PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

BOARD OF GOVERNORS MEETING

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[Transcribed from PCORI webcast.]

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1 P R O C E E D I N G S

2 [8:06 a.m.]

3 CHAIRMAN WASHINGTON: Good morning
4 everyone and welcome to this board meeting of the
5 Board of Governors of the Patient-Centered Outcomes
6 Institute. I'd like to first welcome my colleagues
7 on the Board and colleagues from the Methodology
8 Committee. And then, acknowledge all of those who
9 joined us in person this morning. Welcome.

10 And likewise, welcome to all of you who
11 are joining us by webcast and telecast. If you
12 want to register online or by phone, you can do so
13 by going to www.pcori.org/events. And please note
14 that all the materials that will be presented today
15 and are being considered as we make decisions are
16 available on our website at www.pcori.org.

17 This webcast is being recorded and
18 archived; it will be posted later this week. I
19 also want to bring to your attention, those of you
20 who don't know it, there is a public comment period
21 later today and we will be welcoming comments from
22 those of you who have to offer them.

1 I learned this morning that we're also
2 live Tweeting today. And so, join the conversation
3 at #PCORI. We always welcome your feedback by e-
4 mail at info@pcori.org. And so, with that
5 introduction, I see my Chair beaming here. Did I
6 say something or are you just coming ready for this
7 meeting this morning.
8 DR. KUNTZ: [Off microphone.]
9 * CHAIRMAN WASHINGTON: I think he knows
10 about my association with the luddites, so that's
11 what you're referring to, I imagine. Okay.
12 Well, the first order of business is to
13 approve our minutes from the February and from the
14 March Board meetings. And so, let's start with the
15 February first. Any comments?
16 UNIDENTIFIED BOARD MEMBER: I move to
17 accept.
18 UNIDENTIFIED BOARD MEMBER: Second.
19 CHAIRMAN WASHINGTON: It has been moved
20 and seconded, all in favor?
21 [Chorus of Ayes.]
22 CHAIRMAN WASHINGTON: All opposed?

1 [No response.]

2 CHAIRMAN WASHINGTON: Okay. And no

3 abstentions?

4 [No response.]

5 CHAIRMAN WASHINGTON: Okay, the motion

6 passed. And then the Board minutes for March 2013.

7 Any comments?

8 UNIDENTIFIED BOARD MEMBER: Move to

9 accept.

10 UNIDENTIFIED BOARD MEMBER: Second.

11 CHAIRMAN WASHINGTON: It has been moved

12 and seconded. All in favor?

13 [Chorus of Ayes.]

14 CHAIRMAN WASHINGTON: All opposed?

15 [No response.]

16 CHAIRMAN WASHINGTON: Okay, no

17 abstentions, the motion carries.

18 I'm going to turn the program over to Dr.

19 Selby who will lay out for us what's ahead for the

20 rest of the morning, early afternoon.

21 DR. SELBY: Thank you Dr. Washington.

22 Good morning everyone, Board members, Methodology

1 Committee members, staff -- PCORI staff, growing
2 numbers and guests, here and on the webcast.
3 SO, I'm going to start with as I usually
4 do with an update that will both briefly review our
5 past three months since the February Board meeting,
6 a lot has happened and point the way forward to the
7 rest of this meeting. And also, address some
8 questions that Mr. Lipstein asked at our Board
9 meeting in February, so that is the second item
10 here; the Legislative mandate. Steve asked us to
11 review the mandates from PCORI authorizing
12 legislation and update the Board on where we are.
13 And the process was valuable and does, in fact,
14 point to some activities that are just getting
15 underway and we will be focusing on in the coming
16 few months.
17 I have some outstanding news about
18 additions to the Office of the Executive Director,
19 but you'll have to wait just a bit to hear that
20 news. And also, I want to celebrate the arrival of
21 a number of additional key staff members.
22 So, I'm going to go through the activities

1 pretty quickly, in the interest of time and because
2 you are familiar with them, in general, but there
3 are a few points worth highlighting. The first
4 point is simply that our activities, our budgets,
5 and everything that we do at PCORI are now
6 organized by our Strategic Plan, the five pillars
7 of our Strategic Plan and that's the way I will
8 present the activities to you.
9 So the area of engagement is an area that
10 we've been involved in since day one. Increasingly
11 we're coming to think of engagement as an activity
12 that is done in tight linkage with our research.
13 We trained -- and this is a very exciting program,
14 we trained 17 mentors, there were actually about 10
15 mentors before, these are patient or stakeholder
16 reviewers who join our Merit Review Panels along
17 with scientific reviewers. After the first round
18 of reviews Martin Dueñas and contracts management
19 staff identified 10 mentors and later 17 more.
20 From these patient stakeholder reviewers who were
21 particularly skilled and experienced, and they lend
22 their support through the review process to less

1 fully trained and experienced patient and
2 stakeholder reviewers.
3 It has been very successful during the
4 second round of our peer reviews. We held our
5 first of several planned regional workshops. These
6 are attempts to take PCORI on the road, so to
7 speak, and to get to parts of the country that
8 we're not hearing from much by way of research
9 applications, by way of peer reviewers. And so, we
10 went to Wichita, Kansas and had a day and a half
11 meeting with 63 patients and a wide range of other
12 stakeholders, focused particularly on issues of
13 rural health and really discovered that there are
14 people in the Plain states that understand once we
15 explain PCORI it resonates. They've got a set of
16 research issues that are in some ways unique to
17 their region and enhanced our conviction that it's
18 important to get out. That it's important to get
19 these folks involved in PCORI research activities.
20 Roundtables is something we do frequently, bringing
21 a patient constituency, a physician constituency,
22 to PCORI to have a discussion about particular

1 interests. In the spirit of generating research
2 ideas, in the spirit of stimulating response that
3 comes from stakeholders partnered with researchers.
4 And lastly, although I could go on, and on
5 about the engagement activities we're looking
6 forward with excitement to engagement awards, which
7 will be small grants. An announcement will go out,
8 we believe in July, and these are targeted to
9 patients or to stakeholders or to researchers but
10 it is all about new partnerships, forming
11 partnerships. To begin to develop research teams,
12 multi-stakeholder research teams. We initially
13 budgeted $650,000 for this first year and as the
14 excitement has grown, so has our conviction that
15 this really will seed meaningful patient-centered
16 research experience. We're going to increase that
17 to $1.2 million.
18 This is just a map that we look at a lot
19 and it just shows a kind of swath up the Great
20 Plains from Texas to the Canadian border, where we
21 don't get many research applications and therefore
22 we don't wind up funding much research with the

1 exception of Colorado, which does quite well. Very
2 little activity from the state to date and this is
3 funded research through our first 126 awards. So
4 this is what we would like to see gradually change
5 by among other things, getting more applications
6 submitted, improving the quality of the
7 applications, getting more people from these
8 regions on our review panel studies. Just
9 appreciate the issues that come from this region.
10 You are going to hear later today from Dr.
11 Sherine Gabriel, updating us on the Methodology
12 Committee's activities, but I just wanted to say
13 that the methodology report revisions are underway,
14 incorporating public comments and we will hear
15 about the progress on that today.
16 PCORI issued its first PFA specifically
17 directed to Method research in November and those
18 applications are in, I believe it's in the 120-
19 range and they will be reviewed in mid-June and we
20 will have our first Method awards, Patient-Centered
21 Outcomes Research Method awards in late June.
22 And I just want to report briefly on a

1 meeting, sponsored by PCORI held at the IOM and in
2 collaboration with the IOM, on observational
3 studies and use of observational studies in the
4 learning healthcare system. Our Methodology
5 Committee was heavily involved in putting this
6 together and really did the heavy lifting on
7 thinking about this. It was particularly Steve
8 Goodman, along with a number of Methodology
9 Committee members helping to planning and the
10 presentations, but it really drew a diverse crowd
11 of methodologists from across the country, and by
12 all accounts was both an extraordinary meeting. It
13 also drew one Board member, Larry Becker, for the
14 entire darn meeting. That was impressive. And he
15 said he enjoyed it. But it really did point to
16 some exciting areas in the development of
17 observational methods that we hope will make a
18 major contribution along with randomized trials, to
19 building the evidence that PCORI will support and
20 then disseminate.
21 And I'm happy to say that there's a ton of
22 activity in the area of funding patient-centered

1 outcomes research. You'll hear this afternoon
2 about our proposed slate of Cycle II awards, 51
3 awards totaling nearly $89 million and that's
4 coming up this afternoon.
5 In the last three months, we have posted
6 five day long, multi-stakeholder work groups
7 focused on each one of the five proposed areas for
8 targeted PCORI Funding Announcements. Those are
9 asthma, back pain, uterine fibroids, falls in the
10 elderly, and obesity. And this afternoon you will
11 hear a report from these workshops and a proposal
12 to move forward with -- immediately, with two of
13 these funded announcements. I can hardly say
14 enough, and I'm not going to try, you will hear
15 from Dr. Rachael Fleurence this afternoon on our
16 experience with our first round of four advisory
17 panels. Three advisory panels related to priority
18 areas that did prioritization and a fourth advisory
19 panel dedicated to patient engagement, the practice
20 of patient engagement. These panels, their
21 composition is extraordinary. Their dedication and
22 the extent to which they understand PCORI's mission

1 and are joined with us in addressing it was really,
2 impressed all of us. A wonderful two days. A lot
3 of national leaders in the area of patient-centered
4 outcomes research, a lot of extraordinary patients
5 and other stakeholders.
6 And you will hear this afternoon from Lori
7 Frank about our PCORI Pilot Projects, part of what
8 we call active portfolio management. But I just
9 want to say that those 50 pilot project that we
10 funded, under Lori's leadership and with the
11 collaboration of Academy Health, we are really
12 doing what we hoped which is drawing themes out
13 them and bringing these investigators together
14 across projects. They in turn are collaborating on
15 dissemination. We have a large panel of pilot
16 projects talking about patient engagement at
17 Academy Health and seen another proposal generated,
18 really by these investigators, talking about PCOR
19 and PCORI in a proposed panel at APHA.
20 So, it's really nice to see these projects
21 which are dedicated to patient engagement, really
22 coming together to share learnings and to pull out

1 the themes about how you engage patients and other
2 stakeholders in the research process.
3 You all know and aware that on April 23rd
4 we released announcements for PCORI infrastructure
5 Awards. We call this the National Patient-Centered
6 Clinical Research Network. It's the Board's vision
7 in many ways, a vision of a legacy, of an efficient
8 national infrastructure for conducting patient-
9 centered comparative effectiveness research; $68
10 million total funds both clinical data research
11 networks and patient powered research networks.
12 Letters of intent are due June 14th and
13 applications are due September 23rd.
14 I want to thank the Board, many Board
15 members for contributing to the thinking behind
16 this and there's a lot more thinking to do. This
17 is going to be a major PCORI investment, a real
18 flagship. And it's challenging, others have tried.
19 We are building on their efforts, but we indeed
20 have a lot to think through as this goes for it.
21 And dissemination activities, our Strategic Plan
22 really tells us that dissemination is crucial to

1 achieving our goals. We continue to publish and
2 you can find our publications on the PCORI website.
3 The scientific publications committee met
4 yesterday. We have a number of papers in review,
5 including a paper on our review process or I should
6 say in development, not in interview. On our PCORI
7 review process, which is unique, the scientific
8 community needs to know about it. On how we
9 prioritize research and on how we engage patients
10 and research. Papers on this topic are in
11 development. We really feel that it is important
12 to get the notions of how PCORI does research, what
13 it's looking for out to the research, as well as
14 the stakeholder communities. Papers in development
15 also on PCORI opportunities specifically for
16 nursing research critical to patient-centered
17 research.
18 And then, you were here in the not-too-
19 distant future about are work on the dissemination
20 and implementation blueprint. Part of our
21 Strategic Plan during 2013 is to develop a
22 comprehensive approach to the way that PCORI will

1 both disseminate and implement its research
2 findings. So it will be done, it will culminate
3 with a multi-stakeholder workshop in October and we
4 will have a final plan for presentation to the
5 Board before the end of 2013, and ready to begin
6 the work of dissemination and implementation.
7 So that was a whirlwind summary of
8 activities.
9 CHAIRMAN WASHINGTON: Could we pause for a
10 minute Joe and catch our breath here? Just for a
11 minute.
12 DR. SELBY: Well, I'm still breathing.
13 Aren't you?
14 [Laughter.]
15 CHAIRMAN WASHINGTON: That is quite a bit.
16 Also, just pause for a minute in case there's a
17 question regarding clarification. Please, Ellen
18 MS. SIGAL: Ellen Sigal, Board member.
19 So, hugely impressive work. Question about some of
20 the states or that haven't been involved. It's a
21 little strange. Some of them have a lot of
22 academic research going in and have we reached out

1 to these academic institutions and these groups, I
2 mean that was a little surprising to me.
3 DR. SELBY: We have reached out. We are
4 reaching out. We have more outreach to do, I
5 think. I'm not sure which state you referenced.
6 MS. SIGAL: Texas.
7 DR. SELBY: Okay. It -- Texas is a
8 question mark for me as well. In a number of these
9 states Ellen, it does seem to be more that we're
10 not getting applications submitted than that they
11 are not doing well when they get reviewed.
12 VICE CHAIRMAN LIPSTEIN: Ellen, you know,
13 it's a timely questions. This is Steve Lipstein,
14 by the way. I'm a member of the Board.
15 Joe just recently was the keynote speaker
16 at a CER symposium at Washington University, which
17 was targeted at states from around the Midwest and
18 during the Q&A period, we were just talking about
19 this on the phone. During the Q&A period, a number
20 of people commented about just the research
21 environment in general right now. Feeling like
22 whether it's a result of the sequester and some of

1 the pressures on NIH or the limited funds that
2 PCORI has, that it's getting more and more
3 difficult to succeed in these applications for
4 funding and on top of that in our mandate, where
5 we've required a lot of research have a lot of
6 patient involvement, what we call patient-
7 centeredness here at PCORI. It adds to the degree
8 of difficulty both in preparing an application and
9 submitting it.
10 And so, part of it, I think we're still in
11 a phase in our development where we have to work
12 with the research community and particular help
13 them understand how to do what we expect them to
14 do. What we want them to do. And so, I thought
15 Joe did a great Q&A session with these researchers
16 from around the Midwest and we'll see if it begins
17 to bear some fruit. But it really is going to mean
18 us going on the road a lot more, I think, and
19 answering those kinds of questions.
20 But what I'm hearing, and I'd be curious
21 what other on the Board have heard, is that the
22 research community is just feeling like the degree

1 of difficulty in both applying, preparing
2 applications for funding and then securing the
3 funding is just increasing from all sides.
4 So I don't know if others have heard that
5 as well.
6 CHAIRMAN WASHINGTON: Thanks Steve.
7 Harlan.
8 DR. KRUMHOLZ: Harlan Krumholz, member of
9 the Board. I just want to really support what
10 Steve says. I think this may be one of the most
11 important things that we have to do in the upcoming
12 piece and Joe and I have discussed this as well.
13 But just to bring this into our awareness, I see a
14 lot of talented investigators standing on the
15 sideline. When I ask them why they're not applying
16 to PCORI, they say they're not really clear what
17 we're looking for. They're not clear how to access
18 us. And I know as staff that must be hard to
19 believe, because you're feeling like it seems like
20 the whole world is accessing you all the time.
21 But I think from the researcher
22 perspective, you know, we need to engage them in

1 ways that we haven't. And Steve, even going
2 beyond, you know, the talks, we have to find ways
3 digitally and beyond that I talked to Joe about the
4 possibility of posting successful applications
5 online so people can see templates. I think that
6 we need to have video clips where people can come
7 on a get a quick orientation. And I think we need
8 to go through our networks to tell people that we
9 are looking for talented researchers. We, of
10 course, want them paired with stakeholders and
11 patients and caregivers, you know, we want to have
12 the sensibility that we've been talking about from
13 the outset.
14 But I'm very concerned that a lot of
15 talented people are not finding their way to this,
16 even with the concerns about funding and other
17 sources. And I just want to strongly endorse what
18 Steve said and hope that maybe that's something
19 that we all can as a Board -- final thing, I felt
20 the Methodology Committee can also play an
21 important role in this, as they are such an
22 important group for setting standards. They're

1 also leaders within the research community and I
2 think tapping their expertise to figure out how
3 best to engage the research community and to get
4 people to lean forward and participate would be
5 very helpful.
6 CHAIRMAN WASHINGTON: Thank you Harlan.
7 Two more commenters and then we're going to move
8 on. That's Norquist and Zwolak.
9 DR. NORQUIST: Yeah, Gray Norquist, Board
10 of Governors.
11 So, I agree. What I've been saying for a
12 long time, and one of the things is that we haven't
13 had the staff to really reach out and do this.
14 because at NIH, I mean, when I was there we had a
15 lot of program staff. They'd be on the phone,
16 they'd talk to people, people would call them.
17 "This is what I want to do, what do you think?"
18 And now we've had a few reviews. We actually know
19 what we're going to fund. I think that's
20 important. The other thing that I would think
21 about and what we did, is we used to -- you know,
22 once you got a cadre of people doing your kind of

1 research, they can help others. You know what I
2 mean?
3 And so, somehow we need to have our "own
4 programming," which we have our own grantees who
5 are successfully funded reach out to others and
6 have meetings regionally, and that's an idea that I
7 think we need to think about because we will never
8 be able to do all of it. But once you get a group
9 who knows how to do it, they can kind of
10 proselytize this to others, too.
11 CHAIRMAN WASHINGTON: Zwolak.
12 DR. ZWOLAK: Bob Zwolak, Board.
13 Amplifying those comments. If you look at that
14 map, it appears that Canada starts just north of
15 Massachusetts. And there's an awful lot of white
16 north of Massachusetts, so I think we need to
17 invite -- Joe or potentially the staff, and I've
18 also encountered as I told you, many people that
19 are still perplexed a bit about what constitutes a
20 successful application. So, the idea of posting
21 some successful applications or some more clues, I
22 think, will help people. And if nothing else,

1 we’ll have to drag Joe to New England sometime this
2 summer.
3 UNIDENTIFIED BOARD MEMBER: [Off
4 microphone.]
5 CHAIRMAN WASHINGTON: Joe, I would say
6 this is a case where I would ask you to reflect
7 back to the Board and say, you know, we could use
8 your help, too. In that we have Board members who
9 are all around the country, all the time and I
10 think we should begin to take advantage of you.
11 And it reminded me, we’ve been talking
12 about a national conference of some sort that also
13 would generate activity and attention across the
14 nation and we should resurrect that idea and think
15 about how we’re going to move it forward.
16 DR. SELBY: Could I -- I completely agree
17 with all of the concerns and the suggestions and
18 we’re actually actively digging now through these
19 funded applications just to put, if not whole
20 applications, at least the examples of how the
21 successful ones did their patient and stakeholder
22 engagement, which I think is the part that

1 perplexes applicants the most.
2 CHAIRMAN WASHINGTON: Joe, I sure --
3 DR. CLANCY: So why not the whole
4 application? I mean, absent financial stuff? I
5 mean, on the federal side, this you can get it.
6 DR. SELBY: We could have an offline --
7 DR. CLANCY: Yeah.
8 CHAIRMAN WASHINGTON: Joe, Jesse is
9 waiving his hands.
10 DR. SELBY: Okay, when Jesse waives.
11 CHAIRMAN WASHINGTON: Last one.
12 DR. JESSE: Thanks, Bob Jesse, Board.
13 So, it’s one thing to ask successful
14 applicants about the experience, I think a lot of
15 us are hearing from unsuccessful applicants about
16 the problems they encountered, the frustrations
17 they encounters and are we polling that group at
18 all to try to refine the process?
19 DR. SELBY: When I said examples, I meant
20 examples for applicants who are hoping to get
21 awards, so they’re not -- we’re not just talking to
22 the successful ones, but we’re trying to show what

1 in the judgment of Merit Panels was considered to
2 be really top percent of engagement. But I take
3 your point and we could --
4 DR. JESSE: There's a fair amount of
5 frustration on the part of unsuccessful applicants
6 with the process itself. And it might be useful to
7 burrow into that a little bit.
8 DR. SELBY: Yes, and I mean, that's a
9 mix -- among other things, our inability to fund a
10 high proportion of what we receive. And, a
11 learning curve for applicants in what we're looking
12 for, so, you know, it is partly is on the research
13 community to change. We are talking about doing
14 research differently so there's that as well.
15 Okay, so I will thank you for those
16 comments, all of which we agree with. And move
17 onto this analysis of [off microphone] and what we
18 just did was turn the microphone off.
19 No, what we did was go through the
20 document and pull out places where it in fact says
21 very clearly the "Institute shall." Green dots
22 mean we either accomplished it or we've done

1 everything and we'll continue to do it for those
2 that are continuous instructions. So the National
3 Priorities for Research, establishing and updating
4 the Research Agenda and carrying out the Research
5 Project Agenda, I think we will all agree that that
6 we've accomplished this and we continue.
7 But I want to draw your attention,
8 importantly, to this next -- the next two items
9 actually.
10 So at the bottom of this page it says,
11 "The Institute shall enter into contracts for the
12 management of funding and the conduct of research."
13 So, one thing to be said is that all PCORI funding
14 is through contracts, but that's not what this
15 phrase is talking about. This phrase is talking
16 about contracting for the management of funding and
17 the conduct of research. So, it refers to the
18 management of and oversight of research funding.
19 This is the adjacent language, "And the
20 Institute in contracting shall give preference to
21 the Agency for Healthcare Research and Quality and
22 The National Institutes of Health, if the research

1 to be conducted or managed under the contract is
2 authorized by the governing statutes of that agency
3 of institute."
4 Now, we have had, I would say a contract
5 or a MOU with NIH to do the reviews of the Pilot
6 Projects and we have one now with AHRQ to work with
7 us on topic briefs for our research prioritization
8 process. But it's pretty clear to me that the
9 framers of legislation envisioned a very different,
10 had a different meaning here. They anticipated
11 that PCORI would not duplicate AHRQ for instance or
12 an institute at NIH and become a full service
13 research institute. They anticipated that we would
14 convene stakeholders, we would identify and
15 prioritize research topics, and we would commission
16 research. And that notion leads to a smaller
17 organization and that notion leads to the
18 utilization of infrastructure that has already been
19 created. It points particularly to the
20 infrastructure at AHRQ and NIH, but it also raises
21 the possibility that there's infrastructure
22 elsewhere.

