever.
14 I don't know if that question makes sense but it's
15 more about the methodology.

16 MR. HU: Thank you. It does and, you know,
17 one of the things that we heard and we're obviously
18 working on and centering on is, you know, how can
19 we, PCORI, support the Methodology Committee and
20 host some of these convenings or bring together
21 additional meetings as necessary.

22 One thing that that we do know will take

1 place for any of the work that the Methodology
2 Committee does update it does update its standards,
3 and we'll go through a public comment period as
4 well, before coming back to the Board. So it's a
5 concern that we are trying to address and thinking
6 about as well.

7 And one thing that I -- PCORI is working on
8 establishing a Resource Center, as well, to help
9 support PCORI's work, and as well as support the
10 needs of the Methodology Committee, and address some
11 of these issues.

12 CHAIRPERSON GOERTZ: That's great. Any
13 other comments or questions? Kate.

14 MS. BERRY: Yeah. Just a quick one and
15 Andrew, thank you so much and I know that you guys
16 have done so much work to engage stakeholders on
17 this process. You know, given the questions and the
18 comments, so far I just wonder if there is something
19 in-between the principles and how do we
20 operationalize that that we need to flesh out
21 further and I know that you're trying to get
22 approval today on these, but I hate to say it but

1 they're, you know there's devil in the detail right.

2 And this is so complex.

3 So, you know, just a question there.

4 MR. HU: No thanks, Kate for the question.

5 And you're right, these aren't meant to be

6 principles and they will inform the development of

7 guidance and further work so there's a step down

8 from here.

9 CHAIRPERSON GOERTZ: Andrew, what will that

10 process look like? You know, sort of what are next

11 steps after this.

12 MR. HU: Yeah, so we've already kind of

13 worked in and again, I'll ask Joanna and others to

14 chime in here as well, but we've already kind of

15 developed at least an initial set of guidance and

16 FAQs that were included in Cycle 1 2021's PFA. As

17 we learn more and as you can see the work that's

18 coming in to the LOIs and this process, we can

19 develop further and additional guidance as needed to

20 kind of address some further clarity, questions,

21 provide a little more detail as we learn more about

22 what are the types of things that our applicants are

1 looking for or asking.

2 We're working with our science team, the
3 merit reviewers to kind of flag this so they're
4 prepared to answer and look at applications
5 appropriately. But these are some of the things
6 that we're still working on right now, as we move
7 forward to the next phase of this, which is the
8 development of additional guidance. And obviously
9 working with the Methodology Committee to update any
10 methods and standards on that on that front as well.

11 CHAIRPERSON GOERTZ: Thank you. That's
12 helpful. Any other comments or questions? Mike?

13 DR. HERNDON: Christine, before we make a
14 motion or an amended motion, I just want to go back
15 to Sharon's input and make sure that I was kind of
16 understanding.

17 I understand, I think what Sharon was
18 getting at there may be a difference between
19 treatment options and interventions in her mind but
20 I think in Nakela's -- if I understood Nakela
21 correctly, that treatment options would include both
22 interventions, and there may not be a need for the

1 amendment or they may be. I'm just -- before we get
2 to the voting phase I just want to make sure that
3 the Board is clear on whether we really want to make
4 that amendment or consider it complete as is.

5 CHAIRPERSON GOERTZ: I'm wondering if
6 maybe, you know, Sharon if this would meet the
7 spirit of what you're trying to do and is to replace
8 the word "treatment" with "health options." Because
9 I think what Sharon is trying to say is that she's
10 certainly better at speaking for herself.

11 DR. LEVINE: I don't want to hold up a vote
12 on this, voting on the principles is important so
13 that the rest of the work can proceed and I think as
14 we move on to the next phase of this, we can -- in
15 government, they say, you know, bad legislation can
16 be sometimes fixed by good regulation.

17 And so, as we as we go to the next step in
18 terms of providing guidance to researchers, we can
19 make clear that it's more than just clinical
20 treatments, that this encompasses the full range of
21 interventions that PCORI has studied and will
22 continue to study.

1 CHAIRPERSON GOERTZ: So are you comfortable
2 with leaving the language as is for now, in that
3 case?

4 DR. LEVINE: Yes, I am.

5 CHAIRPERSON GOERTZ: All right. Great.
6 Any other comments or questions?

7 [No response.]

8 CHAIRPERSON GOERTZ: Okay, before we take
9 our --

10 DR. McNEIL: I'm sorry, Chris --

11 CHAIRPERSON GOERTZ: Barbara.

12 DR. McNEIL: I'm sorry. I just caught on
13 to the difference that Sharon, I think, was trying
14 to make with that change. I hadn't gotten it at
15 first.

16 Sharon, I think you may be saying is that
17 not only are we talking about the options that
18 patients have when they undergo a treatment, but
19 that we are also studying the kinds of changes in
20 the settings, the interventions in the settings,
21 under which those treatment options can take place.