1 So, we are very actively looking into the
2 possibilities of working both NIH and a AHRQ on a
3 substantial portion of portfolio as we move from an
4 organization that funded $71 million of research in
5 2012 to one that aims to commit $355 million in
6 2013 and $500 million or more in 2014.
7 The rational for thinking about this, the
8 reason it becomes something that you can recognize
9 as important to consider is obvious. So you will
10 hear this afternoon about work that is underway to
11 partner both NIH and AHRQ on two of our targeted
12 funding announcements. And I hasten to add that
13 the last 18 months has seem PCORI, its Board, the
14 Methodology Committee and staff elaborate a unique
15 way of doing research and we have a different way
16 of soliciting research. We have a different way of
17 reviewing research and we have a different way that
18 we expect people to conduct research.
19 And those principles, those principles
20 that make PCORI research different; we all
21 completely understand have to be preserved as if we
22 enter into contracts or understandings with any

1 agency that would then manage the research.
2 So, that's our aim. I just wanted to
3 alert you to the fact that we will be talking about
4 this more this afternoon, but --
5 DR. WEISMAN: [Off microphone.]
6 CHAIRMAN WASHINGTON: Again, there Harlan
7 we'll do clarification but any discussion this,
8 Joe's asking us to hold until this afternoon.
9 Okay.
10 DR. WEISMAN: On the legislation, when you
11 said the intent was that we don't -- you know, we
12 contract research we don't do research. NIH
13 clearly does intramural research and extramural
14 research. Were you referring to or do you believe
15 the legislation referring to only referring to
16 intramural research or where they also referring to
17 extramural?
18 DR. SELBY: No, I think almost exclusively
19 extramural research.
20 DR. WEISMAN: [Off microphone.]
21 DR. SELBY: That, no we wouldn't -- yes,
22 we would fund extramural research through the NIH

1 or through AHRQ or through -- yeah.
2 CHAIRMAN WASHINGTON: Okay. Thanks
3 Harlan.
4 DR. SELBY: So I will move on now, and
5 like I said we will come back to this this
6 afternoon or later this morning as we talk about
7 the targeted PFAs.
8 There are a number of conditions for
9 contracts; transparency, addressing conflict of
10 interests, methodology standards, expert advisory
11 panels, allowing publication, and issues related to
12 data privacy and ethics. And I think it's green
13 because we've got everything covered except one
14 bullet there and I'll address that in the next
15 slide. But that is the creation of certain
16 specified expert advisory panels and we'll get back
17 to that in just a minute.
18 The next requirements, I think we're doing
19 very well on it. And that is requiring that
20 research be designed to take into account the
21 potential for differences among population
22 subgroups and the effectiveness of healthcare

1 treatments. So all of our funding announcements
2 require applicants to address this issue. We call
3 it inclusiveness. But it really is the about the
4 possibility that treatments differ across patient
5 subgroups.
6 The Methodology Report and Standards go
7 into assessing treatment heterogeneity in depth and
8 the Methodology Committee recognizes it as a
9 central theme. So I think we've done very well and
10 have that one covered.
11 There's another one that is a bit vague
12 and the meaning is not entirely clear and we are
13 going to have to get some consultation on this, I
14 think. Review and update evidence on a periodic
15 basis as appropriate. And since we have not
16 generated evidence, we don't really expect the
17 first research to be done until the end of 2014 or
18 2015, we have a bit of time, but that's one that
19 hasn't been started yet.
20 Then, the Institute shall advise expert
21 advisory panels in carrying out randomized clinical
22 trials. So we recognize that we are beginning to

1 plan this, we'll collaborate with the Methodology
2 Committee and the PDC in preparing a charter, which
3 we'll present at the September Board meeting. But
4 it is the case that out of the first round -- out
5 of the first two rounds of responses to the broad
6 funding announcements, about 45 percent of the
7 funded research is randomized clinical trials. So,
8 we have a body of randomized clinical trials just
9 getting off the ground and as we read the
10 legislation we need to have this clinical trials
11 advisory panel up and advising on these projects.
12 And in the case of a research study for
13 rare disease, appoint an expert advisory panel for
14 rare diseases. And this can be read one of two
15 ways. Either you appoint a separate panel for each
16 study or that you have an advisory panel that
17 advises on a set of studies that we fund.
18 This is a complex area. It's interesting
19 that it's in the Affordable Care Act and crucially
20 important that it's in there and that we attend to
21 it. It's an area that I think we could all use
22 some education on, what the issues are from the

1 rare diseases community, and we actually have a
2 meeting scheduled in very early June with several
3 organizations representing the rare disease
4 community to begin thinking about what a charter
5 for a rare diseases advisory panel would look like.
6 And we'll be in contact with you on that.
7 Provide support and resources to help
8 patient and consumer representatives effectively
9 participate on the Board and advisory panels, and
10 I'll add and review panels. We have a lot to point
11 to there and I've already mentioned the mentor
12 training programs to support those on the Merit
13 Reviews, the training RFP is now out to establish a
14 body of training activities, also, I think the
15 engagement awards provide additional support.
16 And then the Methodology Standards, which
17 are out and that's green and the translation table
18 which we'll hear a little bit more about this
19 afternoon, I think, which is well underway and in
20 progress or our response to that mandate for a
21 translation table.
22 And lastly, this an interesting one that

1 we are going to be working on in the next several
2 months. The legislations says the Institute shall
3 insure that there's a process for peer review of
4 primary research and provide for a public comment
5 period of 45 to 60 days prior to the adoption.
6 This language, it's difficult to grasp exactly what
7 it means, but because we will have primary research
8 coming to the point where it needs peer review in
9 the not-too-distant future. This is another task
10 that we will undertake during this interval between
11 this and the next board meeting, just to figure it
12 out first of all and then to develop a plan.
13 And then the last two on here, not later
14 than 90 days after the conduct of research make
15 these research findings available to clinicians,
16 patients, and the public. This requirement is
17 incorporated into all of our contracts. We'll do
18 it via the website and also in collaboration with
19 relevant organizations. We are mandated to submit
20 an annual report to Congress. The first one, two
21 of them have already gone in -- the one for 2010,
22 the one for 2011 and the annual report that covers

1 the activities for 2012 a draft is circulating now
2 and that will be ready for submission soon.
3 And then I think in the area of disclosing
4 conflicts of interest, we have a well-developed
5 PCORI conflict of interest policy with disclosures
6 of our Board, Methodology Committee, staff, and our
7 advisory panels on our website.
8 So, that's the summary Gene of our read of
9 the legislation and particularly the critical
10 points that we need to work on. The advisory
11 panels and looking at the possibility of
12 contracting more of our research with NIH, AHRQ and
13 other entities.
14 CHAIRMAN WASHINGTON: That's great.
15 Comments?
16 VICE CHAIRMAN LIPSTEIN: This is Steve
17 Lipstein. I requested this review and I wanted to
18 put this in a larger context because from a person
19 who does what I do for a living, you get to observe
20 a variety of aspects of the Affordable Care Act,
21 the law that was passed in 2010 on healthcare
22 reform and passing the law was difficult, but

1 implementing the law has a degree of difficulty
2 that goes with it, too. And I just wanted to take
3 a moment to reflect back, because as Leah as we're
4 coming up on the third anniversary of our first
5 date --
6 [Laughter.]
7 VICE CHAIRMAN LIPSTEIN: It's important to
8 recognize that we have done as well or better with
9 our 60 pages of the Affordable Care Act than most
10 everybody else is doing with theirs and I'm not
11 objective, that's not empirical. That's
12 observational. But I think we have done a very
13 good job with our 60 pages. We meaning the Board,
14 the Methodology Committee, especial Dr. Selby and
15 Dr. Beal, and especially all of the staff behind
16 us.
17 If you look at our 60 pages and you go
18 through them and you see what Joe just reported, we
19 have done very, very well. We could do some things
20 better, we could some things differently, but we
21 have done very well and it's not an easy law to
22 implement as I think others are experiencing right

1 now. And Joe, it gives me an opportunity just to
2 remind me how enormously proud I am of you, the
3 staff, the Board and everybody who has been
4 involved in this effort. So thank you Sir.
5 CHAIRMAN WASHINGTON: Okay. We have
6 Kuntz, and then we have Weisman, and --
7 DR. KUNTZ: Hi, yes, Rick Kuntz, Board
8 member.
9 Joe, that's a good presentation. I just
10 wanted to ask a specific question, maybe it's a
11 little bit too detailed, but in some of the
12 mandates we have about assuring methodological
13 rigor like the treatment heterogeneity part. Do we
14 have a hardwired method to review the grants at
15 some level to make sure their graded and checked
16 off on those specific mandates?
17 DR. SELBY: Great question. And I would
18 say that we are working closely with the
19 Methodology Committee on figuring out the various
20 ways in which we can insure the methodology
21 standards do get incorporated into the research we
22 fund. You will be hearing more on this.

1 CHAIRMAN WASHINGTON: Weisman.
2 DR. WEISMAN: Harlan Weisman, member of
3 the Board.
4 Joe, I'll just echo what has been said.
5 It was a really nice presentation. I agree with
6 Steve that a lot has been done. I have two
7 questions.
8 One is, and I made this comment yesterday,
9 but I thought I would make it in the public session
10 as well, is that review and update evidence on a
11 periodic basis as appropriate. It is true that we
12 won't begin producing the results of research until
13 2015 and later because of the nature of the grants
14 we're funding, but we're doing a tremendous amount
15 of work on landscape reviews and understanding the
16 current state and I believe that would be of great
17 value to many out there in terms of what is -- what
18 we currently know, not just from a research
19 perspective, which would tend to show itself in
20 publications and you told me yesterday there was a
21 plan to publish these.
22 But also, perhaps, to the greater

1 community of clinicians, patients, and others who
2 might benefit from knowing about some of that
3 landscape work and what the current state of
4 affairs is. And it's to me a tremendous
5 opportunity to begin testing our abilities to
6 disseminate and test update in a way that's rather
7 straightforward and easy if we went through the
8 process at looking at those reviews, what we've
9 learned and disseminating it. That was number one.
10 That was a comment, not a question.
11 And number two, is more of a question.
12 And that is on the training of consumer
13 representatives effectively participating on the
14 Board. I think I've learned more from our consumer
15 representatives than they have learned from me.
16 But in terms of expert panels and others, you
17 mentioned the training programs and that we're
18 doing them and certainly that's a green because we
19 are doing them. We put a great deal of effort on
20 it. But can you give us a comment of the
21 effectiveness of the training and how we've
22 measured that effectiveness of the training of the

1 various patients and consumer representatives who
2 are participating in our external activities.
3 DR. SELBY: Well, first of all I agree
4 with your comment about the importance about
5 disseminating our landscape reviews through
6 publications. And I think I'll need to get back to
7 you on the -- I know that there are evaluation
8 activities going on in association with aspects of
9 this training, but I'm not really prepared to give
10 you details at this point.
11 CHAIRMAN WASHINGTON: Before we move to
12 the next section, I would like to take this
13 opportunity to recognize one of our colleagues who
14 is going to be leaving the Board. This is Dr.
15 Carolyn Clancy. A dear colleague that I've known
16 for many, many years and I have just been thrilled
17 at you're level of engagement and participation as
18 you've done over the couple of decades or so that
19 I've known you. You brought your vision and you
20 were quite generous with your leadership and your
21 contributions have been many and significant.
22 So on behalf of all in the PCORI family,

1 all of our staff, the Methodology Committee members
2 and the Board members I would like to present you
3 with this token of appreciation and public
4 acknowledgment --
5 [Applause.]
6 CHAIRMAN WASHINGTON: Wait, wait, before
7 you say anything, we have a couple of more
8 individuals. Our Vice Chair is going to make a
9 comment and our Executive Director.
10 VICE CHAIRMAN LIPSTEIN: Carolyn, one of
11 the true pleasures of serving on this Board is
12 being able to serve with you and over these past
13 three years I must say that of all the people I've
14 e-mailed in the administration, you were the one
15 that e-mailed me back the most faithfully. So we
16 would not be where we are today without your
17 support, your encouragement, and beyond that what
18 the Agency for Heatlthcare Research and Quality is
19 today. It is in no small part because of you. So
20 thank you very, very much for everything you've
21 done for us.
22 [Applause.]

1 DR. SELBY: Yes, Gene already said the
2 word that really I wanted to feature and that was
3 generosity. I think you have been and I'm speaking
4 personally now, you have been generous with your
5 time and sharing your wisdom and your savvy and
6 that coupled with your humor and the incisiveness
7 with which you make comments always keeps me on the
8 edge of my seat when you're card goes up.
9 SO I really want to say a personal thank
10 you. I also want to echo Steve's comment that as
11 I've been here in D.C. I've gotten to know the
12 Agency for Healthcare Research and Quality from a
13 different perspective and come to admire it even
14 more than I did as awardee, an aspiring awardee and
15 recognize, too, how much of it is your investment.
16 Thanks.
17 [Applause.]
18 DR. CLANCY: Well, thank you immensely. I
19 will open these at the break. I know that they are
20 federally approved and within limits and so-forth.
21 [Laughter.]
22 DR. CLANCY: But it really has been a

1 privilege. There's a lot, a lot of moving parts
2 and exciting opportunity and I'm certainly going to
3 miss the frequent interactions with all of you, but
4 I am quite confident that I will be very much
5 working in this field, particularly for the impact
6 on patient care. That is a huge deal. I think
7 PCORI has elevated the conversation, building on
8 other's efforts to engage patients throughout the
9 research process and I think that is going to be
10 paid in dividends for over time.
11 So, thanks very much. And Joe, I'll try
12 not to be quite so incisive.
13 DR. SELBY: Being incisive is good.
14 Okay.
15 CHAIRMAN WASHINGTON: Strategic Plan.
16 DR. SELBY: Okay, staying on -- actually,
17 we have just a bit more before we jump into
18 Strategic Plan. Some extraordinarily good news,
19 especially from the perspective of Dr. Anne Beal
20 and Dr. Joe Selby and that is the arrival of two
21 key players in PCORI's plans and PCORI's future.
22 And I want to start by introducing Dr.

1 Bryan Luce. Bryan -- just arrived. Bryan is our
2 new Chief Science Officer and he actually joins us
3 on May 15th. He comes from most immediately from
4 United BioSource where he's been since 2004.
5 United BioSource, he's been Senior Vice President
6 for Science and Policy. And over this time he's
7 really followed and contributed to the development
8 of the thinking behind comparative effectiveness
9 research, the methods related to comparative
10 effectiveness research, patient-centered outcomes
11 research. He's a real thought leader and has
12 been -- I knew that even when I was in California,
13 that Bryan was really right in the thick of things
14 thinking -- doing the early thinking on this.
15 Before, Bryan also brings experience from
16 MEDTAP International, a research firm that he
17 founded. Prior to that he was Director of
18 Battelle's Centers for Public Health Research and
19 Evaluation. He spent some time as Director of the
20 Office of Research and Demonstrations at CMS.
21 Perhaps when it was called HCFA, I'm not sure which
22 -- it was HCFA at that time.

1 And as a Senior Analyst at the Office of
2 Technology Assessment and before that Bryan was a
3 Special Forces officers and Lieutenant Colonel, now
4 retired from the Army.
5 He has a PhD in Health Services Research
6 from UCLA and we are all very excited to welcome
7 Bryan, in what's now well under two weeks.
8 And sitting right beside Bryan and no less
9 exciting an addition to the PCORI family is Regina
10 Yan. So Regina has been leading organizations for
11 more than 20 years, specializing in financial
12 management, grants and contracts management,
13 program implementation, fund development with a
14 number of leading -- particularly international
15 organizations.
16 First she spent time with the National
17 Academies of Science at the Institute of Medicine,
18 but then she was with the International Research
19 and Exchanges Board, IREX. Then she spent about
20 seven years with the EURASIA Foundation, which is
21 an organization a good deal like PCORI, in fact,
22 federally funded to give out grants. Except that

1 she gives them out or EURASIA gave them out in
2 Eastern Europe and Central Asia. That meant that
3 she oversaw many millions of dollars' worth of
4 research across something like 22 countries.
5 Countries that many of us are not all t5hat
6 familiar with. She was Executive Vice President at
7 EURASIA Foundation, before that she was Vice
8 President and COO, and before that Vice President
9 for Finance Administration.
10 So, Regina has actually been on the job
11 for a week. So I think when you take a former
12 Special Ops officer and a woman who spent the last
13 20 years traveling around Eastern Europe and
14 Central Asia, and you throw them in with two
15 country docs, Anne Beal and Joe, you've got a
16 pretty interesting mix and we can't wait.
17 I want to take a photo the first day all
18 four of us are on the job together. But I want to
19 say now, just a heartfelt welcome to you both and I
20 look forward to you getting to know the Board and
21 Methodology Committee.
22 And one might ask why we're hiring a Chief

1 Operating Officer since we have such an excellent
2 Chief Operating Officer, so this has been known for
3 some time, but now Dr. Anne Beal, who was the
4 organization's first COO and did an extraordinary
5 job in that role, is able to really move to the
6 position of Chief Officer for Engagement along with
7 being Deputy Executive Director, and Anne does an
8 extraordinary job at whatever she puts her mind to,
9 but I think we all feel, and I think Anne feels
10 that this is a particularly good fit for her skill
11 set, background, interests, so we will continue to
12 be the most engaged research institute around under
13 Anne's leadership.
14 So, that's the executive team and their
15 roles. Bryan will have full responsibility for
16 overseeing PCORI's five scientific research
17 programs as well as our engagement research team,
18 and Anne will oversee all of our engagement
19 activities and our substantial PCORI engagement
20 team, and Regina will oversee contracts, human
21 resources, IT, finance, as well as our meetings and
22 special events teams. So, that's the line up on

1 the executive team.

2 And then I also want to acknowledge that

3 we continue growing, and these are six folks who've

4 joined us since our last Board meeting and I know

5 that at least two are in the audience, so I'll ask

6 Adaeze Akamigbo to just stand so people can get to

7 know you. Adaeze is a scientist, a program

8 officer, Senior Program Officer, in our Addressing

9 Disparities program.

10 And Suzanne Schrandt, Suzanne? So,

11 Suzanne comes to us from Kansas. Now, we didn't

12 find her when we were in Wichita, she might have

13 helped steer us to Wichita, in fact, but Suzanne is

14 the Deputy Director for Patient Engagement working

15 under Sue Sheridan.

16 And I don't think that Kelly, Victoria,

17 Rochelle, or Kisha are here, but they certainly

18 have joined us, as have Sandi Myers and Katrina

19 Wilkins.

20 Just want to show you our current staff,

21 and it puts a little bit of a tint or cast on my

22 previous comments about growth. We are heading

1 toward 90 staff, that was what we had budgeted for
2 this year. We have the feeling there that 90 is --
3 if we continue to take on this full portfolio of
4 $350 million worth of research and growing, that
5 this may not be enough, but we are at 73 staff.
6 The bulk of them are in science, that's the 24, but
7 you see substantial numbers in engagement,
8 communications, contracts, finance, and then
9 smaller in the executive, HR, and IT, and meetings.
10 So, that's it for the update, Gene. Do you
11 want to take any more questions before we go on --
12 see if there are any questions before we go onto
13 Strategic Planning?
14 CHAIRMAN WASHINGTON: No, I think we're
15 ready to go on.
16 DR. SELBY: Okay, so, we spoke at length
17 in our February Board meeting about the Strategic
18 Plan, which we've -- with your input we've
19 continued to develop, talked about it a couple
20 times with you in between. Under Michele Orza's
21 leadership, we have engaged the entire PCORI staff.
22 We've talked with the MC as well, and what we're

1 presenting today represents pretty much the next
2 plateau, if you will, in the strategic plan. We
3 feel that this gives us everything we need to move
4 forward, and I want to walk through it with you and
5 see if there are questions, comments, suggestions,
6 and then talk about next steps.
7 So, I wanted to recap it. I'm going to
8 focus particularly on what the Strategic Plan tells
9 us about -- what it points to in terms of critical
10 activities for 2013, what we call the Priority
11 Activities. Sometimes we call these the big rocks.
12 I want to also review plans for monitoring
13 our progress, so this is crucial both --
14 particularly because it in fact is the
15 quintessential Board activity, to monitor according
16 to an agreed upon set of metrics and milestones, to
17 monitor how the staff and the Institute is
18 measuring up to what we planned and promised. And
19 then I want to have some closing comments related
20 to a particularly important strategy, which is our
21 research portfolio.
22 So, this is just a picture of what's going

1 to be expected of us and how we will do it over the
2 next seven years. So, on top, we have our sights
3 set on how we will be evaluated. It's a very wise
4 idea to set your Strategic Plan to how you'll be
5 evaluated, so we get annual financial audits that
6 are submitted to the GAO. We will have a full
7 audit of our processes, procedures, and activities
8 by the GAO beginning at some point in 2014 and
9 delivered in, likely, 2015.
10 Then an eight-year review in 2017 and then
11 the second every five-year review about 2020.
12 We're talking, and you've seen this slide
13 before, we're talking now about the period, we're
14 in 2013, where we are building and implementing,
15 but that will progress over time to where we begin
16 seeing results, and those results ultimately will
17 start manifesting as impact, and these words will
18 become clear to you as I proceed through the next
19 slides.
20 So, again, this is our Strategic Plan, and
21 our Strategic Plan is supported by five pillars or
22 imperatives -- engagement, methods, funding

1 research, dissemination, and infrastructure.
2 So, this is the latest iteration of a
3 picture that pretty much shows the full Strategic
4 Plan. We begin with a set of values that we've
5 agreed upon; patient-centeredness, the usability or
6 usefulness of the research, transparency in
7 everything we do, inclusiveness, which we mentioned
8 a little while ago but which means that we consider
9 the entire community of patients, the entire
10 population of patients, in all of our research and
11 look for differences within that community, and the
12 central importance of rigorous evidence.
13 The strategic imperatives, we've already
14 mentioned and I'm not going to go into them
15 anymore, but those are engagement and methods and
16 research.
17 In the middle column are the activities
18 which we have deemed from the Strategic Plan to be
19 critical in 2013, and a subsequent slide will blow
20 those up so that you can see them. But these are -
21 - by and large, these are -- many of these are
22 foundational activities, activities that have got

1 to be put into place for the Strategic Plan to have
2 a chance of leading to our goals. So, as I said,
3 I'll show you these in moment.
4 We've previously presented our goals and
5 agreed upon them, and those are to increase the
6 availability of usable information, to speed the
7 implementation of that information into patient and
8 clinician practice, and to influence the way that
9 others do research to make it more patient-
10 centered. And those are in support of our mission
11 and vision, which we've gone over with you numerous
12 times.
13 CHAIRMAN WASHINGTON: Joe, could you pause
14 there for just a minute? Give those who are seeing
15 it for the first time and the public just a chance
16 to absorb it. And I would emphasize for the Board,
17 beyond looking at the entire framework of this and
18 making the connections, the central column is going
19 to be key because that's eventually what we're
20 going to be looking at in terms of red dots, green
21 dots, yellow dots, to see whether or not we are, in
22 fact, making progress. But we're only making

1 progress to the degree, even if they're all green
2 lights, that we think that they are aligned with
3 what we really want to do in terms of our goal
4 longer-term, but the focus for the next year is
5 going to be in these boxes that you see right in
6 the center. And so I think it's a very important
7 presentation, but also a very important point
8 that's being made here.
9 DR. KUNTZ: Sorry to interrupt, just a
10 quick clarification. This isn't in the slide deck
11 and the slide, unfortunately, is over-scanned.
12 What are the -- titles of the columns are? Because
13 I think it's a really important slide.
14 DR. SELBY: Oh, okay, so the titles of the
15 columns, Rick, are from left to right, "Our
16 Values", PCORI's values, "Our Strategic
17 Imperatives", "2013 Priority Activities", "Our
18 Goals", our overarching strategic goals, and "Our
19 Mission".
20 CHAIRMAN WASHINGTON: It's not showing up
21 on yours?
22 DR. KUNTZ: It's over-scanned

1 DR. SELBY: It's funny because it looks
2 great on the other --
3 [Off microphone discussion.]
4 DR. SELBY: If somebody from AV, perhaps,
5 could give us a hand at fixing these two screens.
6 DR. WEISMAN: I really like it, but one
7 suggestion, which I think was done in developing
8 this, that since, to reach our vision and our
9 mission to get to our vision, all these things step
10 in place, we must have a further out roadmap, like
11 these are the things that have to occur to get
12 there, and that might be, I'm not sure if that is
13 in the presentation.
14 For our -- not for our consumption, but
15 maybe since we're showing this to the public, it
16 would help them to see how everything we're doing,
17 beginning with 2013, which is the gray column now,
18 will eventually lead to the green boxes on the
19 right.
20 DR. SELBY: Right. The whole message of
21 this presentation is that there are activities
22 we've got to do in 2013 and then there are

1 activities that we continue to do, and the measures
2 of the success of what we're doing tend to grow and
3 mature over time. And I hope I can convince you
4 that I've covered that by the end of this
5 presentation.
6 So, as Gene said so well, the first thing
7 we have to focus on are what are our priorities for
8 this year. So, to identify that, we kept a focus
9 on our three goals, we applied what we call a logic
10 model, which I'll show you in a minute, we gave the
11 highest priority to, first of all, the mandated
12 activities in the statute, the foundational
13 activities, without which we can't really move
14 forward, like infrastructure and plans, and then
15 certain rate-limiting activities.
16 We considered in concert with the staff we
17 considered the resources that are available to us.
18 No resource is more precious than time these days
19 at PCORI, so time really had to be factored in.
20 We moved some activities from 2013 to
21 2014, '15, or beyond, or maybe even out of
22 consideration, and I think in the appendix of your

1 materials you have a list of things we decided not
2 to do.
3 So, here are the ten building blocks for
4 2013. These are things that we absolutely must do
5 in 2013. The first two at the top are obviously
6 ongoing activities, funding research through broad
7 solicitations, which you are well familiar with,
8 and funding research on targeted topics. So,
9 that's, obviously, our bread and butter, that's our
10 long-term responsibility as well as in 2013.
11 But developing a framework for evaluating
12 our work and establishing the baselines is a
13 critical activity. That's actually, I'm happy to
14 say, well underway on a couple fronts. We have a
15 program evaluation group that is in formation that
16 will include, as well as along with staff members,
17 Board and MC members, and several external members
18 as well, and this work is underway. We're really
19 focusing on supporting the Strategic Plan by
20 building an evaluation that allows us to measure
21 progress in the Strategic Plan and building
22 evaluation that allows us to demonstrate that

1 engaging patients and stakeholders makes research
2 more effective, more disseminateable, more
3 relevant.
4 We are well underway, and I'm moving sort
5 of down the left hand column here, toward
6 establishing programs to build the capacity of
7 patient groups to match patients with researchers,
8 and I point to the engagement awards that I
9 mentioned earlier that will be available beginning
10 in -- the announcement will be out in July of this
11 year, that will bring patients and researchers
12 together and provide funding to get started.
13 We have a match program, which will --
14 it's a challenge grant that is now being reviewed.
15 We'll announce the awardees really shortly and that
16 attempts to build an app or an application or a
17 process to actually match patients with
18 researchers.
19 Some of our training programs will build
20 the capacity of patients and patient organizations
21 and certainly our infrastructure awards, the
22 Patient Powered Research Networks, all play into

1 that.
2 The next one, in fact, is to launch the
3 Patient Powered Research Networks and the Clinical
4 Data Research Networks along with a coordinating
5 center, and that's on target to be completed right
6 at the end of 2013.
7 And the last one in the first column, to
8 launch dissemination and implantation plan to
9 promote our methodology standards, that's underway.
10 We continue to develop it, but a number of
11 activities are underway, one of which will be a
12 workshop associated with Academy Health this year,
13 which will focus specifically on PCORI's
14 methodology standards.
15 Developing a skilled community of patients
16 and stakeholders to participate in our research
17 processes, we have a large body of activities
18 already underway in that area, continue to refine
19 those. I mentioned the dissemination blueprint,
20 and that, it's important to say, is done in
21 collaboration with AHRQ, which also has
22 responsibilities in the area of dissemination under

1 the PCORI trust fund, so that activity is well
2 underway and will come in in 2013.
3 Establishing multi-stakeholder advisory
4 panels and workgroups, we've done a lot of that
5 already. We have these two that really stand out
6 as needing to be addressed this year and, as I've
7 said, we're on our way to doing that -- the
8 Clinical Trials Advisory Panel and a Rare Diseases
9 Advisory Panel.
10 And lastly, and you're going to hear about
11 this later today, implement an active portfolio
12 management process, which enables us to be
13 supportive to our researchers and their stakeholder
14 partners and to actually stay on top of the
15 research we're funding to get the most out of the
16 research we're funding, to recognize opportunities
17 that need -- and findings that need dissemination.
18 So, you'll hear more about that.
19 So, those are our ten building block
20 activities for 2013 and I think it's very fair to
21 say that activities are vigorously underway in each
22 of these.

1 CHAIRMAN WASHINGTON: Joe, could we pause
2 for a minute?
3 DR. SELBY: Yes.
4 CHAIRMAN WASHINGTON: One question I have
5 is, what will be our reporting timetable for
6 monitoring progress? In other words, when will we,
7 as a Board, hear about these -- the progress we've
8 made in these areas toward the goal for the year,
9 in the form, I assume, of red light, green light,
10 yellow light?
11 DR. SELBY: Right. So, I failed to
12 mention this title. It fooled me because it's at
13 the side of the slide, but this, in fact, is -- you
14 could say, this is our dashboard for 2013.
15 CHAIRMAN WASHINGTON: That's how I'm
16 looking at it.
17 DR. SELBY: Yeah, it's our dashboard and
18 you'll see some pictures, cartoons, if you will, of
19 what that dashboard's going to look like, but the
20 metrics, developing the metrics, we'll talk about
21 that some today, but the development of metrics for
22 each of these and for our subsequent measures out

1 through time is actually well underway as well.

2 So, we are working on exactly what metrics

3 we'll use to show you our progress in each of these

4 areas.

5 CHAIRMAN WASHINGTON: Right, but I was

6 asking a slightly different question. So, we've

7 got, let's say, we've got four meetings in a year,

8 which means we've got, you know, four quarters, and

9 in some Boards, you take two or three of these at

10 one meeting, you take two or three at another

11 meeting, you take two or three at another meeting.

12 So, you expect, on a quarterly basis, that you're

13 going to hear from key programmatic areas and

14 certain -- so, give some thought to whether it's

15 ten, you know, each quarter or whether you want to

16 spread them out and lump them in a way that makes

17 sense in terms of evaluation.

18 DR. SELBY: Good. Very good. So, I

19 mentioned our logic model and this is it. It looks

20 something like what you saw in the prior slide that

21 people said they liked, but it introduces a new

22 notion, and that is this notion that we are not

1 going to get to this area. This is where we want
2 to get. We want to increase information, speed
3 implementation, influence the way others do
4 research, toward a vision of better healthcare
5 decisions, improved outcomes, better healthcare,
6 health decisions, and improved outcomes.
7 That is not going to be demonstrable for a
8 while, but in the meantime there are a series of
9 metrics that we can look at and monitor, and those
10 are called outputs and they are the product of our
11 strategic activities and they predict, via a logic
12 model, that we will move toward these three
13 critical goals.
14 So, long term, you can imagine a dashboard
15 that will focus on our goals, and even on their
16 impact. So, in the area of increasing information,
17 we can talk really not only about the proportion of
18 study results, but the number of studies and the
19 proportion of all studies with results that are
20 usable.
21 And usable is a word you're going to be
22 hearing a lot from us in the near future. We're

1 working with folks from other organizations on, in
2 fact, developing a notion of usability of research
3 from the patient's perspective and I think that's a
4 word that means that, in fact, these results do
5 support decision-making, by patients, by their
6 clinicians, so, that's goal number one, in terms of
7 speeding implementation, the number of studies, and
8 the proportion of study results that actually do
9 show signs of implementation within five years.
10 And the third, influence how others are doing
11 research, the proportion of patient-centered
12 outcomes research funding that comes not from PCORI
13 but from other funders.
14 So, those, obviously, are long-term goals.
15 We don't have much to report on them in 2013, but
16 that's -- you can imagine that that's a dashboard
17 that we will eventually look to.
18 We've added a fourth, which we call
19 "Operational Excellence", and that is, we think
20 that in many ways it's critical to measure the
21 performance of the organization itself and I expect
22 that we'll be doing a lot of this in concert with

1 the FAAC.
2 So, that's a fourth goal and a set of
3 metrics that we'll keep our eye on.
4 And then, overall, there is a -- the
5 importance of being able to look qualitatively at
6 activities that we're doing, and so our report will
7 tend to feature activities that we're particularly
8 proud of that look, on their face, even though it's
9 qualitative and not quantitative, like they really
10 are bound to move us toward these goals. So, we
11 see our dashboard as always including this
12 qualitative component of stories and examples as
13 well.
14 CHAIRMAN WASHINGTON: Okay.
15 DR. LEVINE: Sharon Levine, Board member.
16 Before you move on from that slide.
17 DR. SELBY: Yes.
18 DR. LEVINE: The speed implementation, I'm
19 assuming that we've agreed that implementation
20 means incorporated into practice?
21 DR. SELBY: Yes.
22 DR. LEVINE: And it would be helpful, I

1 think, to make that clear because implementation
2 means different things in different venues, and
3 we're measuring impact. We're looking for --
4 DR. SELBY: Right. And sometimes it's
5 patient practice and sometimes it's clinical
6 practice.
7 DR. LEVINE: Exactly. Exactly. Yes. Or
8 public health practice.
9 DR. SELBY: Or public health, yes.
10 CHAIRMAN WASHINGTON: Good point. Gail?
11 MS. HUNT: Gail Hunt, Board member. On
12 that same little box there, on speed
13 implementation, I think we should be sure to
14 recognize that there are perhaps results of studies
15 that are done that we have not done that actually
16 have good results that maybe, for whatever reason,
17 haven't been implemented and that we could be
18 helpful in trying to implement them within the
19 five-year period, so we don't just have to wait for
20 our five-year results to come up.
21 DR. SELBY: Allen?
22 DR. DOUMA: Allen Douma, Board. You were

1 talking a little bit earlier about developing the
2 metrics and we're working on that, and looking at
3 the outputs, just the list that's here, I think
4 you've got a really big challenge because at least
5 the words that are in the outputs are not very
6 quantifiable, and so I presume a first step is to
7 convert those words into quantifiable statements,
8 and then actually develop the metrics for them once
9 you've done that.
10 Could we get a sense on the timeline on
11 that, particularly from the Board's point of view?
12 Our next meeting is in September and then there's
13 only three months left until the end of the
14 dashboard year, and we might run out of time before
15 we get any metrics that we can actually evaluate.
16 DR. SELBY: So, I just participated in a
17 meeting on Friday where I was updated on some work
18 that's going on on developing both the evaluation
19 framework and the metrics, so I think -- and I'm
20 looking over at Michele, but I think that we will
21 basically have that wrapped up by the next Board
22 meeting. So, I think we'll have a lot to say about

1 the specific metrics at the next --
2 DR. DOUMA: At the face-to-face Board
3 meeting?
4 DR. SELBY: At the face-to-face Board
5 meeting.
6 DR. DOUMA: Okay, great. And it might be
7 of value to get some input from us as well with
8 regard do we agree with your -- what you're
9 measuring?
10 DR. SELBY: Absolutely. Yes. I think
11 you've got to -- ultimately you've got to agree
12 that the metrics are the right metrics.
13 DR. DOUMA: So, we'll talk about these
14 along the way?
15 CHAIRMAN WASHINGTON: Clancy and then
16 Becker.
17 DR. CLANCY: Carolyn Clancy, Board member.
18 I had a comment, but also wanted to respond to
19 Gail, so I think I'm going to go there first.
20 The legislation says that for AHRQ's
21 allocation from the PCOR trust fund, we actually do
22 have a mandate to disseminate other research. I

1 think that just reinforces the value of
2 collaboration between AHRQ and PCORI here. And it
3 also, frankly, gets PCORI a little bit out of a box
4 of we have to only count what we've specifically
5 funded because all science builds on what has been
6 done previously.
7 My question, Joe, was about whether you
8 and discussed in this increase information, whether
9 you need a modifier there. I mean, after all, in
10 theory, a big part of where the healthcare system
11 is going is making a shift from volume to value.
12 Frankly, if you gave out the money
13 randomly, we will increase information, so it just
14 feels to me like there's a word missing there. I
15 don't know if it's relevant, if it's valuable, or
16 something along those lines, but my guess is that
17 this has already been debated some internally?
18 DR. SELBY: Yep. That's why I said keep
19 your eye on the word usable, I think, or your ear.
20 Usable is yet to be fully defined, but I think it
21 embodies everything that you would hold dear, in
22 other words, it has to be valuable, and not

1 necessarily because it changes practice. I think
2 we hold out the idea that some research builds
3 toward changing practice, and that's the tricky
4 part, really, is how do you identify research
5 that's genuinely useful but doesn't, by itself,
6 change practice?
7 MR. BECKER: Larry Becker, Board. So,
8 back to speed of implementation, and maybe some
9 people have said this in different ways, but, I
10 mean, five years is a long time from now, so
11 understanding up front what the key levers are that
12 need to be hit in order to actually speed
13 implementation so we can course correct before we
14 get out there and say, gee, that didn't quite work,
15 so that we know that we're doing the right kinds of
16 things up front and trying to figure that out is
17 not a simple task. But getting some understanding
18 of those levers would be critically important.
19 DR. SELBY: Yeah, and that underscores the
20 importance of the dissemination and implementation
21 blueprint, the work we will do with AHRQ. We
22 really do need to have a plan, and I think we see

1 the outlines of it and I think we believe that you
2 can engage with the disseminators at the very
3 beginnings of projects rather than waiting until
4 the end, and I think that's -- you know, we're
5 actually banking on that as being a key strategy
6 for enhancing the chances that our research, when
7 appropriate, will disseminate and get implemented.
8 CHAIRMAN WASHINGTON: Joe, can I emphasize
9 the point that Larry is making in a slightly
10 different way, it's a recurrent theme, that if we
11 take each one of these and we take speed
12 implementation, we've got a statement now that
13 clearly defines what we mean by implementation.
14 What I thought I heard Larry saying, and it's
15 embedded in here though, is that we stripped away
16 everything else out at the end, five years, we have
17 speed implementation, and that's in 2018, and we're
18 here in 2013, so what is the causal chain that
19 results in the speed of implementation? And it
20 doesn't have to be detailed, but here are the big
21 five or six things that need to happen over the
22 next five years, and here's the big one that we're

1 going to take in 2013 or 2014, and here's the big
2 one that we're going to take in -- so that for each
3 one of these, rather than the whole framework, we
4 see what -- at least the key steps or big rocks
5 that need to be, you know, in place in order to
6 feel that we've sped implementation.
7 DR. SELBY: And we actually discussed with
8 the COEC yesterday the dissemination and
9 implementation blueprint. And I think, you know,
10 Anne Beal is leading that effort, I'm confident
11 that it will have those big rocks identified and
12 they will turn up as the outputs that we look at in
13 2014 and '15 to give us some confidence that we're
14 following our plan and we have an indication that
15 we're moving in the right direction and can expect
16 to speed implementation.
17 CHAIRMAN WASHINGTON: Great. Thank you.
18 Harlan?
19 DR. WEISMAN: I wanted to supplement on
20 those two comments that -- and I was thinking about
21 this when you were talking about the scorecard and
22 I don't remember which, or dashboard, and I don't

1 remember which one you were on at the time, that we
2 really are talking about a fundamental change in
3 the way research is done and perhaps even bigger in
4 influence and change in healthcare.
5 And whenever there's change, whether it's
6 small or large, there's natural resistance, and it
7 isn't because of bad intent, it's just human
8 nature, we're talking about changing behaviors, and
9 behaviors can be changed, but they're awfully hard
10 to change, whether it's the way research is
11 conducted, the way we think about research, it's
12 the way medicine or clinical care is practiced,
13 change is involved.
14 And I think we've done a really good job
15 of getting ourselves on board with this, I'd give
16 us probably an A on that, although it took us a
17 while to get there, and I'd probably give us a very
18 low grade on how well we've managed the change that
19 we're trying to have happen in terms of
20 communicating it.
21 And I think one of the things that both
22 Larry and Gene are talking about plays to that idea

1 of really thinking out, not just a communication
2 plan, because communication plan implies telling
3 people what we're doing, and change --
4 communicating change and bringing people on board
5 is far more than telling or even selling, which,
6 and I think we're trying to sell to people who
7 don't necessarily think they need to be sold
8 anything because they're happy or they have another
9 idea of what it ought to look like. We're talking
10 about how do we get people to understand what we
11 understand and embrace what we have embraced.
12 That's a much tougher task, and I don't know how
13 much time we've spent in really thinking about
14 that.
15 You know, what we tend to do is just tell
16 people the same thing over and over again and say,
17 why don't you get it? You know, listen to us, and
18 clearly, that isn't as effective as spending more
19 time on thinking about where they are and how do we
20 bring them to where we are while we're listening to
21 them.
22 DR. SELBY: That's an excellent point. I

1 just wrote down communicate change, and I think
2 that's a good point. I will say that I think we
3 have thought about this a fair amount in the plan
4 and we place a lot of emphasis on demonstrating
5 that change makes a difference through evaluation,
6 so demonstrating that the ways -- demonstrating to
7 researchers, demonstrating to stakeholders that
8 having them involved has made the research
9 different.
10 DR. WEISMAN: The only thing I would tell
11 you is that change and resistance to change has a
12 very emotional aspect, and fighting change or
13 arguing for change along only intellectual,
14 rational, logical grounds, entrenches the other
15 side to fight you back with their facts, and what
16 happened and what transformed, I think, the Board,
17 and members of the Institute, was not just the
18 factual reasons to be doing this, but it captured
19 our hearts as well as our minds. And I think maybe
20 we haven't done a good job in capturing the
21 imagination and the hearts of people, the emotional
22 buy-in that's really important if you're going to

1 get change, because it's a tough thing to do, it's
2 really tough, and you run into resistance, and I
3 think that's what's happened, and I'm worried that
4 we're not taking it -- so, it's not just
5 communication, I said not communicating change, but
6 communication as an aspect of change management.
7 We haven't really thought out all the steps that
8 are necessary to occur, I think, you know, along
9 the lines maybe that Gene was talking about.
10 CHAIRMAN WASHINGTON: Okay. Good point.
11 Douma?
12 DR. DOUMA: Allen Douma, Board.
13 Just to build a little bit on what
14 Harlan's talking about with regard to communication
15 plan. Communication is not just telling and
16 developing a communication plan is the core of what
17 we need to be focusing in on now. And the core of
18 that is to decide what change in people's thoughts
19 and behaviors do we want to occur as a result of
20 our communication plan.
21 And then, it's not until you make those
22 decisions of what the end result is you're trying

1 to achieve before you can actually define a really
2 good communication plan and we talk about it, but I
3 think we need to be more prescriptive and more
4 focused on that aspect of it.
5 CHAIRMAN WASHINGTON: Okay. Please
6 continue Joe.
7 DR. SELBY: Okay. So, I think this is
8 where we were. Just pointing out these six outputs
9 and at our last meeting we discussed outputs and
10 Steve Lipstein suggested that nine was just about
11 too many for anybody to keep an eye on. And we got
12 it down to five at one time, Steve and we had to
13 give in and go back up to six. But it's down at
14 the request of some Board members, actually.
15 So, dissemination and implementation
16 activities is an output and there you have our six
17 and we're going to move onto dashboard that shows
18 them.
19 CHAIRMAN WASHINGTON: Joe, just so you
20 know, there is some literature on the cognitive
21 burden of whether it's five or six or seven or
22 three. Most of the literature show that when you

1 go beyond five you lose doctors, so, keep that in
2 mind.
3 DR. SELBY: How about hospital
4 administrators?
5 [Off microphone discussion.]
6 DR. SELBY: But how hospital
7 administrators?
8 CHAIRMAN WASHINGTON: They're much
9 smarter, so they can handle the six.
10 [Laughter.]
11 DR. SELBY: Again, a very crude rendering
12 here of a dashboard that would draw your attention
13 to the six outputs that we featured on the previous
14 page and we will develop metrics for those, which
15 we'll get into a bit in the slides to come. We
16 preserve this qualitative featured studies portion
17 of the scorecard, the dashboard, and keep
18 operational excellence at least for those of us who
19 want to keep an eye on that.
20 So this is too much to look at, but its
21 intention is down the left hand column are the six
22 outputs and the intention in this slide is to show

1 over time the metrics, and you can begin to see
2 some metrics here, begin to mature for any
3 particular output so that we start with just a
4 number of people trained, but then a number of
5 people involved in PCOR by 2015, we're looking at
6 the number of people involved in PCOR -- not just
7 PCORI work, but PCOR more broadly who receives some
8 PCORI support. And survey result, like the level
9 of interest in PCOR. And I will actually move onto
10 the next slide.
11 The idea here is that as we begin to
12 develop our metrics, we see an evolution of the
13 metrics to capture the point in time that we're in
14 and how we're moving toward our goals.
15 So, here's an example from building a
16 portfolio of patient-centered outcomes research
17 studies. In the early implementation phase, early
18 in 2014, we can look at the number and types of
19 topics that we've targeted. The number of types of
20 studies that we've funded. And also importantly,
21 the bottom one in this column, stakeholder views of
22 the appropriateness. So we do believe that surveys

1 of appropriate stakeholder populations;
2 researchers, patients, patient leaders, clinicians
3 and others, will be a critical part of evaluation.
4 And we aim to get baseline results on that,
5 hopefully in 2013.
6 But as we go on in 2014, for the studies
7 that are funded we begin to look at the usability
8 of those studies. So we established criteria for
9 is this the kind of study that we want to fund.
10 Usability is something in our view you can assess
11 as soon as you've funded a study, you go back and
12 assess it more carefully when the study is done and
13 you've got results. And then overtime we can begin
14 to look at studies that for which results have been
15 implemented.
16 And the same on the bottom, again, this
17 notion we're going to be assessing through surveys,
18 assessing stakeholders views of the quality and
19 utility of the studies that we've completed. And
20 then later on in time, in the lower right hand
21 corner, the proportion of study results that have
22 in fact had an impact on health outcomes.

1 VICE CHAIRMAN LIPSTEIN: Joe, I think this
2 is brilliant. And it's brilliant for a couple of
3 reasons. One is as Board members, I think it's
4 important, you know, there's a lot of detail here,
5 but as Board members I think we want to know that
6 you've thought about how the metrics will mature
7 over time. That's very creative and it gives us a
8 sense of direction. That's number one.
9 Number two is, it also helps us dispel the
10 notion that research is an instantaneous kind of a
11 thing. So we can't fix problems through research
12 in immediate time. Because this lays out how it
13 really works, so I think this is a great tool to
14 show how the metrics and the deliverables will
15 mature over time and is very reassuring.
16 DR. SELBY: Okay. So, again, here's --
17 CHAIRMAN WASHINGTON: Harlan has a
18 comment.
19 DR. WEISMAN: I like it, too. But to me,
20 I know we're calling it portfolio management and I
21 don't want to get, you know, slice on words too
22 much.