22 DR. LEVINE: That's exactly right.

1 DR. McNEIL: So the treatment options alone
2 -- I'm sorry I didn't quite catch it the beginning.
3 Treatment options alone does not capture, I think
4 what we're getting at. We're trying to look at the
5 totality of experiences that a patient has, and
6 those include both the actual intervention, the
7 medical or surgical intervention that the patient
8 has, as well as the setting in which it is
9 accomplished. And for example we've talked about
10 medical decision-making, informed medical decision-
11 making. That is one of the things that we've
12 studied in the past.

13 And that is not a treatment option, it's a
14 setting or it's something else, in which the
15 treatment changes are embedded.

16 So I think Sharon is onto something, but
17 I'm not sure that we have the wording quite right
18 and if we don't, I think, if that's where she's
19 going, treatment option alone doesn't capture her
20 sentiment.

21 Do I have that right Sharon?

22 DR. LEVINE: Yeah. You got to what I was

1 trying to -- the point I was trying to make better
2 than I did Barbara. And I guess I am okay though
3 with making clear in supporting documents what we
4 intend here. And this isn't limited to the actual
5 therapy, but both the setting community versus
6 hospital versus home, kind of thing. There are
7 multiple interventions that we study and the
8 collection of data on the burdens and economic
9 impacts of any of the interventions we study must be
10 appropriate to the aims of the study, I guess.

11 DR. McNEIL: Sharon, I think a principle is
12 a principle and it doesn't get refined by further
13 subdivisions. I mean, that should be an overarching
14 concept, if I'm understanding what a principle is.
15 So, and I don't think the analogy of government and
16 regulations quite fits here, because treatment
17 options is very, very specific. It's Drug A versus
18 Drug B or a urethral sling or a drug.

19 What you're saying is, is it an in-home
20 physical therapy or is outpatient physical therapy,
21 or was an ambulatory blood pressure monitoring or
22 was in-office monitoring, or something like that.

1 So I really think they're different and I don't
2 think that they should be further explicated by a
3 little footnote in the next document.

4 So it could be the impacts of treatment
5 options in their settings?

6 MR. HU: So, if I may jump in real quick.
7 I know the language of the principles is obviously
8 what's on the slide right now, in the Principles
9 Document itself there is obviously more context to
10 each of the other principles and for this one,
11 pulling directly from the language, and I hope this,
12 I think it kind of addresses the issue that is being
13 discussed.

14 But the language is, "PCORI encourages
15 investigators to capture appropriate and relevant
16 cost burdens and economic impacts associated with
17 the impact of an intervention for two or more
18 alternative approaches that are studied within the
19 context of CER." So I think the intent of the
20 principle itself does try to be holistic, in the
21 sense of what we're capturing in this discussion and
22 in the course of what PCORI studies.

1 DR. LEVINE: That language that you read is
2 exactly what I was trying to get to.

3 DR. SIEGEL: Yeah, I think that the issue
4 is it didn't quite make it into the language of the
5 principle itself. It's very much in the Principles
6 Document.

7 MR. HU: Yes.

8 DR. SIEGEL: I'll defer to you Sharon on
9 whether you think the language of the principle
10 itself really should be tweaked or whether we can
11 rely on the larger document.

12 DR. McNEIL: This is Barbara; I think it
13 should be tweaked.

14 DR. RHODES: This is Karin Rhodes; I agree
15 that it should be tweaked slightly. And what about
16 economic impacts of intervention options?

17 DR. McNEIL: Oh, that's better thing.

18 CHAIRPERSON GOERTZ: Yeah, I was thinking
19 that same thing.

20 DR. LEVINE: Yeah, intervention options
21 must be appropriate and relevant to the aims of the
22 study.

1 DR. McNEIL: That would work.

2 CHAIRPERSON GOERTZ: So Andrew and Nakela,
3 do you have any concerns about making that change?

4 DR. COOK: That was where I was going when
5 I first heard Sharon's comment, was wondering if
6 interventions would be more considered all inclusive
7 if treatment options wasn't signaling that.

8 CHAIRPERSON GOERTZ: Is there anyone that
9 feels uncomfortable with making that change? Mike?

10 DR. HERNDON: I was just going to say, when
11 I think of intervention, I agree with you Nakela and
12 I'm especially thinking about social determinants,
13 you know, when we talk about interventions with
14 community health workers and peer navigation and
15 that sort of thing, and I think interventions gets
16 added, and I think when we get to the motion phase,
17 just interject that in place of treatment and I'd be
18 good with that.

19 CHAIRPERSON GOERTZ: Is there anyone who
20 does not feel comfortable with that because if,
21 then, I think we can amend the motion. So in fact,
22 to that language so that, you know, so that we don't

1 have to do anything further at the time that we make
2 the motion.