1 This is more to me like program management
2 or project management of our portfolio. But
3 portfolio management, to me, is the strategic
4 aspect of what you're doing based on what your
5 strategic goals are. So, for example the number of
6 studies that will have results or things that we
7 will have results in the next two years versus five
8 years, you know, short-term versus long-term, new
9 topics versus old topics, or this field versus that
10 field.
11 That to me is a portfolio question in
12 which the Board plays a role with the Institute's
13 staff, whereas project management, program
14 management is something that allows the Institute
15 to manage itself once those strategic choices of a
16 portfolio are made.
17 So I don't want to diminish this, because
18 I think it is extraordinarily important and I'm
19 really glad to see it. It's a very useful way of
20 tracking and measuring what we're doing and
21 reporting what we're doing. But it's not quite the
22 same thing as I think of when I think of a

1 portfolio process, which is a section of choices.
2 DR. SELBY: That's a very useful comment
3 and I think it's one we'll take to heart. I would
4 say that if we do the kind of management that
5 you're speaking of, we have a better chance of
6 getting to that third column. We'll have more
7 useable results, they will be more often
8 implemented, and they'll have more impact if we've
9 done the Portfolio management selectively and
10 thoughtfully, right, we'll have more in a higher
11 proportion, but to articulate that and it isn't
12 easy. Is very helpful.
13 At the end of my presentation you are
14 going to see a couple slides that begin to get at
15 that.
16 CHAIRMAN WASHINGTON: Okay. Douma.
17 DR. DOUMA: Allen Douma, board. Just
18 quick. Just to reinforce what Harlan was saying,
19 there is that difference and I think it's an
20 important difference. It would be interesting,
21 although it's a thought process obviously. It
22 would be interesting for all of us to weigh in at

1 some point on what proportion of studies being on
2 track do we think would be successful. And first
3 of all we need to figure out what usability means,
4 and once we've done that is our assessment of what
5 percentage of studies end up with usability or
6 useful information.
7 Just to get what our expectations are for
8 ourselves, so that when we get out two or three
9 years then we hit or we don't hit whatever we
10 decided, at least we'll be forewarned.
11 A little minor thing. On this slide and
12 the next slide, 2016 is missing. I'm not sure why,
13 but it may show to people on the outside world that
14 we've got something planned in 201y6 and we're not
15 telling.
16 [Laughter.]
17 DR. SELBY: I'll take full responsibility
18 for that. It used to say 2013, 2015, and 2017,
19 which wouldn't have bothered anybody then they
20 would have seen we're just trying to spread things
21 out. And I said no, this is really -- we're
22 talking 2014 here for this and I messed it up. So,

1 we'll think of a way to fix it so we don't raise
2 that question whether we're taking 2016 off.
3 Okay, so a little closer look now. This
4 is our early implementation dashboard, a preview of
5 it. And you'll appreciate that in 2014 we're going
6 to be focused mostly on outputs and here are some
7 beginnings of some proposed metrics, or at least
8 the sources of metrics in 2014. So again, don't
9 let the arrows at the top, the dates distract you.
10 This entire dashboard is the 2014 dashboard, so
11 you'll see it's mostly numbers and types of topics
12 and numbers of standards developed, numbers of
13 PPRNs and CDRNs funded. Still pretty numerical
14 early counts. But I don't want to suggest that
15 we've done all of our thinking about the metrics
16 for even this early implementation dashboard.
17 Harlan?
18 DR. KRUMHOLZ: [Off microphone.]
19 MS. GOERTZ: Harlan, can you turn your mic
20 on?
21 DR. KRUMHOLZ: Oh, sorry. Harlan
22 Krumholz, from the Board. I was just saying John

1 Eisenberg liked to do this, where he sort of almost
2 simulated, say okay today the results came in.
3 What's going to happen? How are things going to be
4 different? How will it be received? What are we
5 doing about it?
6 And I always remember at least in a
7 session I was with John that he did that, that was
8 so powerful. And these kinds of simulations I
9 think you're able to do with the funding. Say okay
10 -- just with the team. Because you've laid this
11 out now, you're basically saying okay, look at the
12 best case scenario. It's the strongest possible
13 result that you would have expected given the
14 design in the study, now what's going to happen?
15 And it just would -- I think would be
16 helpful as an exercise, both for us and for your
17 team.
18 DR. CLANCY: So just to a word to the
19 wise. Harlan was the only person who aced this
20 particular exercise.
21 [Laughter.]
22 DR. CLANCY: Other people were very, very

1 uncomfortable as I recall. But, I do remember --
2 CHAIRMAN WASHINGTON: Zwolak, please. And
3 would you each use your microphone? This is being
4 recorded in addition to people wanting to hear it
5 more clearly.
6 DR. ZWOLAK: Bob Zwolak, Board member.
7 Using my mic.
8 This is spectacular. I think it's just
9 wonderful. And I'm wondering as we go along,
10 necessarily have these in boxes, but for instance
11 as PCOR methods involved, are we going to determine
12 how our research portfolio incorporates the PCOR
13 methods and likewise as we develop the data
14 networks, how are they doing to crosslink with the
15 research portfolio? Is the research portfolio
16 going to take advantage of the data networks and
17 the PCOR methods and the skilled PCOR community?
18 DR. SELBY: Good thought.
19 CHAIRMAN WASHINGTON: And Joe, when I'm
20 sitting here thinking, at the level of the Board
21 and I go back to quarterly reports to whenever
22 you're going to report on progress. We're not

1 going to want this kind of detail at every Board
2 meeting. You and Michele, and the group, you need
3 to step back and think, okay. What will the
4 dashboard really look like when we're reporting to
5 the Board? Behind which we will know there's more
6 detail and if we want more detail, then we can
7 drill down to it, but it's a higher level reporting
8 that we're going to want at the level of each one
9 of these goals as well as with each one of our
10 imperatives and as it relates to our working
11 activities.
12 DR. SELBY: Yeah, that notion of being
13 able to drill down is, I hear that word a lot these
14 days in our discussions. They show me a picture
15 and they say, and yes, you can drill down.
16 CHAIRMAN WASHINGTON: Okay.
17 DR. SELBY: And so, the big question is
18 what's on the front? What's at the top?
19 CHAIRMAN WASHINGTON: Right. That's
20 exactly right.
21 DR. SELBY: What do you look at and then,
22 those of you who like to drill down will most

1 certainly be able to.
2 And, again, I'm just going to move quickly
3 through this. This is the next year when we're
4 toward full implementation and these are beginning
5 to mature now. You've seen some of the, for
6 example, in the research portfolio the proportion
7 of studies that are on track, the proportion of
8 studies that by our measure look like they will be
9 usable to decision-makers, and for completed
10 studies, the quality and degree of uptake. And
11 that's really is measured through surveys, again.
12 And in each one of these, the metrics are
13 changing as we go through time.
14 So here's 2017 and so here, for example,
15 is a metric. The proportion of PCOR studies that
16 adhere to our methodology standards, the usability
17 of results from those studies, that adhere to the
18 standards. Again, we have metrics in each one of
19 the output areas, but they are now much further
20 along and they are actually moving towards our
21 goals.
22 CHAIRMAN WASHINGTON: Hunt.

1 MS. HUNT: Gail Hunt, Board.
2 Joe, when you talk about surveys, I think
3 of surveys of being very broad, like we're going to
4 survey physicians to see if they understand PCORI
5 or they know more about PCORI or whatever. Are we
6 also planning on more intense surveying of people,
7 patients and caregivers a primary care docs, who
8 are the focus of implementation? So actually
9 finding out whether there's been implementation of
10 a specific project that has great results and going
11 and looking and seeing how that's worked in
12 whatever the area is?
13 DR. SELBY: Well, I think we have to
14 choose our survey respondent populations very
15 thoughtfully. We're going to want some that we
16 think are worth measuring over time. You know,
17 just broadly, so get a baseline and see if we're
18 moving it. But then as we begin to have specific
19 results, I agree with you there that it may well be
20 that if we've made a big investment and have some
21 results that we think impactful in a particular
22 community, then we would, you know, add in a later

1 year a targeted evaluation of that or we could.
2 CHAIRMAN WASHINGTON: Okay, Clancy.
3 DR. CLANCY: So, just a quickie, because
4 you know, the fact that you don't have the
5 Paperwork Reduction Act to deal with is just so
6 spectacular. You can also build on other people's
7 surveys. So Gallup and you name the pollster, will
8 let you buy space to put in one or two questions,
9 which is another way to go about it.
10 For us, whether it's a 100 questions or
11 one single item, there's a whole process. But you
12 don't actually have to deal with that.
13 CHAIRMAN WASHINGTON: Okay.
14 DR. SELBY: Good. So here's a picture.
15 Those who are really working on the metrics and the
16 dashboards have no bounds on their imagination. So
17 this is a proposed, Gene, perhaps a top level --
18 perhaps, this would be the set of metrics that the
19 Board said, you know, we want to keep our eye on
20 most closely. Perhaps not, but it's just for
21 example under Skilled PCOR Community. The number
22 of stakeholders that were trained.

1 This is an early, this is a very early
2 implementation phase. So we're looking at counts,
3 so the numbers of stakeholders that we've trained
4 and the methods in the Methods category. It's the
5 number of number of PCOR methods projects we've
6 funded and what they're focused on.
7 These actually look like the methods for
8 all of our research, not just the Methodology
9 awards.
10 MR. BECKER: Just as long as we're
11 imagining and dreaming, Larry Becker, Board.
12 And I can't read it exactly, so I'm going
13 to turn around here. So in the upper right hand
14 corner, you talk about funded, total funded, number
15 of projects, employees and staff. As long as we're
16 imagining, I wonder if we could imagine a fifth
17 line that said customer satisfaction? In other
18 words, what do our customers say about our outputs
19 and where do we stand?
20 DR. SELBY: That's very good. I think we
21 really do see that, you know, what the research
22 community is saying about, what the patient and

1 clinician communities is saying about is very
2 important, but when you say customers you may mean
3 our awardees in particular?
4 MR. BECKER: I think it could be a whole
5 series of people and I think we need to define who
6 our customer is and once we do that, keeping track
7 of them, because at the end of the day in 2017,
8 '18, '19, someone's going to make a decision about
9 whether it ends. So the customers will decide out
10 fate.
11 DR. SELBY: Very good.
12 MR. BECKER: Thanks.
13 DR. SELBY: So this slide just makes the
14 point that our dashboard will evolve over time.
15 That in 2013 you'll see a dashboard that really
16 looks like those really big rocks that I showed you
17 a while back. 2014, we'll begin having a dashboard
18 that is really focused on outputs and operational
19 excellence. And as we move through time, the
20 dashboard begins to focus a little bit less on the
21 outputs and more on our goals and ultimately on the
22 impact it will have.

1 So, as I said the development process for
2 these metrics is well underway and I can say with
3 confidence that we will have sets of metrics to
4 show to you and to discuss with you and get your
5 input on as we go through the next several months
6 and I think a mock dashboard with the detail of the
7 actual metrics we're proposing is not at all out of
8 the question for the September Board meeting.
9 So, this is just a closing word on the
10 Strategic Plan, per se, and how it might be used.
11 So, this proposes a quarterly dashboard. Gene, I
12 think your thought that the quarterly dashboard
13 might -- we really might accompany that with a
14 discussion of one or two items per quarter is a
15 good idea. But we start with the review of the
16 previous year. That will be the fourth quarter's
17 dashboard and an annual report. We go through the
18 mid-year and then around the time the third
19 quarter's dashboard is available to look -- we
20 begin proposing the budget for 2014, or for the
21 following year. So this applies to any particular
22 year and with the dashboard in mind, the budget is

1 arranged according to the imperatives and the
2 activities, and we also have a time when we set the
3 specific milestones that we think we should hit for
4 the coming year even as we approve the budget for
5 that year.
6 So that's our vision of how the dashboard
7 would be integrated into Board activities and used
8 to guide, particularly, the budget development
9 process and the annual reporting at the end of the
10 year.
11 CHAIRMAN WASHINGTON: That's great Joe.
12 We have a couple of comments or questions. So I'll
13 start with Hole-Curry and the Gabriel, and then
14 Norquist.
15 MS. HOLE-CURRY: Leah Hole-Curry, Board
16 member. Just a quick clarification around the
17 potential for highlighting a few. We would still
18 get the dashboard report on all -- each quarter,
19 correct? On all measures? And then you would --
20 the reporting would be to highlight a few each
21 quarter?
22 DR. SELBY: Yeah.

1 MS. HOLE-CURRY: But we wouldn't see it
2 for a whole year?
3 DR. SELBY: Absolutely.
4 MS. HOLE-CURRY: Okay, that makes sense to
5 me. Thanks.
6 CHAIRMAN WASHINGTON: Gabriel.
7 DR. GABRIEL: Sherine Gabriel, Methodology
8 Committee. So the dashboard's really helpful but
9 when I look at the dashboard I still see boxes that
10 say Methodology Committee, boxes that say other
11 stuff, other activities of the PCORI. And one of
12 the challenges we've had is how best to integrate
13 our work. So how can the work of the Methodology
14 Committee really be integrated and advance some of
15 the key strategies of PCORI, rather than simply,
16 you know, counting new standard or counting how the
17 standards have been adopted?
18 So, I'm just wondering how those more
19 integrative goals are going to be advanced, since
20 you know, it's something that we've struggled with,
21 I think since day one.
22 DR. SELBY: We have a just a little bit of

1 a structural issue here that we've named as one of
2 the outputs, PCOR Methods. That is clearly not in
3 our minds meant to suggest that's where Methodology
4 Committee activities go. In other words, if we
5 don't have Methodology Committee contributions to
6 building our research portfolio, we're making sure
7 it follows methodology standards, then it's much
8 less likely that it's going to be impactful. And
9 so, the methodology is there. The CDRNs and the
10 PPRNs, the Methodology Committee, I think, has a
11 lot to contribute to thinking about the
12 infrastructure that we're building. The
13 evaluations we certainly hope there's substantial
14 Methodology Committee representation in our
15 evaluation group. And similarly, and we already
16 know there's substantial Methodology Committee
17 involvement, so I see Methodology Committee
18 integrated with us in every one of these outputs.
19 And, in fact, methods there is really
20 focused on kind of what we funded rather than what
21 the Methodology Committee did. So I think, that
22 just says the Methodology Committee is just hand-

1 in-hand with the Board and the staff in all of
2 these activities.
3 CHAIRMAN WASHINGTON: Norquist and the
4 Douma.
5 DR. NORQUIST: Gray Norquist, member of
6 the Board. I have two issues. One, it's fine. I
7 think one of the things that worries me this
8 allusion earlier about our cognitive abilities,
9 that you get so many boxes -- so much stuff here
10 that, you know, we have some beautiful trees, we
11 miss the fact that the forest doesn't look very
12 good or something. So, somehow we've got to be
13 able to scale back up because we can get so focused
14 on the details, we miss the big picture and then we
15 have nothing.
16 The other thing I would say, in looking at
17 all of this. I always thing, because I've shown
18 some of our stuff to a people in my office and they
19 look at it and they go: "What? I don't understand
20 it." And part of the criticism we had about our
21 communication and what we'll talk about tomorrow is
22 some of what we do makes perfect sense to us, we've

1 been at it but if you're the average person on the
2 outside trying to understand this, I don't even
3 know where the fuel gauge is. You know, what I
4 mean? It's like are we running on empty? The car
5 is going to run off the road because I don't -- I
6 think people will get this on some level, but it's
7 too much. So I think another aspect here is to
8 think about how communicate this to our consumers,
9 if you will, so they really understand it quickly.
10 They're not going to go through all of these
11 things.
12 So that's a task for our Communications
13 group to really think about how to present this
14 kind of information outside of, excuse me, a wonky
15 group, so to speak. Okay?
16 DR. SELBY: Yeah, I think we can clearly
17 work out with the Board what level of information,
18 what quantity of information, the number of
19 different metrics they want to see. But I do think
20 that as soon as they see a metric that is not
21 exactly where they wanted it to be. They're going
22 to want much more detail. You're going to want

1 much more detail to begin to understand it, so,
2 what's on the top, what we look at as an initial
3 screen is absolutely crucial and we'll have to work
4 that out.
5 DR. NORQUIST: Yeah, I think that's an
6 issue of thinking who your audience is. You
7 carried all of this stuff -- let's just say some on
8 the Hill or something, they would be like, "Oh no,
9 give me what the one or two things are and let's
10 make it very quick and easy." You know what I
11 mean?
12 It's just tailor this to the audience
13 you're going to have -- we may want all of the
14 detail.
15 DR. SELBY: Yes.
16 CHAIRMAN WASHINGTON: Douma.
17 DR. DOUMA: Hi, Allen Douma, Board. Would
18 you go to the last slide?
19 Yeah, that slide. Maybe purely semantics,
20 but maybe not. You're talking about the dashboard
21 all the way through and you get to the end and then
22 you talk about milestones. Is milestones a synonym

1 for dashboard?
2 DR. SELBY: Actually the dashboards had
3 the milestones on them, I think.
4 DR. DOUMA: Milestones are typically part
5 of a dashboard, but not all of the dashboard.
6 DR. SELBY: Yes. And you see in the upper
7 right hand==upper left hand corner, we actually
8 have a placeholder for milestones. So, out of the
9 metrics that are shown here, they're -- you know,
10 some you may not set milestones, but some of them
11 you will and those will be featured there.
12 DR. DOUMA: Well, if you go back to that
13 slide, I would just suggest that it would be better
14 in the last slide, if milestones there -- in this
15 slide, was replaced by dashboard since that's what
16 we're doing. If that's what we mean?
17 Also, question. Could you talk about the
18 decision to review the dashboard all the way
19 through on a Board call versus a face-to-face
20 meeting?
21 DR. SELBY: That's a good question. I
22 have to say, I didn't quite notice that until now

1 and I think probably whether we talk about it on a
2 Board call or not, I think the critical thing would
3 be that we do in fact talk about it in public
4 meetings.
5 DR. DOUMA: Yeah. Okay, thanks.
6 CHAIRMAN WASHINGTON: Okay, Zwolak, sorry.
7 DR. ZWOLAK: Bob Zwolak, Board member.
8 I just wanted to react briefly to Gray's
9 comment. I'm starting to feel good about this
10 basket of measures as a Board member, and so, I
11 want to speak up in appreciation of what you've
12 done.
13 I think that Gray's comment is very
14 important because we have a whole number of
15 different audiences who are not going to want to
16 have the level of detail that we necessarily want
17 to have. So, I think it's a translational issue.
18 Personally, I think this basket of measures is
19 starting to feel pretty good to me.
20 DR. SELBY: I think we have a big basket
21 of measures and we create dashboards that are
22 tailored to the audiences. Exactly, yes. I mean,

1 Regina as the COO is going to want gory details on
2 a very large number of metrics and Bryan is going
3 to want and Anne is going to want and I’m going to
4 want to see a lot of detail and the Board is going
5 to have a certain level that it wants to start
6 with.
7 CHAIRMAN WASHINGTON: Norquist.
8 DR. NORQUIST: And I’ll make sure -- you
9 misunderstood, I’m not saying this wasn’t a good --
10 I said that at the beginning. I’m just saying you
11 have to make sure you tailor it to the different
12 audiences. I don't want us to get stuck in this
13 particular --
14 DR. SELBY: Right. Okay. So, in closing,
15 I want to just say a word and this gets back to
16 Harlan Weisman’s comment about being strategic
17 about the research, your funding. We really do
18 need to maximize our -- I mean, we have a limited
19 amount of funding, maximizing, and a little bit of
20 time -- our research portfolio’s efficiency and
21 ultimately its impact. So, that involves planning
22 beforehand on how do we attract and select the best

1 proposals and a matter of fact what kind of
2 proposals do we solicit? During the funding
3 period, how do we manage and facilitate and support
4 the completion and dissemination of the studies
5 that we fund, and after funding, how do we
6 disseminate and how do we measure and learn from
7 that dissemination and update?
8 So, critically important to manage that
9 portfolio and Harlan really put his finger on
10 several issues that we talked about a lot, but I
11 don't think we've put them into the -- I honestly
12 don't think we've gotten down to quite this level
13 of strategy at which is short term versus longer
14 term. It's complex, there's a lot of tradeoffs,
15 large number of studies in different topics versus
16 smaller number of focus topics. That actually is a
17 topic that we have discussed. So, this final here
18 just shows you our view from the staff level of
19 what's likely to happen over time as we get more
20 and more strategic about managing our portfolio.
21 In 2013, if you add up the funding that we
22 anticipate to getting to the broad announcements,

1 in response to the broad announcements, and the
2 funding we anticipate committing in response to
3 Targeted Funding Announcements plus the
4 infrastructure which I include as a Targeted
5 Funding Announcement, about one-third of our
6 funding is you'd call targeted and two-thirds is
7 broad. But as the number of Targeted Funding
8 Announcements increases in collaboration with our
9 advisory panels, we anticipate that as early as
10 2014, we'll have a portfolio that's about half
11 targeted and half broad and we anticipate that over
12 time, just because of the continued flow of
13 critical ideas, the conviction on the part of the
14 staff and then the Board that these represent
15 crucial areas for PCORI to make investments. I
16 think it's predictable that more than half of our
17 funding will be directed funding and that's
18 certainly the way that we are thinking and it's
19 open for discussion.
20 That's open for discussion and just to say
21 in closing that we're hoping that we will finalize
22 the draft plan, including if you can believe it a

1 written version, so, something beyond the
2 PowerPoint of the strategic plan and we will seek
3 your approval.
4 And Gene raised the point last time of
5 getting public input. This is not something that
6 the statute says we need to get public comment on,
7 but getting public input and I think this speaks to
8 Gray's and earlier comments about making sure that
9 people begin to understand what it is we're trying
10 to do here. Mechanisms for getting public input
11 would be an interesting question to put to the
12 Board. We continue working on our evaluation
13 framework, developing those metrics and creating
14 tailored dashboards for the Board, for the staff,
15 and for others. And then, of course, over time, we
16 will keep revisiting the strategic plan.
17 I think it's fair to say that it's seeped
18 into the way that we think and talk already at the
19 staff level and it's been an extraordinarily useful
20 exercise and will continue to be so for us in
21 conversations with each other and increasingly I
22 think board activities will be around looking at

1 the dashboards, looking at our performance, looking
2 at the milestones, if you will, that is the targets
3 on those metrics and figuring out what we're doing
4 well and what we need to perhaps change or improve.
5 So, with that Gene, yes --
6 CHAIRMAN WASHINGTON: Okay.
7 DR. SELBY: We have a few more minutes for
8 questions and particularly that question about when
9 we get the strategic plan that we're comfortable
10 with and it's a form that can be disseminated or
11 shared, what's the Board's thoughts and advice on
12 getting public input?
13 CHAIRMAN WASHINGTON: Okay, and before I
14 open it up, I would also like to invite all those
15 in attendance as well as those that are listening
16 to us on the telephone there, video, that please
17 send us your thoughts about the best way for us to
18 share this with you and solicit your feedback.
19 I see a few cards up. I'm going to start
20 with Weisman, then Douma, and just work our way
21 around and Hunt.
22 DR. WEISMAN: Joe, I really do like what

1 you all put together. The amount of work and
2 particularly the progress between beginning and end
3 is really remarkable.
4 I want to go back to the earlier comment
5 and you acknowledged it. Our vision when it was
6 stated was really putting 2019 out there because
7 it's a question of whether PCORI continues or not
8 at that point. Obviously, that question could come
9 up any time, but at least that's the end as it's
10 defined in the legislation and I'm wondering in
11 order to achieve that vision, what our expectations
12 are on what our work product will be at that point.
13 So, I think we've defined nicely 2013, 2014, and
14 2015, but it's just getting things underway.
15 So, I really would encourage us to be able
16 to articulate what our work product will be at the
17 end, not in exquisite detail because, of course, we
18 don't know, a lot of things are from solicitations
19 of grants and from advisory groups and so forth,
20 but there must be -- I think the public and the
21 stakeholders in general would very much like to
22 know what they could expect that we could set

1 expectations for where we’re taking things and what
2 it will look like. Like if the only thing we’re
3 saying is oh, there will be a bunch of studies and
4 we won't start getting results until 2015 and we
5 think a lot of them will be useful, that isn't
6 enough for me and I think if we really put that
7 stake in the ground of 2019 and really flesh out
8 what that’s going to look like, what is that
9 information that patients, consumers, caregivers,
10 clinicians will have and payers and other parts of
11 the health care system will have at their disposal
12 as a result of our work, the more we can paint that
13 out for people of what that looks like.
14 Take the current vision which is sort of
15 an impressionist painting and turn it into a
16 realistic painting of that world and how we’re
17 going to get there, including our infrastructure
18 build, our change in the way of helping contribute
19 to health care becoming more patient-centered and
20 then the means by which we’re going to do that. I
21 think that direction will be extraordinarily
22 important for us, but will also help get people

1 onboard with what we're trying to do.
2 CHAIRMAN WASHINGTON: Thank you, Harlan.
3 Allen.
4 DR. DOUMA: Allen Douma, Board.
5 One of your last slides, the pie chart
6 showing movement from more broad funding to
7 targeted funding, my interest in this is because
8 I'm so profoundly ignorant about why we would make
9 those choices. It would be really helpfully and
10 particularly since there's so many smart
11 researchers on the Board itself to have a little
12 more conversation about the why behind the what
13 because I couldn't explain it to somebody at this
14 point why we would make that decision and I'm not
15 questioning the decision at all, just understanding
16 what's behind it.
17 DR. SELBY: Well, I think I can give you a
18 very brief answer. If you solicit the issue broad
19 funding announcements, you get a real bouquet of
20 individual projects, but you don't have a focused
21 body of work on a particular area, you haven't
22 thought about putting several projects together

1 into a portfolio that really aims where you've had
2 stakeholder input, researcher input beforehand
3 saying this is a high-priority topic, these are the
4 studies that need to be done, and if you do these
5 studies, you have a good chance of moving the
6 needle.
7 So, those are the kinds of studies we mean
8 when we say "targeted funding," and we think that,
9 on average, you have a better chance of moving the
10 needle than you do with the broad solicitations
11 which tend to attract high-quality studies, very
12 interesting studies, studies we are extremely proud
13 of, but they are across every condition known to
14 man and prevention, diagnosis, treatment, and it's
15 a little bit more difficult to see your way through
16 to impacting population health with just one study.
17 CHAIRMAN WASHINGTON: Could I say, Allen,
18 that I think most of us consider this to be an open
19 question, so, there will be debate along the way.
20 Joe is laying out a target, so to speak, of what it
21 might look like based on this supposition about
22 potential impact of one approach versus the other.

1 DR. EPSTEIN: [Off microphone.]
2 CHAIRMAN WASHINGTON: Okay, Hunt. Okay,
3 please since we're going this way.
4 That's all right, you keep mike off, Dr.
5 Epstein. Keep your mic off, okay. Go ahead.
6 MS. HOLE-CURRY: Leah Hole-Curry, Board
7 member.
8 I also had a question on this one. I
9 think what would be helpful is to tie this approach
10 back to some of our strategic initiatives and as we
11 evaluate the research to see whether the
12 supposition that the targeted produces better
13 outcomes that we have identified is true before we
14 move to the 2015 target.
15 CHAIRMAN WASHINGTON: Yes.
16 MS. HOLE-CURRY: So, I would support more
17 information before we decide that this is the
18 strategy to get us to the initiatives that are laid
19 out.
20 DR. SELBY: Good point.
21 CHAIRMAN WASHINGTON: Okay.
22 MS. HUNT: Gail Hunt, not a lady on the

1 Board.

2 [Laughter.]

3 CHAIRMAN WASHINGTON: Whoa.

4 MS. HUNT: I agree with Leah, and that was

5 going to be my point that I think for example in

6 the disparities which is a broad area, some of

7 those grants or contracts we're funding are going

8 to be sort of moving into the targeted area. There

9 are not just totally dealing with disparities in

10 general but about specific disease issues around

11 disparities, and so, I think we should have a

12 discussion at 2014 before we move into the let's

13 make a more targeted and less broad.

14 CHAIRMAN WASHINGTON: Okay. Why don't we

15 stay this way and we'll go around it? Levine.

16 DR. LEVINE: Just a tactical question.

17 CHAIRMAN WASHINGTON: Name please.

18 DR. LEVINE: Sorry, Sharon Levine, Board

19 member.

20 A tactical question around the funding we

21 get to award research grants continues through

22 2019?

1 DR. SELBY: Yes.
2 DR. LEVINE: Is that correct?
3 DR. SELBY: Yes.
4 DR. LEVINE: Money is awarded in 2018 for
5 more than a one-year grant. How does that mesh
6 with the date for reauthorization and the fact
7 that, I mean, are we thinking through --
8 DR. SELBY: It's a fabulous question.
9 It's one that's on all of our minds, particularly
10 the folks in finance and the folks on the FAAC.
11 We're actually going to be talking about it
12 tomorrow morning a bit in a committee meeting at
13 seven o'clock. You're invited and my sense is that
14 we're going to come of that meeting with some
15 questions that we need to put to the GAO about that
16 because you can imagine that it's possible that we
17 will get a big influx in mid-2019 and then not be
18 able to spend any after --
19 DR. LEVINE: Because we're building
20 momentum.
21 DR. SELBY: -- the end of September. If
22 that should be the case, we hope it's not for

1 several reasons, but if it should be than that
2 would say fund some long studies early and have
3 their tails go into 2019 so that you actually pay
4 the money out almost as soon as it arrives.
5 DR. LEVINE: Okay, and then just a related
6 question. In terms of both the networks that we're
7 investing in, is there a plan for them to be self-
8 sustaining long-term, a business plan that says --
9 DR. SELBY: Right. I think at this point
10 what the funding announcement says is that there
11 will be a Phase 2, but they are very definitely
12 designed and intended to drive toward
13 sustainability. Sustainability doesn't mean
14 necessarily that you don't need any infrastructure
15 support, but that basically you grow and survive in
16 part by doing the work.
17 And basically I just want to add one
18 thing. That notion of getting all the money in
19 July or August and having to shut down the end of
20 September would be a horrible way to run a business
21 and we trust that it doesn't turn out that way, but
22 it's unclear; your question is right on target.

1 DR. LEVINE: Thanks.
2 CHAIRMAN WASHINGTON: Krumholz.
3 DR. KRUMHOLZ: Thanks, I just wanted since
4 --
5 CHAIRMAN WASHINGTON: Harlan.
6 DR. KRUMHOLZ: Harlan Krumholz, Board
7 member.
8 Since we're in the strategic planning
9 mode, I was hoping to see the Board get animated
10 not just about process, which is so important, but
11 about what are some of the big ideas that we're
12 lifting and some of it is around the general ideas
13 we've been talking about for a long time and that
14 are integrated into this plan, but I hope also
15 we're able to bring the energy around some
16 different ideas and I at least wanted to throw out
17 two that are some of my favorites, if you don't
18 mind.
19 One quickly is I've been thinking a lot
20 about sustainability and we talk a lot about
21 dissemination, but what truly anchors this kind of
22 work in the marketplace, what kind of research

1 truly reshapes the way the patients receive care
2 and promotes better outcomes. If you're in the
3 basic sciences and you're trying to find a cure to
4 cancer, I mean, it's pretty clear what you're
5 trying to do.
6 We're much more distal than that, we're
7 proximal to the patient and proximal to the care
8 delivery system, but we're in a very different
9 position. So, if we're going to come up with
10 insights, we're going to generate knowledge.
11 If we wanted to get anchored, the question
12 is: Given the current environment, and that's
13 changing, but given where we're seeing things, and
14 the dynamic changes, what truly anchors this kind
15 of change? What was it if we're going to fund a
16 program would get Steve Lipstein, who might have
17 jurisdiction over some of those kind of care
18 facilities, to say that's exactly the information
19 I've been waiting for and I'm going to pull the
20 trigger on this because I just learned something
21 from PCORI versus Steve saying that's just another
22 article passing over my desk and I've got bigger

1 fish to fry than to worry about whether I can
2 implement that?
3 To what degree are we exciting
4 entrepreneurs around the country? When I look at
5 Datapalooza and I see the number of entrepreneurs
6 that are coming to the government and trying to
7 help leverage the efforts that they're making in
8 order to extend the reach of the data and to try to
9 make sure that it’s having impact on people and to
10 be able to demonstrate that impact because there
11 are people willing to pay for those services
12 because their reshaping of the data is adding such
13 value to data that’s otherwise sitting fallow in
14 the databases of the government that they've got
15 business models and they’ve got people willing to
16 invest and they're trying to make that go and to me
17 that’s the ultimate test of sustainability,
18 someone’s willing to pay for it.
19 So, what are we doing to think about this
20 because how much research is being done in our
21 fields that no one would be willing to pay for it
22 after it’s done, I couldn’t go up to auction and

1 sell it really. It'd be very penny auction even
2 though millions might have been spent on it that
3 isn't really reshaping the way in which patients
4 are cared for and isn't that really fundamentally
5 elevating the outcomes of patients that are
6 achieving?
7 Arnie and I have gone back and forth on a
8 number of descriptive studies on disparities, but
9 we can talk even about what works to fix
10 disparities, but if it's not going to anchor, be
11 embedded, if people aren't going to be eager for
12 it, if we can't sell it, then it doesn't make much
13 difference how insightful and clear it is. So,
14 that's one point I want to make, which is where are
15 we thinking differently about having our
16 Datapalooza where it's actually not only -- and I
17 was saying, and I Tweeted this, why can't we do
18 Hackathon equivalents where we're pulling people
19 together?
20 I saw a Hackathon where it started off
21 where people said what do you hate about buying a
22 car and that led the entire group of a very diverse

1 group of individuals to say you know what I hate, I
2 hate X, Y, Z. And people saying what if we weren't
3 constrained to do it the way we're currently doing
4 it? And then it starts getting into well, what
5 kind of business would you do?
6 And I'm not just saying business, but what
7 is it that would drive value in a new way of doing
8 this that would lead Steve to say wow, this not
9 only is good for patients, but it helps me stay
10 open because I've got a mission to serve a wide,
11 broad community and we're having trouble making our
12 budget each year and we've got to figure out how to
13 stay open.
14 So, you can show me the best thing in the
15 world, but if it's going to break my budget, I
16 would love to do it, but I'm not going to be able
17 to do it. And so, we have to find ways that are
18 attentive to the various forces within the health
19 care system to be able to drive this kind of peace.
20 The second one I want to just raise
21 quickly is this notion about the cycle time with
22 which we need to generate new knowledge and my

1 continued commitment to the idea that what we can
2 do differently is to focus very specifically on the
3 patient-reported outcomes because I still see this
4 as a large missing piece that I think patients
5 would have a demand to know if I undergo
6 chemotherapy, how will I feel? How does it really
7 feel? What do different people feel like in
8 experiencing this course? And once I'm given this
9 diagnosis, what are the various trajectories? Now
10 personalize it to me. Best that you know about my
11 characteristics.
12 Going back to the four questions, what's
13 going to happen to me if I undergo an ablation for
14 atrial fibrillation; lay it out for me. I mean,
15 what are the possible courses? But more than that,
16 tell me how people feel. Tell me six months later
17 after people have hip replacement who are the
18 people who say I'm really glad I did this versus
19 the people who say I regret having that surgery.
20 And, of course, you're going to say well,
21 the people with complications, but it's not always
22 that way. Take the people without complications,

1 go six months out, say how many people are glad
2 that they made that choice under best case
3 circumstances? We lack this information now. This
4 is the vital information that I believe need to
5 inform choice about what does it feel like and what
6 do people like me say after they've been through
7 it? Are they saying it was tough, I sort of needed
8 to have strength and courage to go through it, but
9 six months later, I am so grateful because of the
10 way I feel.
11 And if we can start figuring out how to
12 communicate that because I feel in medicine we are
13 handicapped in our ability to convey percentages,
14 likelihoods, and so, we need to figure out, not
15 just to say well, gosh, patients can't understand
16 that. We need to pioneer novel ways of helping
17 people understand and make those choices that with
18 the understanding what's likely to happen to them,
19 not just death or not, but how they feel. So,
20 those two leverage points to me are areas that we
21 can truly distinguish ourselves, and we talk about
22 this plan.

1 I'm so grateful that Joe's putting this
2 process in place and the processes are so important
3 to the success of the organization, but I'm not
4 hearing at the Board meetings the energy of the
5 fostering ideas, the excitement that I did when we
6 first got together about some of the ideas and I
7 worry that we've just become a group that is
8 marching forward but that we're not like walking
9 out saying like I'm on that PCORI Board and I can't
10 wait to get to the Board meeting because it's like
11 the kind of ways that the ideas that are being
12 fostered and listening to the new approaches that
13 are being made are fundamentally shaping our view.
14 That's all.
15 CHAIRMAN WASHINGTON: That's great.
16 Steve, I had a comment, and --
17 VICE CHAIRMAN LIPSTEIN: Harlan's a
18 brilliant diagnostician because he knows where all
19 my buttons are. And this one, the one he brought
20 up earlier about fall prevention in the elderly I
21 think is a good case on this because as some as you
22 know, I'm interested in fall prevention in the non-

1 elderly because I know people who have disabilities
2 that cause balance challenges, and if I ever worked
3 with the elderly, I'd get hit.
4 CHAIRMAN WASHINGTON: You would.
5 VICE CHAIRMAN LIPSTEIN: So, a part of it
6 is when I think about this as a hospital
7 administrator person, we always talk about fall
8 prevention in the hospital, but there's a lot of
9 fall prevention that needs to occur outside the
10 hospital, and one of the fascinating things about
11 this is if you ever spend a Saturday -- you
12 probably don't do this because you have more
13 exciting lives than I do, but spend a Saturday in a
14 medical equipment store where they have lots of
15 equipment for fall prevention and watch how people
16 go through and make decisions about what they think
17 will help them maintain balance, they really don't
18 have a lot of information that helps guide their
19 decision-making, and so, this is a big rock, fall
20 prevention, and we have the wherewithal to take
21 this evaluation outside the hospital environment,
22 where I'm worried that when we put out our PFA,

1 we'll get a lot of grant applications from people
2 who have been studying falls in hospitals for a
3 long time, but we don't want to do that.
4 He's shaking his head no, and so, that's
5 really a great opportunity.
6 But I do think Harlan makes a good point.
7 Now that we have this framework in place and now
8 that we as a board have been a governing board for
9 a while, and so, we've got all of our governance
10 processes, the structures, and framework in place,
11 we do have an opportunity now to step back and
12 devote more of our time and energy to the kinds
13 of -- I guess topic generation might be a way to
14 think of it that Dr. Krumholz is asking for. But
15 fall prevention really is a great one.
16 CHAIRMAN WASHINGTON: Okay.
17 DR. KRUMHOLZ: Just a follow-up point, I
18 was thinking more, Steve, is you're a decision
19 maker with regard to whether you would implement
20 such programs. So, we need your perspective about
21 what is it about these that would make you say yes,
22 we're doing this at BJC and because of X? It's a

1 consequence. I wasn't commenting on importance of
2 topic.
3 VICE CHAIRMAN LIPSTEIN: Right.
4 CHAIRMAN WASHINGTON: Right.
5 Okay, Jesse.
6 DR. JESSE: This is Bob Jesse, Board.
7 So, I was going to pull on a couple of
8 threads that Harlan started to lay out, but that
9 conversation leads to one of them, and that is the
10 first is value. We accrue a lot of information,
11 but how do we take all that information and bring
12 value to the health care system for it? Knowledge
13 is information put to productive use and I think
14 we're spending a lot more time talking about
15 generating more information and less time really
16 understanding how to implement that in ways that
17 improve outcomes for patients in ways that they
18 understand and some of that is, again, a language
19 issue. We need to spend a lot more time listening
20 to the conversation among patients, between
21 patients because they in a construct of health
22 literacy, we may be the illiterate ones, not the

1 patients. They very specifically know what they
2 want.
3 And I think we as a board spent much of
4 our time in the early days really trying to burrow
5 into that, really trying to get into the notion of
6 how do we begin to speak in the language of
7 patients to try and drive our agendas about meeting
8 some of those needs?
9 For the record, I actually am excited to
10 come to board meetings.
11 CHAIRMAN WASHINGTON: Thank you, Jesse.
12 DR. JESSE: And one thing that Harlan who
13 has taught us a lot about in the past but didn't
14 really get into, and that is the whole notion of
15 open science and how do we set up the principles
16 for discovery that say if we indeed are going to
17 really change how medical research is done, do we
18 begin to enact these principles at the front end?
19 If you get a PCORI grant, these are the principles
20 around how the dataset you generate gets handled in
21 the immediate, near, and then long term, and I
22 think that's one of the discussions and whether

1 that's in the purview of the Methodologies
2 Committee or a broader Board decision, I think at
3 some point we need to begin to discuss that.
4 CHAIRMAN WASHINGTON: Yes, Harlan, just
5 for the record, Leah Hole-Curry is on her honeymoon
6 at the Board meeting, so --
7 [Laughter.]
8 DR. KRUMHOLZ: That's why I came this
9 time.
10 CHAIRMAN WASHINGTON: So, she's excited.
11 [Laughter.]
12 CHAIRMAN WASHINGTON: Goertz, please.
13 MS. GOERTZ: Christine Goertz, Board
14 member.
15 I just want to emphasize the point that's
16 been made about having an opportunity to really
17 brainstorm and set aside the time. So, for the
18 last three or four months, it has been my intent
19 and almost every time the PDC has met both during
20 our two-hour calls and in-person to set aside some
21 time to talk about what Harlan had called the big
22 rocks that Arnie now says we're dropping, but and

1 each time, that has been pushed off the agenda just
2 because we have so many other things that we're
3 trying to do and I would love to find a way either
4 through the committee structure or even more fun I
5 think for the whole board to have some protected
6 time where we really are able to have the type of
7 conversations that Harlan and Steve are both
8 talking about.
9 CHAIRMAN WASHINGTON: Okay, Joe.
10 DR. SELBY: I just want to say that I
11 appreciate those comments and Harlan's, as well.
12 And it is true; it feels that we're always doing
13 all the things that we have to do so we don't get
14 time to do this.
15 But a word of comfort, if you take a look
16 at the research we've funded, you will be delighted
17 by the extent to which we've incorporated the
18 thinking of the Board and staff and Methodology
19 Committee into what we request and into the ways
20 that it's reviewed so that there are many projects
21 that we're funding that incorporate these ideas of
22 what is important to patients. The projects that

1 get funded, and admittedly, the pay line is not
2 high, but they are very distinctive, I think, and
3 so, I say this to myself as much as anybody, really
4 getting familiar with the portfolio of funded work
5 is crucial and it's also exciting.
6 CHAIRMAN WASHINGTON: Okay.
7 DR. KRUMHOLZ: And I just feel the need to
8 say the comments are said with admiration for the
9 accomplishments --
10 DR. SELBY: Right.
11 DR. KRUMHOLZ: -- that have been made and
12 with an eagerness to come to each of the Board
13 meetings. But it's with a challenge for us for the
14 future more than that, but I totally agree with
15 you, Joe.
16 CHAIRMAN WASHINGTON: Okay, that's what we
17 took.
18 We're already 15 minutes over, so, I have
19 Douma and then Becker and Gabriel and Epstein, and
20 then we're going to wrap it up.
21 Please.
22 DR. DOUMA: Allen Douma, Board.

1 I just want to really reinforce what
2 Harlan is saying and what we've heard after his
3 comment. I think it's critically important. I
4 think it's particularly important that we have a
5 process, whether it's through the committee level
6 or through the Board level, that's recognized,
7 agreed to where we gather input, creative ideas
8 from everybody, the Board and other people who
9 perhaps are listening to us now on the Internet so
10 we have this defined process and there's somebody
11 on staff who's responsible for collecting the ideas
12 and vetting the ideas and bringing them back to the
13 Board to talk about them. Yes, I think it's well
14 worth out of 70-some that we have to add another
15 staff person just to do that. I think that'll keep
16 us in the forefront and we won't have to refer back
17 to what we have been doing, but what we will be
18 doing.
19 MR. BECKER: Larry Becker, Board.
20 I just wanted to comment on the confluence
21 of what Harlan and Steve just said and falls and
22 Steve's example of going to the medical device

1 store, oftentimes, it’s the simple stuff and it’s
2 stuff that other people have lived, but as we get
3 to a place as a patient and you’ve said health
4 care’s everyone’s destiny that being able to
5 disseminate and share those learnings so that when
6 you go to the store and you go and you look for the
7 right kind of equipment for your home, you get the
8 right kind of stuff. I mean, we’ve spent all this
9 money; we have this knowledge, finding a way to
10 share that knowledge so that each one of us isn't
11 learning because we’re going through it the first
12 time.
13 DR. GABRIEL: Sherine Gabriel, Methodology
14 Committee.
15 I’m actually back to the slide, but first
16 of all, just to say this is an incredible advance,
17 an incredible piece of work, the strategic planning
18 and the sort of strategic path that you and the
19 staff have helped craft here.
20 I completely take your point with respect
21 to targeting, that once you identify a few targets,
22 you will certainly make more progress on those

1 targets than if you had a broad announcement. My
2 question has to do with how those targets are
3 chosen. If that's the case, then we must be very
4 strategic and thoughtful about how those targets
5 are chosen. What is our process with respect to
6 choosing those targets at present?
7 DR. SELBY: Well, subsequent
8 presentations, particularly the presentation on the
9 advisory panels will detail that. So, I think it's
10 the advisory panel process with topic generation,
11 input from board, staff, advisory panel members
12 that will get us to a set of topics that the Board
13 will then prioritize, that the Board will then make
14 decisions about, but I think we talk a lot too
15 about -- again, I just want to say that the
16 advisory panels, we're all delighted to have them
17 onboard as our thought partners, in particular in
18 the specific priority areas, but we also talk a lot
19 about well, if we set up this process, then does
20 that sort of foreclose the possibility that
21 somebody may have a brilliant idea in the middle of
22 a board meeting, and the answer is very clearly

1 not, that we together with the advisory panels and
2 the Board want to build a process that keeps PCORI
3 open to these obviously great ideas when they
4 arise, however they arise.
5 So, I think that's our aim and I think
6 we're succeeding in building a stakeholder-driven
7 process and the Boards mostly certainly are among
8 the stakeholders as is the staff and as are the
9 advisory panel members and the Methodology
10 Committee. So, but we do want a process that we
11 can point to, to say why did we choose that?
12 CHAIRMAN WASHINGTON: Okay. Dr. Epstein.
13 DR. EPSTEIN: Do I have the last word?
14 CHAIRMAN WASHINGTON: I have the last
15 word. Here it's a penultimate last word, okay?
16 [Laughter.]
17 DR. EPSTEIN: What will it take for me to
18 trade up in the draft? I'll leave that.
19 So, I'm going to mostly follow-up on
20 Sherine and Harlan. I'm in a business where you
21 usually try and be first to say something, but in
22 this case, I think what Harlan said was so incisive

1 and thoughtful that I want to just underscore what
2 I think the implications are.
3 For us, I think that arguably the most
4 valuable part of our portfolio is the comparative
5 effectiveness portfolio. Done a different way, but
6 nonetheless, comparative effectiveness and that's
7 going to draw us into two lines of questions when
8 we're done. Has the information told doctors,
9 patients, and the stakeholders more about what
10 works and what doesn't? Do we now know when this
11 is done in a definitive way, but why millions of
12 people who are getting this before and now we don't
13 give it to them or vice versa.
14 And then second, and I think Harlan
15 pointed to this in a way that really got my
16 attention, which is decisions like Steve, decision
17 makers are really important. He's not the only one
18 running a large org. Docs are important, patients
19 are critical, other stakeholders are important.
20 But we need to ask the question: Is this work
21 going to produce information that will change what
22 they do? And I'd urge us to use that metric as we

1 think about the program, the targeted programs
2 we're going to hear about this afternoon.
3 Yesterday, I sat on the PDC and I think
4 there was enough of a case for one or two of them,
5 we thought. The answer to that was a qualified
6 probable yes and for others, we were less sure, and
7 I think that should guide us.
8 The second point is really just a
9 corollary to what Sherine was on. We're going in
10 the same direction, which is if you're talking
11 about moving targeted programs from roughly one-
12 third of the portfolio to two-thirds, as you've
13 heard, we don't really know the exact number, but
14 that's a really good place and pencil to be pushing
15 us. Some of what we can do as a board is
16 independently bring ideas here, and we have to some
17 extent, but I think this is also a really
18 structured way that we can build into every meeting
19 some period of time in which we're focusing on the
20 next generation of targeted PFAs and asking the
21 questions that Harlan just asked about those
22 targeted PFAs to remind us.