3 Any concerns about moving forward in a
4 direction? Andrew, are you okay with that?

5 MR. HU: Yep. I think we're okay.

6 CHAIRPERSON GOERTZ: Okay. All right.
7 Then what I'd like to do is go ahead and move
8 towards a motion and a voice vote. Just before we
9 do that for record keeping purposes, I wanted to
10 note that James Schuster had to leave the call and
11 is not in attendance, and obviously Sharon Levine is
12 now in attendance. So --

13 DR. SCHUSTER: This this is James. I'm
14 back.

15 CHAIRPERSON GOERTZ: Okay, great. Great,
16 James. Okay, James is back Sharon is back, we still
17 have a quorum, so I think we're in good shape. And
18 so --

19 MS. WILSON: One more. Michelle McMurry-
20 Heath had to leave the call, I just wanted to put
21 that in there.

22 CHAIRPERSON GOERTZ: Okay, thank you. All

1 right. So what I'd like to ask then is for a motion
2 to approve PCORI's principles for the consideration
3 of the full range of outcomes data in PCORI-funded
4 research, including the amended language to replace
5 treatment options with intervention options in
6 principle three. So that's the motion that I'm
7 looking for.

8 DR. HOWERTON: This is Howerton, so moved.

9 CHAIRPERSON GOERTZ: Howerton. Okay, thank
10 you. Can I get a second please?

11 DR. HERNDON: Mike, second.

12 CHAIRPERSON GOERTZ: Okay, Mike. Thank
13 you. Is there any further discussion?

14 [No response.]

15 CHAIRPERSON GOERTZ: All right, in that
16 case I'm going to ask for a voice vote. All those
17 in favor, please say aye.

18 [Ayes.]

19 CHAIRPERSON GOERTZ: Opposed?

20 [None.]

21 CHAIRPERSON GOERTZ: Abstentions?

22 [None.]

1 CHAIRPERSON GOERTZ: All right, the motion
2 passes. Thank you everyone. Thank you Andrew.
3 Great, great work we really appreciate you and for
4 you and your entire team.

5 Nakela, I am going to -- I'm going to turn
6 the meeting back to you then for any closing remarks
7 that you might have.

8 DR. COOK: Thank you. And thanks for a
9 great meeting today. It's actually the first
10 meeting that we've had, where we've had to go
11 through so many slates all together and provide that
12 type of context for the slates to facilitate the
13 Board's deliberation. So I hope you found that
14 helpful in terms of getting some overviews that
15 allowed you to really see how things are aligning
16 with our commitment plan.

17 I also thought it was just a rich group of
18 slates that you looked at from targeted PFAs, the
19 additions to the broads and the D&I solicitations,
20 and we also had some really rich discussions around
21 the three PCORI funding announcements for the next
22 cycle, for Cycle 2 2021. And we're seeing momentum

1 around those two priorities, from our reauthorizing
2 legislation and also saw some momentum around an
3 area of urinary incontinence that we've been working
4 in, and heard the comments about the importance of
5 thinking about surgical approaches in addition to
6 non-surgical approaches and approaches when we're
7 thinking about urinary incontinence in the future.

8 I also appreciate the great discussion
9 about the niche for PCORI related to priorities for
10 COVID-19 and we look forward to coming back to talk
11 more fully and comprehensively about some of the
12 activity going on in that space and I mentioned some
13 of our ongoing work with other federal agencies and
14 hopefully we'll be at that point where we can
15 discuss some of that more publicly at our next
16 meeting where we can tee that up for discussion.

17 Also, I just wanted to mention that in
18 addition to some of the work that you've seen
19 related to COVID-19 with the enhancements in the new
20 awards and the solicitations we had with our
21 engagement and dissemination and implementation
22 activities for COVID-19. We also are working on

1 another targeted funding announcement under our
2 previously approved authorities that would be fast
3 tracked and we're looking forward to talk with you
4 further on that.

5 And we also had special areas of emphasis
6 in our broad announcement in Cycle 1 2021 related to
7 COVID-19. So we will be looking at slates from
8 those solicitations at future board meetings.

9 And I heard the importance of some
10 recurring updates at the Board level related to our
11 COVID-19 activities.

12 And then lastly, related to cost
13 principles, again, I want to commend our hard-
14 working team that has really engaged, I think all of
15 you and the stakeholder community very extensively
16 and in a remarkable way to bring the principles that
17 you saw today to consideration for your approval and
18 glad that we're moving forward on those and really
19 look forward to this next steps. So working with
20 the Methodology Committee, the new economic resource
21 center that we'll be pulling together to support our
22 activities and the awardees, and bring in some of

1 the expertise around the space, as well as thinking
2 about that guidance that will stem from the
3 principles and we're continuing to refine that for
4 our applicants.

5 And so, a very great meeting and I'm
6 looking forward to our next one and I'll turn it
7 back over to you, Christine to wrap this up.

8 CHAIRPERSON GOERTZ: Thank you, thank you
9 so much Nakela. I want to close by once again
10 congratulating our new awardees and for thanking
11 those who joined us today via webinar and
12 teleconference. A reminder that all materials
13 presented to the Board today will soon be available
14 on our website. Today's webinar was recorded and
15 the archive will be posted within a week or so. We
16 always welcome your feedback at info@PCORI.org, or
17 through our website at www.PCORI.org.

18 Thanks again for joining us. Have a great
19 afternoon.

20 [Whereupon, at 2:58 p.m. EST, the Board of
21 Governors meeting was adjourned.]

22