1 CHAIRMAN WASHINGTON: First, and I have a
2 couple of comments to make, but first I want to
3 really applaud all the work that Joe and Michelle
4 and others at staff have done in bringing before
5 the Board this just impressive body of work that
6 represents, I believe, a significant step forward
7 for the whole organization. So, thank you,
8 everyone.
9 [Applause.]
10 CHAIRMAN WASHINGTON: And what I've
11 learned from riding bicycles, as some call the
12 false peak, which means you go up a hill and you're
13 pumping as hard as you can because you think that
14 you're going to get to the top, and when you get to
15 that peak, you realize it's a false peak, you just
16 can't see the other one that's over there and you
17 gear up. And it's testimony that we've been
18 successful with the strategic planning effort and I
19 can tell you how many conversations I've had with
20 Board members over the last couple of years and
21 months about we've got to have a strategic plan and
22 I know the group world. The fact that we're now

1 having a conversation about sort of what's next to
2 me is testimony that you've hit this out of the
3 park, the Board is completely satisfied with it, at
4 least where it is at this point, and so, these
5 comments are in light of a transition to what we
6 now need to do and where we need to focus our
7 energies.
8 And I would throw out to the Board that as
9 we think about whatever our individual big rock or
10 big rocks are, that one way to test this framework,
11 and that's what it is, is to see where your big
12 rock or your big idea fits within this framework.
13 You should be able to pinpoint, and if it doesn't,
14 then it means that we need to modify it in some
15 kind of way, but I'm going to argue, would be
16 willing to lay some odds that the overwhelming
17 majority are going to fit somewhere within this
18 framework, and so, I take the comments really to
19 mean we now had a framework, we now have a process,
20 we want to go back to thinking more about how we
21 move the organization along within this framework
22 and get back to ideas and questions which will help

1 us maintain the focus as we move forward.
2 But I would say to the Board that at this
3 point I'm going to challenge you either in writing
4 or in some form to think about Harlan has
5 articulated a couple of what he considers to be big
6 ideas for himself that he'd like to have on the
7 table, Steve has articulated one very specific
8 idea. I would think that we all do that, and like
9 Joe, I think we're going to discover when we step
10 back and look at it, that we're actually in our
11 research portfolio been listening and have been
12 incorporating many of those suggestions. And, yes,
13 there will be some new ideas that we can use to
14 further reshape our portfolio as we move forward.
15 But I want to close this session by
16 saying, I mean, I think this has been a marvelous
17 discussion, very stimulating, and represents to me
18 how far the Board and with the help of Joe and all
19 the staff, the institute has come. So, thanks to
20 everyone for your continued engagement and
21 contributions.
22 And so, with that, it is now 10:35. We're

1 20 minutes over, so, we're going to take a 15-
2 minute break. And so, we will be back at 10:50.
3 Thanks.
4 [Recess.]
5 CHAIRMAN WASHINGTON: We're going to
6 continue in this next session with a discussion
7 about targeted PCORI funding announcement. So, Dr.
8 Selby.
9 DR. SELBY: You all know that we launched
10 this initiative to create an initial set of
11 targeted funding announcements in September and we
12 have come a long ways. We had identified five
13 topics. In the last three months we held all-day,
14 multi stakeholder advisory panels on each of the
15 five topics, stimulating meetings, and our program
16 directors, Chad Boult, Romana Hasnain-Wynia, and
17 David Hickam, are here to report to you on the
18 recommendations from those work groups.
19 You'll see that the recommendations
20 varied, just as we expected they would, and I'll
21 say, and Christine can add to this, that we have
22 presented these on several occasions to the PDC and

1 in addition to describing the results of the
2 workgroups and the directions we're thinking of
3 going, two of these targeted PFA ideas have been
4 endorsed by the PDC and we're here to seek Board
5 approval for moving right along quickly with
6 developing the funding announcements that go with
7 them.
8 So, I think, the agenda says we'll start
9 with Dr. Chad Boult.
10 DR. BOULT: Thank you all. I will briefly
11 review PCORI's progress toward launching, really, I
12 guess, it's first targeted PCORI funding
13 announcement called "Preventing Injuries from Falls
14 in the Elderly."
15 We have some slides.
16 DR. SELBY: Do you have the advancer?
17 DR. BOULT: So, as Joe mentioned, we
18 convened a multi-perspective workgroup on March
19 12th and it was a very productive day. We had
20 national experts in the topic of preventing falls,
21 as well as patients, caregivers, and people with
22 other perspectives in the room.

1 And the workgroup identified four broad
2 research questions related to preventing injuries
3 from falls in the elderly, and they are briefly
4 summarized here.
5 What is the comparative effectiveness of
6 different models of, first, medication management,
7 in other words, evaluating and modifying an older
8 person's medication regimen so as to reduce the
9 risk of falling that might be attributed to the
10 medications?
11 Second, what would be the comparative
12 effectiveness of different models of tailored
13 treatments for specific balance deficits? In other
14 words, all balance deficits are not the same. Some
15 are caused by strokes, some are caused by diseases,
16 like Parkinson's disease, others are caused by
17 medications, and so on.
18 And so, we need to advance the science in
19 this area of figuring out exactly what treatments
20 are appropriate for what deficits.
21 The third question about the comparative
22 effectiveness of models of IT, a lot of interesting

1 new IT for, for instance, measuring people's
2 balance, day to day, moment to moment, what's
3 causing them to be off balance, for monitoring
4 them, people can wear monitors that detect and
5 record their falls, their near falls, their
6 activity levels, and so on, and also the use of IT
7 for messaging, in other words, if the person has a
8 treatment plan to prevent falls, a way to send them
9 messages and receive messages back from them about
10 their adherence to their treatment and the results
11 of their treatment on a minute to minute or hour to
12 hour basis.
13 And the fourth realm of comparative
14 effectiveness has to do with different models of
15 multi-factorial, personally tailored, fall
16 prevention programs, either in institutional, or
17 possibly both, in community settings as well.
18 These were the broad questions that the
19 working group came up with and we then went about
20 trying to determine which of these the staff would
21 recommend to go forward for possible PCORI funding
22 announcement, and we considered these factors in

1 making our decisions: the need for the research,
2 in other words, what's the variability in practice
3 out there? Does everyone agree on the same
4 approach and they're doing it? And the answer was
5 a resounding no. There's virtually no agreement
6 and very little consistency in practice in terms of
7 preventing falls.
8 So, there's a great need for comparative
9 effectiveness research so that patients, doctors,
10 other health professionals, and even system leaders
11 can make good decisions based on credible evidence.
12 The second criterion was the likelihood
13 that the new evidence that would come from the
14 study would lead to widespread improvement in
15 practice and then fewer injurious falls, in other
16 words, what would the uptake be? Would this be
17 something that patients would adopt, doctors would
18 adopt, other professionals, systems? And so, we
19 considered that likelihood.
20 The third factor was the time needed to
21 produce results. So, we have to consider, some
22 questions can be answered relatively quickly in the

1 space of maybe two or three years, others may take
2 a decade, and most are going to be somewhere in
3 between.
4 And the fourth factor that we considered
5 was the opportunities that we had before us to
6 leverage the PCORI support in collaboration with
7 other organizations, such as NIH.
8 So, we went through a process considering
9 those factors for those questions that I mentioned,
10 and we now present to you this proposal for going
11 forward: that we collaborate with NIA or another
12 trial center, two, first solicit and review
13 applications from research collaborations in the
14 field, and then after selecting a winner, to co-
15 manage a cooperative agreement with an awardee.
16 And then, as a result of that cooperative
17 agreement, to collaborate in implementing and
18 evaluating the effectiveness of a preventive
19 program that includes screening of older people to
20 identify those at high risk of falling, assessing
21 them to determine each individual’s set of risk
22 factors for falling -- why are they at risk -- and

1 then third, designing a tailored, multi-factorial
2 treatment for each person. So, depending on their
3 profile of risk factors, design a treatment
4 protocol that aligns to address each of their risk
5 factors.
6 That's the protocol that has been
7 developed by a joint panel of the American
8 Geriatrics Society and the British Geriatrics
9 Society. So, this would be a test of the
10 implementation of that protocol in real life
11 settings.
12 So, the contractor that would win this
13 agreement would comprise several types of experts,
14 people who are experts in falls prevention, health
15 services researchers, provider organizations, and a
16 patient advocacy organization.
17 The design would be a randomized trial
18 where the people in the experimental arm would
19 receive this intervention that I've described, and
20 the people in the control arm would receive usual
21 care. This would be focused on people age 65 or
22 over, and the outcomes -- primary outcome would be

1 the rates of fall related injuries. We'd also
2 measure as secondary outcomes total falls, fear of
3 falling, functional independence, and other
4 outcomes that are important to patients,
5 caregivers, and providers.
6 So, we ask for any questions and also,
7 ultimately, for a Board decision on moving forward
8 with this.
9 CHAIRMAN WASHINGTON: I'll start with
10 Barnett.
11 MR. BARNETT: Just go back one slide, if
12 you would? Kerry Barnett, on the Board. I guess
13 I'm just not clear who the contractor is here. It
14 appears -- we're going to solicit a number of
15 applications, we're going to choose a contractor,
16 but the first bullet, halfway down there, seems to
17 suggest that the contractor is actually kind of a
18 committee, a multi-headed committee, if you could
19 explain that.
20 DR. BOULT: Yeah. We see it as a
21 consortium. It would have a leader and the leader
22 might be a falls expert, might be a health services

1 researcher, could conceivably be someone
2 representing a provider organization, but we
3 imagine that the consortium that would win the
4 contract would have to have at least the
5 representatives shown in the first bullet as a part
6 of their consortium.
7 MR. BARNETT: And we expect them to put
8 this consortium together as part of the application
9 process or we're going to choose somebody to head
10 it up and go out and create a consortium?
11 DR. BOULT: I think an application that
12 already had the consortium would be much stronger
13 than one that said they were going to create the
14 consortium.
15 CHAIRMAN WASHINGTON: I'm sorry,
16 Christine, please. Put this all in context.
17 MS. GOERTZ: Yeah, Christine Goertz, Board
18 member and chair of the PDC. I just wanted to let
19 the Board know that this is -- this is a process
20 that the PDC has been very involved in throughout
21 its inception and development and we had a very
22 detailed discussion about the proposal yesterday,

1 and while we still have questions, primarily
2 because there are a lot of details that had not yet
3 been worked out, and are planning to continue to be
4 involved as a committee in the further refinement
5 and development of this proposal that the PDC did,
6 in fact, vote to recommend that the Board consider
7 approval of this particular proposal.
8 CHAIRMAN WASHINGTON: That's a very
9 important statement that you just made. Thank you.
10 Okay. So, why don't we just work our way around,
11 simplify my day? Douma, and then Clancy, Becker,
12 and Newhouse.
13 DR. DOUMA: Allen Douma, Board, and Arnie,
14 thank you for making me feel really good about
15 being first, but I'm probably the most ignorant,
16 and out of that ignorance, I want to bring up
17 something that I think would be helpful
18 generically, and in particular, using this as an
19 example, perhaps, to be illustrative.
20 What you talk about in one of your bullets
21 in making a selection is likelihood that new
22 information would lead to widespread improvement in

1 practice and outcomes. It would be really helpful
2 for someone like me to have like a description of
3 what actually was done and what kind of
4 quantitative analysis, perhaps, if any, was done,
5 to understand that process as it applies to this
6 particular targeted funding, but to all of the
7 other funding in the future as well.
8 DR. BOULT: This is a really essential
9 point that you raise, and I think it's one of the
10 main guides for us, at least in my program, for
11 selecting these targeted PFAs. And within this
12 likelihood that it would lead to change are the
13 concepts of sustainability, for instance. In other
14 words, an intervention that can only operate with
15 contract funding does not have inherent
16 sustainability. So, we look at that strongly.
17 But we don't have a quantitative method
18 for doing this, as yet. We look at this and use
19 our best judgment about the possibility of the
20 intervention if it were successful in the research
21 for it to be widely disseminated and adopted by
22 organizations because it would be attractive to

1 them, and then it would be sustainable because
2 there's a business case for it.
3 DR. DOUMA: I have a sense of what the
4 generic things are that would go into the thinking
5 process, but again, it would be helpful and this is
6 not for today, but in the future, to actually have
7 a case study of how did it work in this particular
8 instance that led you to make the decision you did.
9 DR. BOULT: Right.
10 CHAIRMAN WASHINGTON: We have a
11 clarifying, complementary comment here.
12 MS. HOLE-CURRY: This is Leah Hole-Curry
13 on the Board. So, Allen, I think to your question,
14 what you're asking for, is how, if these are the
15 criteria by which the topic was selected, how did
16 this topic rate and how did it rate versus other
17 topics. So, I think that's something that we've
18 talked about internally as well and whether or not
19 they were ranked and the input of the expert panels
20 was considered as well as the background research
21 that was done on the topic.
22 So, providing a little bit more of that

1 detail was, as even a background document, I think
2 is a good point and something that we've talked
3 about on the PDC is trying to mature that piece of
4 it.
5 CHAIRMAN WASHINGTON: Clancy, then Becker,
6 and Newhouse.
7 DR. CLANCY: So, I have a bias here, which
8 is on behalf of some relatives for whom falls were
9 a critical inflection point, and not in a great
10 direction. I'm thrilled about this.
11 I would have to guess that the biggest
12 risk factor for falling is that you've fallen
13 before? It seems to hold up in every other area of
14 medicine. Is that correct?
15 DR. BOULT: Especially if you have fallen
16 more than once.
17 DR. CLANCY: Got it. The other question I
18 had is, you're comparing the intervention to usual
19 care. Why is that? And what is usual care in this
20 construct? I mean, it strikes me it will be pretty
21 tricky. And I'm sorry I couldn't get to hear this
22 at the PDC or RDC, I'm not sure which we are just

1 yet, yesterday.
2 DR. BOULT: Well, usual care is a very
3 heterogeneous situation and we're not going to
4 define that up front, but the applicants will,
5 depending on the setting they choose. So, an
6 applicant might say they're going to test the
7 protocol, the AGS-BGS protocol in assisted living
8 facility or they might say they want to test it in
9 the community or in a nursing home environment, and
10 then the usual care would be different in each of
11 those settings, but they'll have to describe to us
12 what that would be.
13 And we -- the only other choice is to come
14 up with a different falls prevention program and
15 compare it to that, but we don't think we're at
16 that point. The best that there was available
17 right now is this protocol, it's an evidence-based
18 protocol developed by the world's -- or at least
19 the English speaking world's leading experts in
20 these two societies for what is recommended as a
21 falls prevention protocol, and so compared to -- we
22 don't have anything really, other than usual care,

1 that would be a valid comparator.

2 DR. CLANCY: Among a number of issues, it
3 just strikes me that you'd -- the applicants or the
4 people in the study would need to figure out or
5 assess whether folks had inadvertently, not as part
6 of the treatment protocol, but been part of other
7 well intentioned efforts to help them avoid
8 falling.

9 DR. BOULT: Yeah.

10 DR. CLANCY: The last comment I'll just
11 make very -- fear of falling, I think, is big, but
12 I also think it's got more generalized impacts and
13 I'm hopeful and optimistic that as the actual
14 details get unraveled, you could get to that. I
15 mean, there's something about overall confidence
16 that has been heartbreaking, at least for folks I
17 know.

18 DR. BOULT: Yeah. And it has implications
19 for people's ability to carry on their life roles,
20 because if they lose that confidence and have that
21 fear every day, they tend to constrict their world,
22 do less, get de-conditioned, and accelerate the

1 downhill spiral.
2 MR. BECKER: Larry Becker, Board. So, the
3 phrase "likelihood that new evidence" piqued my
4 curiosity and I wondered if you would comment on
5 what process might be followed by these folks who
6 get selected in terms of looking at the old
7 evidence, and whether that's been useful, where the
8 holes are, and whether, in fact, that's been
9 implemented or not leading to clues about, so what
10 might we avoid in the gathering and implementation
11 of the new evidence, if there is some?
12 DR. BOULT: Let me make sure I understand
13 your question. You're talking about why would the
14 new evidence be more likely to create universal
15 change, whereas the old evidence hasn't?
16 MR. BECKER: Why, in a sense, did the old
17 evidence fail to make the changes -- what was
18 deficient about it, and what are we doing to
19 understand that, and then, ultimately, built on
20 that so that whatever we spend our resources on,
21 makes it even better rather than it maybe not
22 getting implemented either.

1 DR. BOULT: So, what we have in the
2 literature review that we did leading up to this is
3 literally hundreds of randomized trials of either a
4 single intervention, like what is the effect of
5 reviewing this person's medicines or what is the
6 effect of looking at their feet and their footwear,
7 lots of studies like that, and dozens and dozens of
8 other randomized trials looking at various
9 combinations of interventions, these multi-
10 factorial approaches.
11 But they're all small, they're all
12 underpowered in terms of detecting injuries,
13 difference in injuries, most of them -- almost all
14 have been powered to detect a reduced number of
15 falls, but without any ability to say with any
16 statistical confidence that it changed the amount
17 of injuries that occurred.
18 So, by two main factors that distinguish
19 this kind of a study from the previous studies that
20 have produced evidence are: Number one, that this
21 is an evidence-based protocol that incorporates the
22 best evidence from all the hundreds of studies that

1 have been done, so it's got that weight behind it.
2 And then, second, it would be large enough so that
3 it could actually determine whether injuries were
4 reduced.
5 And, of course, we're all aware that
6 although we can't measure cost effectiveness, that
7 we certainly care a lot about older people getting
8 injured from their falls, and those injuries have
9 consequences, they require medical care, which
10 incurs cost, and so an intervention like this, if
11 it were successful in reducing injuries, and we
12 could show that pretty conclusively, then there
13 would be a case for others, perhaps, to look into
14 the costs of doing the intervention compared with
15 the cost saved because people didn't get injured
16 and have to be hospitalized and put in nursing
17 homes.
18 CHAIRMAN WASHINGTON: Newhouse and then
19 Sigal.
20 MS. NEWHOUSE: Robin Newhouse, Methodology
21 Committee. So, just have a question and a comment.
22 First of all, I'm so thankful for this focus. I'm

1 a daughter of an 81-year-old father who I promised
2 he'd be safe until his death, and he has fallen six
3 or seven times, and I have been to the medical
4 supply store because I bought a bed alarm about a
5 month ago.
6 Which gets me to the science question.
7 The falls in people over 65, in my observations --
8 my father's in an assisted living -- is not just a
9 matter of the intervention, it's a matter of the
10 context. So, these studies have to consider the
11 type of staffing that's available, for example, in
12 these assisted livings it's all unlicensed,
13 assistant personnel. They have a great will and a
14 great heart, but in terms of the science and
15 developing a protocol, it's not something that's
16 really in their portfolio.
17 So, I think the attention to understanding
18 why it works is more than just the intervention.
19 So, I'm hoping that there's more staffing
20 variables, there's more observational kinds of data
21 being collected so that we understand why it works
22 and under what conditions, because a randomized

1 control trial itself really won't give us the
2 answers we need.
3 But incredibly important area, those of us
4 that are caregivers would be incredibly thankful if
5 PCORI could answer this question, and help us and
6 these medical supply stores, understand what bed
7 alarm, you know, to buy, and what are the best
8 strategies. And, you know, of course, the last
9 thing they offer are things like sitters, and it's
10 not about an intervention like that, really, so,
11 thank you and please consider those health service
12 contextual variables as well.
13 DR. BOULT: Yeah, thank you very much. In
14 the presentation that we did yesterday, we
15 presented considerably more detail, including the
16 requirement that this be a mixed method study where
17 we looked at barriers and facilitators to
18 implementation in the various settings where this
19 protocol could be used.
20 MS. SIGAL: Ellen Sigal, Board. So, the
21 PDC had substantial conversation on this, so I
22 don't want to repeat what was said. I think that

1 we unanimously think this is very important.
2 However, I do want to repeat that it is really
3 important to get to some level of specificity
4 because of the heterogeneity of the population, and
5 we're asking a huge amount of questions and, you
6 know, 65 to 75, huge variables in age and
7 conditions, so if we're going to have an outcome, I
8 would just stress that we really try to be tangible
9 and maybe not ask so many questions, but a few that
10 would be meaningful.
11 So, I think that we'll get there, and I
12 assume -- I know we discussed yesterday, this will
13 go back to PDC for refinement, but I do want to say
14 publically that I think this is a very important
15 subject.
16 CHAIRMAN WASHINGTON: Okay. Zwolak,
17 Levine, and then Weisman.
18 DR. ZWOLAK: Bob Zwolak, Board. I also,
19 in my day job, live in this space and applaud the
20 concept that we've chosen to attack falls because
21 it's enormously important for senior citizens.
22 If I understand this correctly listening

1 yesterday, what you're testing is a combination of
2 nine different evaluations and interventions, all
3 of which have been assessed and recommended by the
4 two geriatric societies. So, my question is one
5 from the perspective of an IRB, for instance,
6 considering this. What will be your control
7 groups, considering that what you're recommending
8 as the test are treatments recommended already in
9 practice guidelines? The IRBs sit and wonder about
10 controls. Will the controls be historical? Do you
11 have historical data? Or if they're better, if
12 they're contemporaneous, will an IRB be thinking
13 that you're withholding currently recommended
14 therapy from the control group? And that troubles
15 me a tiny bit.
16 The other question is, how will this
17 eventually -- the results of your study eventually
18 make it down to the seemingly very granular level
19 of Steve and the medical device store?
20 DR. BOULT: Certainly the control groups
21 will have some degree of assessment and treatment
22 of people at risk for falls, and there will be no

1 attempt whatsoever to blunt that. So, in other
2 words, people would get whatever falls intervention
3 program their providers would provide, even in the
4 control group. So, that's okay. And that's the
5 standard against which this comprehensive approach
6 would be compared. So, I don't think there's any
7 issue about ethically withholding treatment that's
8 been recommended. It's out there, it's available,
9 it is used, but very inconsistently, and that's the
10 comparison group.
11 Because this is what we would call a
12 pragmatic controlled trial, it will be trying to
13 get -- gather information to answer a variety of
14 stakeholders' questions. So, we will want to know,
15 not only did the number of injuries from falls go
16 down as a result of this, but we'll want to know,
17 what did the providers think of it? How satisfied
18 were they with implementing this? What did the
19 patients, what did their family caregivers think of
20 it?
21 And so, we'll try to answer those
22 questions so that at the end of the day, if, in

1 fact, it reduces injuries from falls, then we can
2 turn to providers who would be charged with using
3 it and answer their questions about what providers
4 who've already done it, what did they think of it?
5 Did it fit into the way they did business? And was
6 it satisfying? And would they want to continue
7 doing it? And same kind of questions for patients
8 and their families.
9 CHAIRMAN WASHINGTON: Levine.
10 DR. LEVINE: Sharon Levine, Board member.
11 I'm having -- maybe because I'm a pediatrician, but
12 I'm having a little trouble wrapping my head around
13 whether this is a study, a randomized control
14 trial, or a portfolio of randomized control trials.
15 If you -- could you go back to the prior slide?
16 So -- well, it's the one that had
17 contractor and awardee on it. Yeah, so is the
18 awardee the contractor? Is that the same person?
19 DR. BOULT: Yes. One.
20 DR. LEVINE: A, an awardee. And that
21 individual will either come with or constitute a
22 consortium of interests. And the selection of

1 people -- 100 percent of those enrolled in this
2 randomized control trial, and I assume you're going
3 to need a very large number because it's a
4 pragmatic trial.
5 DR. BOULT: About 5,000.
6 DR. LEVINE: Five thousand -- would be
7 anyone 65 years or older who would be screened?
8 DR. BOULT: Correct.
9 DR. LEVINE: And either assigned to a --
10 will they all have the risk assessment? Is 100
11 percent of the 5,000 --
12 DR. BOULT: They would all be screened,
13 initially there's a brief screen to determine who's
14 at risk, and then everyone who, in the experimental
15 group, the intervention group, everyone who
16 screened positive, in other words, they are at risk
17 -- high risk for falling, they would all receive
18 the comprehensive assessment of their individual
19 risk factors.
20 DR. LEVINE: So the 5,000 are all people
21 who, through some screening process, are determined
22 to be at risk?

1 DR. BOULT: No, I'm sorry, let me run it
2 through again. So, there would be 5,000 total,
3 2,500 in the experimental group, 2,500 in the
4 control group. Of the 2,500 in the experimental
5 group, they would all be screened. We might find,
6 perhaps, 40 percent of them were at high risk.
7 Those 40 percent would get a comprehensive risk
8 assessment and then would get a tailored program to
9 address those risks.
10 DR. LEVINE: Okay. And with that number
11 and that design, you can answer multiple questions?
12 DR. BOULT: Yeah, it's preliminary because
13 we don't know the setting exactly, so we can't
14 specify the exact design. That will depend on the
15 applications that we get. But we've made some
16 assumptions in coming up with these numbers, and
17 our goal, though, was to create a sample that would
18 be large enough to be powered to detect significant
19 reduction, not just in falls, but in injuries from
20 falls.
21 DR. LEVINE: And will it be a setting or
22 multiple settings? So, will it be --

1 DR. BOULT: That's up to the applicants.
2 An applicant might say they wanted to address
3 people in assisted living and nursing homes or
4 people in the community who show up in emergency
5 rooms. There's a variety of approaches that could
6 be suggested to us.
7 DR. LEVINE: But one will be selected? I
8 mean, it will be a single trial?
9 DR. BOULT: Yeah. Logistically it would
10 be very difficult to split this and then try to
11 pool the data in order to come up with sufficient
12 power. It could be done, but it would be much more
13 attractive to have it all in one system.
14 DR. LEVINE: Thank you.
15 CHAIRMAN WASHINGTON: Okay, Weisman,
16 Douma, Kuntz.
17 DR. WEISMAN: Harlan Weisman, Board
18 member. I'm going to reinforce, I think, some of
19 the things that you've already heard, but I'll put
20 out the caveat. I totally support this, but I'm
21 very biased and I probably wouldn't vote on it. I
22 think I'd probably have to recuse myself, but one,

1 I'm a former NIA intramural investigator, so -- and
2 two, my father died of a subdural hematoma. My
3 father was 93 years old, very healthy, exercised
4 every day, was an active playwright with his plays
5 being performed in multiple theaters across the
6 East Coast and had just gotten a play accepted for
7 off Broadway, ironically, I live on the street
8 where the theater was now or have an apartment on
9 the street where the theater was in New York.
10 And I experienced what this is -- what
11 it's like to deal with falls.
12 So, there's prevention so that he wouldn't
13 have fallen in the first place, because he was a
14 very active guy. In fact, I diagnosed his subdural
15 over the phone when I recognized he was having
16 memory problems acutely and some confusion and we
17 got him to a hospital, but from the very beginning
18 I had a very -- numerous and poor interactions with
19 the healthcare system.
20 In fact, it probably colored me a little
21 bit -- this was in 2010, I was already on the
22 Board, I was already meeting a lot of people and

1 patients, families, and others, who were
2 interacting with their healthcare system, and it
3 was really very healthy for me to experience first-
4 hand.
5 But this issue of settings is incredibly
6 important. It is very different to do fall
7 prevention at home to prevent the first fall, my
8 father's first subdural, and then as he made his
9 way through the healthcare system at extremely good
10 places in the Washington, DC area, I learned that,
11 for example, once you make it out of the acute care
12 hospital, anything that happens, whether it's in a
13 rehab hospital, assisted living, a nursing home,
14 whatever it is, is almost entirely dictated by
15 reimbursement and Medicare guidelines.
16 And to a T, every place you look at has
17 exactly the same approach because it is everything
18 that will be reimbursed. You're basically handed
19 that the moment you enter and are made to read it
20 before you even get a tour because they want you to
21 make sure that, and a lot of it, a lot of the
22 disclaimers and everything, is against holding

1 anybody liable for fall prevention.
2 And, you know, you'll see lots of --
3 you'll learn a lot about nurse to staff ratios,
4 other staff ratios, and then find out it's a
5 fiction anyway because whatever they say, there's
6 usually at most one RN, if any, at night, and the
7 best way of dealing with this is that people ignore
8 alarms, I know that, even if you have them there,
9 and the best way of handling old people who are in
10 danger of falling is to tie them down in the bed,
11 and that happens more than you'd want to think.
12 And I had a good experience because I make
13 a lot of money, more than most people, and I was
14 able to have somebody, a nurse, if it wasn't me or
15 my sister, sitting by my father's bedside
16 protecting him from what was being done to him or
17 not done for him, and those are all setting issues
18 and confounders in all of this that really bother
19 me, because I'm concerned that we can show
20 something very beautiful in a randomized trial in
21 which we're measuring things, and it will, perhaps,
22 not have real world validity or applicability

1 unless we can find a way of real world testing some
2 of this, because I suspect that a lot of it has to
3 do -- particularly in facilities -- has to do with
4 things that are not related to specific
5 intervention, but related to something that's
6 missing from healthcare, and that's care.
7 And if there is true care in delivery of
8 these, I think you can go a long way, and
9 ironically, you know, you said, Sharon, you're a
10 pediatrician, and there are a lot of good
11 geriatricians, most of whom have nothing to do with
12 these facilities nor are there, they're
13 understaffed, under -- and these are expensive,
14 really good ones.
15 So, I think this is extremely important.
16 I was biased toward it. But, you know, things like
17 length of stay in these facilities and specific
18 interventions, if they're being driven in the real
19 world by reimbursement considerations, it almost
20 doesn't matter how it works, and also it's not
21 clear to me that this -- the confounding of setting
22 and the specific healthcare system in which it's

1 being conducted, may be the most important
2 determinants of the outcome of fall prevention than
3 any specific thing that you're doing in it.
4 And I also worry that the people who are
5 going to apply for these grants are the very people
6 who are probably already doing extraordinary
7 efforts and will get a good result, but it won't be
8 -- as I said, it won't be applicable, you know,
9 things like training and the number of staff
10 available, the socioeconomic status of the
11 individual, all those things -- and where they're
12 located -- matter so much that -- I don't want to
13 be overly nihilistic because I love it, I just
14 don't know what the solutions are.
15 It's really important to do though.
16 DR. BOULT: Harlan, I'd just comment that
17 I think all of us feel your anguish and your
18 family's anguish and it's the reason why many of us
19 left our previous occupations and came to work at
20 PCORI to try to deal with these issues.
21 DR. WEISMAN: By the way, my father had a
22 complete recovery and died of a second subdural

1 hematoma from the second fall. That's the end of
2 the story. Sorry.
3 CHAIRMAN WASHINGTON: Douma.
4 DR. DOUMA: I almost want to apologize for
5 bringing something up that is so superficial
6 compared to what I just heard. I have experience
7 with my father, which is equally profound, to me,
8 anyway, but I feel for what you were talking about
9 a lot. And it is superficial, but I think it's
10 important at least to say what we're not going to
11 fund.
12 The description of the targeted funding is
13 preventing injuries from falls. Are we going to be
14 looking at falls that occur but were preventing
15 injury with things like changing the environment
16 with sharp objects, with helmets, et cetera? Is
17 that part of the equation? Or really looking at
18 preventing falls and we're interested in whether
19 they cause injuries?
20 Can somebody -- let me just be specific.
21 Could I come in and say, I'm going to make
22 everything in my apartment round and soft and

1 spongy and I won't get hurt if I fall. Is that on
2 our table?
3 DR. BOULT: Yes, I think so. We're aiming
4 at reducing injuries, and obviously you have to
5 reduce falls in order to reduce falls injuries, and
6 so they're inextricably linked, but --
7 DR. DOUMA: Well, and my example is, I
8 would submit, I think it's being nitpicky, but you
9 could have just as many falls, but you're
10 decreasing the injuries because of what you're
11 falling on?
12 DR. BOULT: Yeah. That's our focus, is
13 the injuries.
14 CHAIRMAN WASHINGTON: Kuntz.
15 DR. KUNTZ: Rick Kuntz, part of the Board
16 -- member of the Board of Governors. I just want
17 to make a general statement. I think it's
18 important to identify these devastating conditions,
19 the human conditions we have, such as falls, as
20 being a really critical, important thing to try to
21 solve, but also I think that part of our job here
22 is to determine whether or not they can be solved.

1 One could make a case that this might be a
2 chaotic situation, the ubiquitous, you know,
3 presence of gravity, you know, makes this a very
4 difficult thing to classify. And while I would
5 hope that we'd find solutions for this, I think we
6 also have to determine, we have, you know, critical
7 resources and we have to make -- we have to balance
8 the critical needs in our society with things we
9 can actually solve.
10 And so, listening to this discussion, I
11 think it's important to kind of sort that out and
12 understand whether or not we're trying to stop
13 tornados and fix the weather, which is a chaotic
14 situation, or we're going to put a school guard at
15 the crossing zone, which actually is a very
16 discreet thing that can be solved.
17 DR. BOULT: Maybe just to give a little
18 encouragement. The Cochran Collaboration has done
19 a couple of recent surveys of all the literature on
20 this, as recently as six months ago, and concluded
21 that there's a -- on average, there's about a 23
22 percent reduction in falls that are possible

1 through these combined, multi-factorial approaches,
2 though we're not going to eliminate them all
3 together, but we certainly -- there's the
4 potential, even with previous sort of incomplete
5 approaches to reduce falls by around a quarter.
6 DR. KUNTZ: If that's solved already, then
7 why don't we implement those programs? Or are we
8 testing -- are we just confirming that?
9 DR. BOULT: Yeah, that evidence is out
10 there and it's not being implemented, so what we're
11 trying to do here is show that a systematic form of
12 implementation in one or more settings can actually
13 lead to widespread adoption.
14 CHAIRMAN WASHINGTON: Okay. Becker.
15 MR. BECKER: Just a quick question. Does
16 anybody want to have a discussion about the
17 strategic use of NIA in this process?
18 CHAIRMAN WASHINGTON: It looks like Ellen
19 Sigal has a comment related to that.
20 MS. SIGAL: We spoke about that
21 extensively because they're efficient, they have
22 the mechanism, they certainly have the knowledge.

1 What's very, very important is that the PCORI
2 branding and input and evaluation be part of it,
3 and Francis and Kathy have assured us that that
4 will happen, because we don't want to just have
5 them do it, we want to really be able to shape it
6 and to do it in a way that's very substantial that
7 really answers the questions that are most
8 important for PCORI and have the Board and our
9 experts involved, and our patient-centered value is
10 a part of it, but what we're told, and I and others
11 asked the question, is that this is now going
12 through legal counsel and they believe they have
13 the mechanisms for doing it, and the legislation
14 does call for NIH. You know, so as long as we can
15 shape it, there's no reason not to do it that way,
16 I think.
17 CHAIRMAN WASHINGTON: Norquist.
18 DR. NORQUIST: I may be the only
19 geriatrician here, I'm a geriatric psychiatrist, so
20 I deal with these kind of issues all the time. So,
21 I won't give you stories and all that kind of
22 stuff. What this is reminding me of is when I was

1 at NIH and we had to do all this comparative
2 effectiveness research and we started on looking at
3 depression, and you cannot imagine the numbers of
4 comments, the design issues, all this stuff, and at
5 the end of the day we had to say, you know what,
6 let's pick one question here, let's be very
7 specific what the question is that we're going to
8 do, because the contractors will be all over the
9 place confused, we cannot solve all of the issues
10 about falls, but we can start somewhere, at one
11 point.
12 And so, without second guessing, the only
13 thing I would say to you is that when you go out to
14 bid the contract, that when you get together with
15 folks, that you're very specific, what is the
16 question that you want to ask in all the ones about
17 falls, and maybe you're going to have to narrow
18 your population, and then I would strongly urge
19 you, because I'm sitting right next to the
20 Methodology people, to get them engaged very early
21 on, because we had to do that, because in our
22 depression study, we went to primary care clinics,

1 which everybody thought was going to be a disaster
2 because we different -- and then people wouldn't
3 select what the thing was, and we came up with this
4 idea, which I love to keep repeating, because it
5 makes me sound very intelligent, equipoise
6 stratified randomization, which actually allows you
7 to let people make choices and then you can sort
8 for that later and fix it.
9 So, their --
10 UNIDENTIFIED BOARD MEMBER: [Off
11 microphone.]
12 DR. NORQUIST: Equipoise stratified
13 randomization. Isn't it wonderful? And I actually
14 know what it is.
15 Anyway, so what I would say at this point
16 is, it's an incredibly important topic. I would go
17 back to what Harlan K. said earlier, which is that
18 we need to pick the big topics and then focus, but
19 it's a complicated topic, because I see it all the
20 time, but there are answers and we need to test
21 what we think is the best possible solution and put
22 that out for bid.

1 DR. BOULT: Thanks. And I don't know if I
2 mentioned it earlier, but we're envisioning this to
3 be a cooperative agreement, which allows PCORI and
4 NIH to have involvement in the steering committee
5 as the whole process unfolds over five years.
6 CHAIRMAN WASHINGTON: Hunt.
7 MS. HUNT: Is it -- some reason that we
8 haven't used the number for how much money in the
9 budget this is going to represent? It's a contract
10 or cooperative agreement of $30 million?
11 DR. BOULT: That's right. That was the
12 NIA's estimate of the budget for doing a properly
13 powered study to show a decrease in injuries from
14 falls.
15 MS. HUNT: Can I just follow up then? We
16 need to -- one of the many things we need to
17 clarify, and this is following up on Larry's
18 comment too, is what their "in kind" -- what --
19 we're coming up with the $30 million. What are
20 they -- what's the "in kind" that they're coming up
21 with?
22 DR. BOULT: These are ongoing negotiations

1 right now. They've expressed an interest and an
2 acknowledgement of the need to make some in kind
3 contributions, but I think because they're in
4 process, I probably shouldn't speculate much more
5 about the details, but they're in agreement with
6 that concept.
7 CHAIRMAN WASHINGTON: Christine, any
8 concluding remarks before I provide some summary.
9 MS. GOERTZ: Just -- I just want to
10 reiterate what's been said about the agreement with
11 NIH. I mean, they really -- we had both Francis
12 and Dr. Richard Hodes, the director of NIA, on the
13 phone with us yesterday and both of them reiterated
14 the fact that they would -- they were very
15 committed to working with PCORI to make sure that
16 this was, in every way, a PCORI-driven effort and
17 also that their intent was that all of the
18 management would, in fact, be an in kind
19 contribution from NIH, which obviously is a great
20 cost savings to PCORI as we're moving forward.
21 Now, they did reserve the right, if it
22 became horrifically expensive for some sort of

1 unforeseen reason, that they might come back to us
2 on that, but that their intent, at this point, is
3 that it would be an in kind contribution.
4 CHAIRMAN WASHINGTON: Okay, so, before we
5 -- because -- Dr. Levine, you have a frown, which
6 is unusual for you.
7 DR. LEVINE: I think I'll pass on
8 explaining the frown for now.
9 CHAIRMAN WASHINGTON: Okay, but before we
10 vote, because we do in this case, about whether or
11 not we want to move forward today, I want to remind
12 everyone that the point that we're at now
13 represents, again, multiple steps. We decided some
14 time ago that we wanted to develop some more
15 focused PCORI funding announcements.
16 We then had an exercise that involved
17 quite a bit of work on behalf of staff and in
18 consultation with others, to identify what those
19 areas would be. Originally, I think we identified
20 four, and then we added a fifth one.
21 And then, on top of that, we took that to
22 our newly established workgroups. So, we've got

1 workgroups now with experts who have now taken the
2 topics. So, we've gone from the big area of just
3 targeted, down to identifying five topics, which
4 one of them happens to have been or is fall
5 prevention in the elderly, then we brought together
6 outside experts, in terms of a working group, to
7 sort of say, this is a general area where we
8 believe, given what we know, you should be focusing
9 your attention.
10 And based on that, under Chad's direction
11 and others with Joe, we've now come up with sort of
12 a set of questions, which he laid out. And now we
13 have comments that will get incorporated into that.
14 But at the end of the day, what's on the table is,
15 do we move forward with developing a PFA related to
16 fall prevention in the elderly in this general
17 area?
18 Okay, and so, this is an question of all
19 those who --
20 DR. SELBY: Francis is on the phone.
21 CHAIRMAN WASHINGTON: It looks like
22 Francis is crying to speak. I think he's saying

1 “trying,” but it looks like “crying” to speak.
2 Francis, we don’t want you crying.
3 DR. COLLINS: Can you hear me now?
4 CHAIRMAN WASHINGTON: Yes.
5 DR. COLLINS: Oh, because I’ve been
6 speaking quite a lot, but I don’t think you’ve
7 heard a word. I think we had some technical issue.
8 So, I just wanted to reiterate that NIH is
9 very enthusiastic about the partnership proposed
10 here on this project and I think it’s already been
11 well stated by Chris and Ellen and others, that we
12 had a very good conversation about this yesterday.
13 Richard Hodes is listening to the
14 conversation right now but is not in a position to
15 be able to be heard and as the director of NIA, I
16 think he also wants to provide strong assurances
17 that we would do this in a partnership that
18 reflects PCORI’s very strong interest in patient-
19 centeredness and to make sure that we do this in a
20 fashion that meets those goals, and that NIA is
21 prepared to be a donator of the in kind staff time,
22 which is pretty significant in a project of this

1 magnitude, and so just again to reiterate, that we
2 think this could be a great opportunity to work
3 together.
4 CHAIRMAN WASHINGTON: I'm going to call
5 the question, having explained what's on the table.
6 All who support moving forward to develop the PFA
7 related to falls prevention in the elderly and this
8 general area, raise your hands.
9 [Show of hands.]
10 CHAIRMAN WASHINGTON: Okay, we have 17 --
11 Francis, I take it you're a yay?
12 DR. COLLINS: I am a yay.
13 CHAIRMAN WASHINGTON: So, we have 18 out
14 of 21. We have two Board members missing. And all
15 Opposed?
16 [No response.]
17 CHAIRMAN WASHINGTON: Any abstentions?
18 [One.]
19 CHAIRMAN WASHINGTON: Okay, so we have 18
20 in favor, we have one abstention, and two people
21 absent.
22 DR. DOUMA: Just a clarification on your

1 wording. It says, we just approved moving forward
2 in this area and let me give a hypothetical. What
3 if we find we get more confirmation from Cochran
4 and from the guidelines that have been created that
5 a major issue, if not the major issue, is that it's
6 the -- actually the implementation of what is
7 already known is more of a barrier to decreasing
8 injury than knowing more? Do we still have the
9 opportunity to branch down later on or even focus
10 on that more later on?
11 CHAIRMAN WASHINGTON: I would think so and
12 I would trust that Joe and staff and PDC and others
13 involved would take advantage of just that kind of
14 discovery.
15 So, Joe, we have support and we're going
16 to move forward. And thank you very much, Chad.
17 DR. SELBY: Thank you very much.
18 DR. BOULT: Thank you all.
19 CHAIRMAN WASHINGTON: And I want -- thanks
20 to everyone involved including all the staff and in
21 particular also those involved in the work groups,
22 the experts who came forward to assist us.

1 DR. SELBY: So, I'm not quite sure how
2 we're doing on time here, but --
3 CHAIRMAN WASHINGTON: Well, we're behind,
4 I can tell you that.
5 DR. SELBY: It's crucial to hear from Dr.
6 Hasnain-Wynia. I think, David, we're going to have
7 to defer those which don't have an endorsement from
8 PDC for moving forward, but we feel a real urgency
9 at PCORI to get these targeted funding
10 announcements developed, posted, and we sincerely
11 hope, funded by, at, or near the end of the year.
12 So, I recommend we turn this over to Romana.
13 DR. HASNIAN-WYNIA: Hello everyone. My
14 name is Romana Hasnain-Wynia and I am the director
15 of the Addressing Disparities Program at PCORI, and
16 my goal is to really talk to you today about the
17 proposed targeted funding announcement for asthma.
18 We also had a workgroup for treatment of
19 obesity, and there are slides, I think, in your
20 Board Book related to that, but because of time
21 issues, I won't go through the obesity discussion
22 of the workgroup and focus on asthma.

1 So, just briefly here, we identified the
2 goals of the program in Addressing Disparities. I
3 think many of you have already seen this, so I'm
4 not going to read this slide, and again, it's
5 referenced in your Board Book.
6 Again, we have had two ad hoc workgroups,
7 one on treatment options for severe asthma in
8 African-Americans and Hispanics/Latinos, which was
9 held on March 1st, and then the second workgroup
10 that also fell under the disparities program was
11 obesity treatment options in diverse populations.
12 That workgroup was held on April 16th, and we
13 continued to receive questions through April 30th,
14 so we're still synthesizing the information, but
15 the information that we have synthesized to date,
16 is available in the Board Book.
17 So, the goal of the targeted workgroup, I
18 think it's important to reemphasize why we pulled
19 this workgroup together, and you can see it was to
20 obtain input from experts, including patient
21 stakeholders and others.
22 We wanted to work with this group to

1 identify the high impact research questions that
2 will result in findings that are likely to endure
3 and that are not currently studied, and to
4 understand the potential for the research to lead
5 to improvements in practice, and again, to confirm
6 the importance and timeliness of particular
7 research questions within the area, in this case,
8 of addressing asthma disparities.
9 And then, finally, I think it’s also very
10 important to recognize that the goal of the ad hoc
11 workgroups was to reach consensus, and as all of
12 you know, when we strive for consensus, everybody
13 gives up a little and everybody gets a little, so
14 it wasn’t really a prioritization process, per se,
15 it was really a consensus-driven process.
16 And we took all of this information and
17 synthesized it, and this is what I’m going to
18 present to you.
19 So, our chair and moderator for our
20 workgroup was James Kiley from NHLBI, and we
21 continue to work with NHILBI in terms of
22 identification of the gaps that the workgroup

1 addressed.
2 We put forward to the workgroup the
3 criteria for the research gaps that we wanted to
4 have highlighted, so, again, to be patient-
5 centered, to assess current options, the potential
6 to improve care, particularly patient-centered
7 outcomes, to provide knowledge that is durable, and
8 to be comparative, to compare options.
9 So, what we ended up with at the end of
10 the day was six overarching themes, and these
11 themes were distilled from about 60 topics or
12 questions that were submitted vis-à-vis the
13 workgroup members and also vis-à-vis others who
14 submitted information through our website, through
15 Twitter, et cetera.
16 So, what I'm going to do here is go
17 through each of these key themes, because these are
18 the areas where the workgroup identified key gaps
19 in addressing asthma disparities, and what we did
20 after the workgroup meeting is that we went back
21 and we looked through the literature, we looked at
22 the Cochran review, to confirm that these gaps

1 were, in fact, real and to really validate that we
2 were -- if we were to move forward with a targeted
3 funding announcement, that we were addressing gaps
4 that needed to be addressed based on the criteria
5 that I've already identified.
6 So, the first gap, focusing on
7 communication, what we found was that there were
8 very few studies that examined whether or how
9 different provider and patient communication or
10 engagement strategies might affect outcomes in
11 asthma. There were a few studies, for example,
12 that looked at mobile phone messaging to facilitate
13 self-management and provider interventions to
14 promote patient-centered care in clinical settings,
15 but those studies were not necessarily focused on
16 asthma care. So, I think that's just important to
17 recognize.
18 And then in terms of what you see on the
19 slide here, are examples of potential desirable
20 studies that might be considered.
21 Moving on, we also identified the
22 integration of care for asthma, for severe asthma,

1 and in particular, for reducing disparities as one
2 of the gaps, and again, when we went back to look
3 at the literature and we looked at the Cochran
4 review, in particular, we found that there were
5 several studies comparing newer models to usual
6 care, but there were no studies that actually
7 compared innovative models to one another.
8 So, it's just important to recognize that
9 what we found was, again, comparisons of one model,
10 for example, using some kind of high tech
11 intervention, using smart phones, et cetera, but
12 using that -- comparing that to usual care versus
13 comparing two different, innovative models.
14 We could not find any studies that
15 examined integration of pharmacists into the care
16 team. This was particularly important because it
17 was something that was raised by multiple workgroup
18 members as a really important area, so we think
19 that there are opportunities here.
20 And then finally, there were no studies
21 that examined models to examine transitions in
22 care. And, again, you can see examples of

1 potentially desirable studies that could be
2 considered within this particular domain.
3 Moving on to systems, we found very little
4 in the area of systems. Basically, in the Cochran
5 review, we only found one study on asthma that
6 basically assessed a web-based, comprehensive,
7 health enhancement support system. There were no
8 studies that addressed data integration to identify
9 or target high-risk communities or comprehensive
10 interventions that linked multiple systems, in
11 particular, healthcare systems with home or work-
12 based or school-based, for example.
13 I'm not going to go over behavior, because
14 we actually kind of melded it -- it trended very,
15 very closely with the communication domain, so
16 I've, in a sense, addressed it.
17 There was a lot of focus here in the
18 response to therapy, in terms of the workgroup,
19 really emphasizing this as one of the key gaps.
20 What we found were three studies, which addressed
21 modifiable factors such as baseline vitamin D
22 levels. There was one study that addressed genetic

1 factors. And then we found 19 reviews, but of
2 those 19 reviews, only five were moderately
3 relevant to disparities.
4 So, what I mean by that is that there
5 wasn't information on racial or ethnic or language
6 groups, so even though they were relevant to the
7 topic, they did not target disparities
8 specifically.
9 There is also quite a bit of current work
10 taking place, for example, the BELT Trial, which is
11 being led by Elliot Israel in Boston, which is
12 looking at the effect of LABAs versus other
13 treatment in African-Americans in particular.
14 We're very interested in the potential gap here in
15 response to therapy because we do think that there
16 is an opportunity here to do a real comparative
17 effectiveness study to engage patients and also to
18 potentially work off of current work that is in the
19 field.
20 So, we're very mindful of the timeliness
21 issue in terms of proposing a funding announcement
22 that calls for projects that can be completed

1 within a three-year timeframe. So, given that, we
2 would like to be able to encourage potential
3 applicants to really build off of current work, so
4 long as that work is making a unique contribution
5 or extending work that is currently underway.
6 And then, finally, a gap that was
7 identified again by the workgroup relates to the
8 environment, and you can see some of the sample
9 desirable studies in the bulleted points here. I
10 will say that this is a really important area,
11 however, I think that this is an area that others
12 are addressing quite effectively. There's the
13 Coordinated Federal Action Plan to reduce racial
14 and ethnic disparities in asthma. There's a lot
15 of good work taking place at the CDC. So, I don't
16 believe that this is a space that PCORI, per se,
17 needs to place a lot of focus because there's other
18 areas where I think PCORI's investment would see a
19 stronger return on investment.
20 So, at this point, what we are proposing
21 is a portfolio of projects, about eight to ten,
22 within the area of addressing asthma for African-

1 American and Hispanic/Latino populations. If, in
2 fact, we move forward with this and we do end up
3 supporting a number of studies in this area, I
4 think that there is a real opportunity here to
5 develop a learning network and to also potentially
6 work off of other work that is currently underway
7 at PCORI, particularly around the patient powered
8 research networks that you heard about earlier from
9 Joe.
10 So, at this point, I'm happy to take
11 questions. Thank you.
12 CHAIRMAN WASHINGTON: Christine, please.
13 MS. GOERTZ: Christine Goertz, Board
14 member and chair of the PDC. Just, again, we had a
15 very detailed -- well, a somewhat detailed
16 discussion about this yesterday at the PDC and we
17 were presented with four concepts for targeted PFAs
18 for our consideration and of those two, we felt
19 that two of them were ready to move forward and two
20 were not, and this was the other one that we felt
21 was ready to move forward.
22 CHAIRMAN WASHINGTON: Douma.

1 DR. DOUMA: Allen Douma, Board. This
2 comes out of my experience and shows somewhat how
3 old I am. Back in the early 80s I worked for the
4 AMA and one of my areas of responsibility was
5 doctor/patient communications, and we looked at
6 asthma, and there were studies going on in the
7 early 80s. My question is, when we do a review,
8 how far back do we go before we think something's
9 invalid?
10 DR. HASNIAN-WYNIA: In this case, we kept
11 it within about ten years.
12 DR. DOUMA: Okay, because there was a lot
13 of stuff going on before that.
14 DR. HASNIAN-WYNIA: Yeah.
15 CHAIRMAN WASHINGTON: Norquist?
16 DR. NORQUIST: Yeah, and maybe this is to
17 Christine and Romana, what I'm unclear about, you
18 said -- I mean, the first one we talked about, the
19 targeted, it was a little more -- we were coming
20 down to one specific. You're talking about eight
21 to ten questions, and so, you know, that implies a
22 smaller, I mean, the studies themselves may be

1 smaller. I mean, what specific topics out of all
2 of these did you guys narrow down? It might be
3 helpful because when I think about voting to move
4 forward, it would help me to know exactly what -- I
5 mean, instead of a broad concept, it sounds like
6 you narrowed this more, and I didn't hear that
7 actually when you said --
8 DR. HASNIAN-WYNIA: Yeah, so, what I
9 highlighted here were the five main gaps that were
10 identified by the workgroup. I mean, one pathway
11 for us would be to issue a funding announcement
12 that motivates all five gaps and request proposals
13 that addressed any one of them, and we can provide
14 sample questions. The other pathway, which I think
15 for a targeted funding announcement is more
16 appropriate, is to target maybe one to three gaps.
17 One of the things that I think is really
18 important to recognize is that the gaps that were
19 identified are interrelated, so communication
20 barriers and integration of care and systems are
21 highly interconnected.
22 One of the topics that did rise to the top

1 much more specifically was within the area of
2 response to therapy, so one of the questions that
3 many on the workgroup, and then we went back and
4 verified, that's much more specific is the question
5 of both modification and adapting the current
6 guidelines for asthma, which have been in place --
7 the NHLBI guidelines have been in place for 20
8 years.
9 There is still quite a bit of question
10 about the most effective ways for, particularly
11 clinicians, to enhance clinician implementation of
12 the guidelines. The question within the
13 disparities domain is not just the implementation
14 of the guidelines, but also the modification of the
15 current guidelines, which again may connect to some
16 of the other gaps that we've identified because
17 some of the barriers that we know are very, very
18 closely related to issues that were addressed in
19 the other gap around communication and integration.
20 DR. NORQUIST: Let me just push you a bit
21 on that. So, the issue is, is that the gaps are
22 broad concepts, and so if you go out and say, we

1 want funding announcements in the broad, you can
2 get a lot of very specific questions. If we're
3 going to really be targeted, as we say, we may want
4 to a priori say these are the very specific
5 questions that we want answered within integration
6 of care. I mean, this one first bullet here has
7 got tons of different research projects that could
8 be there. So, if you really want to be targeted,
9 you may say, these are the ones we're prioritizing
10 first, this is just advice, otherwise it sounds
11 like just a general funding announcement to me.
12 DR. HASNIAN-WYNIA: Right.
13 CHAIRMAN WASHINGTON: Add something?
14 DR. SELBY: Yeah, just to point out,
15 because this is the first time we've all been
16 through this, that we predicted and it came to pass
17 that out of the workgroups would come different
18 approaches to targeted funding announcements and
19 you heard a very specific study from Chad and you
20 did hear this idea of a portfolio study from
21 Romana.
22 I think we have had conversations,

1 including yesterday, that -- and I think your point
2 is a very good one, and I expect that we will
3 clarify a set of questions and say, we're
4 interested in proposals that address one or more of
5 these questions, because Romana says they're
6 related, but we will also craft language that says
7 -- and I'm not sure, Romana, if you've mentioned
8 the dollar amount yet. I don't believe I heard --
9 did you say that?
10 DR. HASNIAN-WYNIA: I did not. So, we
11 have $17 million for this particular targeted
12 funding announcement.
13 DR. SELBY: So that's the proposal on the
14 table, and the language will say that we have $17
15 million and it will not say that the upper limit is
16 $2 million.
17 So, we will be open to a smaller or larger
18 set of larger or smaller projects depending on how
19 the special emphasis panel that's convened with
20 patient stakeholders and asthma experts to review
21 these helps us prioritize them.
22 DR. NORQUIST: About that, say an issue

1 about that that worries me a little bit is if you
2 have a pot of money, and I can imagine several
3 studies that come in at $17 million, and then
4 you've got 10 that are at $2 million or something,
5 and then you better be sure how you're going to
6 make that selection because somebody come in with a
7 blockbuster study of $17 million on asthma
8 treatment and very specific, so I would just warn
9 you in advance, that could be a problem. I mean,
10 we ran into this all the time -- and I'm sure
11 Carolyn has run into this sometimes too with these
12 announcements, but I mean, just be aware, that
13 could be a big issue.
14 DR. SELBY: And we will have the usual,
15 you know, if your proposal is more than X amount, I
16 don't think we've actually settled on the amount
17 yet, but if it's bigger than a certain amount,
18 you've got to talk us in advance.
19 So, anybody that was permitted to submit a
20 $17 million application would have talked to us in
21 advance.
22 CHAIRMAN WASHINGTON: Joe, this point is

1 important because when we do vote, we're voting on
2 a portfolio of studies, and even though we don't
3 know the exact number, you're giving us a range of,
4 you know, six to eight or whatever the number is
5 going to be, I think it would be a different
6 conversation, although the outcome might be the
7 same, if we were talking about one study.
8 And so, let's acknowledge that we're
9 talking about here guidance that says you're going
10 to fund a portfolio of studies, and so we're not
11 voting on one for $17, just to clarify that
12 particular point. Good point, Norquist.
13 Yeah, Leah, please.
14 MS. HOLE-CURRY: Leah Hole-Curry, Board
15 member. I think this is along the same lines. The
16 gaps are significant and I think the group did a
17 great job of getting it to the five, but I think
18 for the purposes of what we had originally
19 anticipated for targeted funding announcements, we
20 should prioritize within those and select a few of
21 those gaps, and I don't know that we necessarily
22 have the knowledge to decide which ones, but using

1 the criteria that brought us here to begin with
2 might be the proper approach.
3 So, I don't know if that's necessarily a
4 actual amendment to the motion, but I think moving
5 forward on all five is counterproductive to the
6 targeted, even though we may eventually do that for
7 this round, I suggest a smaller group, and you all
8 could decide how to get to that group.
9 CHAIRMAN WASHINGTON: Good point. Epstein.
10 DR. EPSTEIN: Arnie Epstein, Board member.
11 I was on the PDC that discussed this yesterday. I
12 supported it then, I support it now. Truth and
13 consequences, I do want to say a word of what I
14 think we're getting and what we're not getting.
15 Having said I support this, which I do, this goes
16 against some of the criteria that I set up myself
17 personally for what I would support things for.
18 Number one, I wanted an important issue.
19 Number two is I wanted information to be lacking
20 that I thought would tell us what works better and
21 what doesn't. And number three was I wanted to
22 find some external shock to the system that

1 increased the probability in my mind that we could
2 discover something which had heretofore not been
3 discovered. And I'm not convinced that number
4 three holds here and I've watched this literature
5 closely for many years, and this is a very tough
6 nut to crack.
7 I can think of almost no articles that
8 have done this or studies that have done this, so
9 it's formidable. I support it, having said that,
10 because I've chatted with Romana and seen her
11 present, and it's clear to me that she understands
12 the issues really well and has -- is headed for the
13 right direction, and I can't think of anything
14 that's particularly more important or more in line
15 with what PCORI's objectives ought to be, so I'm
16 personally persuaded to move there.
17 I do take as friendly amendments the
18 caution that Gray and Leah have put up about maybe
19 we'll do better to concentrate further. I find
20 myself nodding when I hear them about that.
21 CHAIRMAN WASHINGTON: Thank you, Arnie. I
22 would expect that that particular criterion, his

1 last one, would weigh in your thinking as you're
2 deciding how you focus and prioritize among the
3 five areas.
4 DR. HASNIAN-WYNIA: Absolutely.
5 CHAIRMAN WASHINGTON: Levine, please.
6 DR. LEVINE: Sharon Levine, Board member.
7 Just a quick -- in the category of systems, there's
8 an awful lot of innovative thinking -- I'm not sure
9 how much work, but thinking, around the use of
10 mobile health technologies, particularly in hard to
11 reach populations, and I'm hoping that when you
12 describe systems you're including mobile health
13 technologies explicitly.
14 DR. HASNIAN-WYNIA: Yes and it came up
15 quite a bit during the discussion as well.
16 CHAIRMAN WASHINGTON: Okay, are we clear?
17 I know we are, but I was going to ask, are we clear
18 about what we're voting on? Okay.
19 Similar to our last discussion, you know
20 how we've arrived at this point now. We're really
21 looking at a proposal that's been endorsed by our
22 Program Development Committee, being brought forth

1 by staff to spend $17 million focused on this
2 particular targeted PFA in the area of asthma,
3 particularly as it relates to health disparities,
4 and in this case, the motion is calling for a PFA
5 focused on treatment options for severe asthma in
6 African-Americans and Latinos.
7 And you've seen the questions, you've seen
8 the background, you've heard the discussion. We're
9 going to, if we approve this, rely on the judgment
10 and expertise of not only our staff and PDC, but
11 others who have been engaged with us through our
12 workshops and our other expert groups to more
13 clearly define and prioritize how this would appear
14 in the public.
15 With that description as to what we're
16 voting on, all in favor moving forward?
17 DR. SELBY: Ask for a motion first.
18 Actually, formally call a motion.
19 CHAIRMAN WASHINGTON: Okay, somebody's
20 saying they want us to have an actual motion.
21 Okay, so --
22 UNIDENTIFIED BOARD MEMBER: So moved.

1 CHAIRMAN WASHINGTON: I have a motion.
2 UNIDENTIFIED BOARD MEMBER: Second.
3 CHAIRMAN WASHINGTON: Second. All in
4 favor?
5 [Show of hands.]
6 CHAIRMAN WASHINGTON: Okay. So, we have
7 17.
8 Francis, are you still on?
9 [No response.]
10 CHAIRMAN WASHINGTON: Francis has moved
11 on. That crying was just breaking him up. Okay,
12 all opposed? Any abstentions? Okay, motion
13 carries. Thank you.
14 Joe, we're at a point where it's after
15 noon, and I think we need to take a break or we're
16 going to take a break. Do you want to tell the
17 Board and the staff sort of how we might cover
18 these other topics that you wanted to cover today?
19 Or do you want to think about that over lunch and
20 we'll update people when we return?
21 DR. SELBY: Well, my motion would be to
22 try as best we can to make up time this afternoon,

1 but anticipating that we probably won't be able to,
2 I expect that we're going to go to 5:30 instead of
3 5:00.
4 CHAIRMAN WASHINGTON: Let's look at the
5 agenda.
6 DR. SELBY: But starting what -- when do
7 you want to return? An hour from now?
8 CHAIRMAN WASHINGTON: It's an hour from
9 now, which would give us 50 minutes about, that's
10 about right.
11 DR. SELBY: It's 12:15.
12 CHAIRMAN WASHINGTON: It's actually only
13 giving you 45 minutes, but we're behind, so we're
14 going to reconvene, but before we go, I really do
15 want to thank Romana for superb work and leadership
16 in bringing this forward, and likewise again to
17 Chad. Thank you. This is important stuff.
18 DR. SELBY: And thanks to David for
19 intending to present.
20 CHAIRMAN WASHINGTON: And for your
21 patience. So, we'll see everyone at 1 --
22 DR. SELBY: Gene, can I -- I have one very

1 brief correction to a slide I posted and something
2 I said earlier. There was a modest discrepancy in
3 the dates presented on the slide, and we will
4 correct the slides before they go up on our
5 website, but I want anybody who was listening to be
6 aware that -- and this is good news -- the letter
7 of intent deadline for the National Patient-
8 Centered Clinical Research Network is not June
9 14th, it's June 19th, so you have five more days to
10 deliberate on your letter of intent.
11 And the applications are due September
12 27th instead of September 23rd. This is all over
13 our website already, but just so we didn't create a
14 disparity, you have four more days to work on those
15 applications.
16 CHAIRMAN WASHINGTON: Okay. See you at
17 one o'clock.
18 [Whereupon, at 12:17 p.m., a luncheon
19 recess was taken.]
20
21
22

1 A F T E R N O O N S E S S I O N

2 [1:12 p.m.]

3 CHAIRMAN WASHINGTON: We're live. Good
4 afternoon everyone. Welcome back to this afternoon
5 session of the Board of Governors meeting for the
6 Patient-Centered Outcomes Research Institute.
7 We're now going to move into our next
8 topic, which is a discussion on the advisory panels
9 and we have Dr. Rachael Fleurence to introduce this
10 topic for discussion. Thank you.
11 DR. FLEURENCE: Thank you, Gene. So, I'm
12 going to be talking about the advisory panels that
13 took place April 19th and 20th in Alexandria,
14 Virginia.
15 We have some questions that we'd like you
16 to consider as I present, so asking you to think
17 about feedback on both the run of the advisory
18 panels and on the outcomes that we obtain from the
19 advisory panels, and then if you have any
20 recommendations for future advisory panel
21 activities.
22 So, just as a quick recap about the

1 advisory panels, they're authorized in PCORI's
2 authorizing legislation. The expert panels are
3 here to help us assist PCORI in achieving its
4 goals. Their purpose is to work with both PCORI
5 staff and the Board to identify research priorities
6 and topics, but also to provide input in other
7 activities such as patient engagement.
8 The framework and composition, they're
9 composed of 21 members and they each have a
10 charter, a term duration, and a clearly-defined
11 scope of work. The members were selected based on
12 their expertise and ability to contribute to the
13 work of the specific panels.
14 Just a quick reminder of where the
15 advisory panels fit into PCORI's overall structure,
16 so the advisory panels are set up to give advice
17 and to provide input. PCORI staff manage the day-
18 to-day activities of the panel and they also carry
19 out PCORI operations.
20 The Board of Governors provides overall
21 governance and insight and oversight and they
22 approve PCORI strategy and direction.

1 So, I'm going to provide you with a recap
2 of what happened on April 19th and 20th in
3 Virginia. We had three scientific advisory panels
4 meet, one was for assessment of options, one was
5 for improving health systems, and one was for
6 addressing disparities. We also had a patient
7 engagement panel as well.
8 The Scientific Advisory Panel has a number
9 of tasks. They are tasked with identifying and
10 prioritizing research topics within their area.
11 They're tasked with providing us with feedback on
12 specific research questions and possibly on study
13 designs, and then further down the road, they're
14 going to help us look at our research portfolio and
15 identify potential gaps, as well as consider study
16 findings and give us information on how to better
17 disseminate and implement research results.
18 The Patient Engagement Advisory Panel has
19 -- their role is to assure the highest patient
20 engagement standards and to help PCORI establish a
21 culture of patient-centeredness in all aspects of
22 its work.

1 The specific tasks of the Patient
2 Engagement Advisory Panel is to give us advice on
3 how to identify research topics that are important
4 to patients, but also to advise us generally on the
5 conduct and review of research, to advise us on how
6 to evaluate the impact of patient engagement in
7 research, and then generally to advise us on
8 communications, outreach, and dissemination with
9 that particular perspective of patient engagement.
10 So, the panelists were selected and came
11 to meet in person on April 19th and 20th. Prior to
12 the meeting itself, we did send them out some
13 materials and some orientation to PCORI. My
14 colleagues developed PCORI one-on-one training that
15 they took online prior to coming.
16 We had developed some research
17 prioritization training materials that they were
18 sent and they were able to read prior to coming to
19 the meeting, and then for the scientific panels,
20 they were all given between 10 and 20 topics to
21 review, and these topics were sent to them with
22 associated topic briefs using our five criteria for

1 research prioritization.
2 On the day itself, they were provided with
3 additional training in the morning on how to
4 conduct research prioritization, and then they
5 broke out into their specific groups for the next
6 day and a half in order to fulfill the tasks that
7 we'd asked them to do.
8 So, the patient engagement panel, which
9 was led by my colleague Sue Sheridan had a number
10 of outcomes on April 20th and they're listed on
11 this slide. Her panel started working on the
12 framework of their work plan for their patient
13 engagement panel. They also made suggestions to
14 improving the PCORI ambassador program and they're
15 in the engagement awards, and then they made
16 recommendations on how to enhance best practices
17 and meaningful patient engagement in research.
18 For the scientific panels, I'm going to
19 list for you the topics that came out as
20 priorities, so I'm starting with David Hickam's
21 panel, assessment of options. They were provided
22 with 20 topics to conduct prioritization on and

1 these are the four topics that came out ahead of
2 the pack.
3 The first one is research in ductal
4 carcinoma in situ, the second one is comparing
5 strategies for managing symptoms in osteoarthritis,
6 the next one is comparing treatments for migraine
7 headache in adults with episodic and chronic
8 migraine headaches, and then the last one was
9 comparing effectiveness of medication regimens in
10 adolescents and young adults with bipolar disorder.
11 So, this was the first scientific panel
12 assessment of options.
13 Moving on to the addressing disparities
14 panel, which was led by my colleagues Romana
15 Hasnian-Wynia and Adaeze Akamigbo. They had five
16 topics come out as high priority topics. The first
17 one is health communication associated with
18 competing treatments, so how to -- what are the
19 better communication models for patients and
20 clinicians to communicate risk to minority
21 populations.
22 The second one was heart attacks among

1 racial and ethnic minorities, so looking at the
2 intervention -- looking at different health
3 interventions to enhance the Million Hearts Program
4 and reduce major vascular events among racial and
5 ethnic minorities.
6 CHAIRMAN WASHINGTON: [Off microphone.]
7 DR. HASNIAN-WYNIA: Because it's about
8 communicating risk so that's how the link is --
9 about communicating risk.
10 VICE CHAIRMAN LIPSTEIN: [Off microphone]
11 -- come up from this panel at all?
12 DR. HASNIAN-WYNIA: Yes, it did.
13 VICE CHAIRMAN LIPSTEIN: Are we allowed to
14 ask questions? I don't know what, Gene, the
15 protocol here is.
16 CHAIRMAN WASHINGTON: Well, if you have a
17 question, a clarifying question about the slide,
18 yes.
19 VICE CHAIRMAN LIPSTEIN: So, people, when
20 you're addressing disparities, I just didn't see it
21 in the slide and maybe it came up in the
22 conversation, but people with resources have to

1 solve -- are able to solve problems differently
2 than people without resources. It's not here.
3 MS. FLEURENCE: It's not there, but it did
4 come up in the discussions. Yes.
5 VICE CHAIRMAN LIPSTEIN: Great. Thank
6 you.
7 MS. FLEURENCE: Yes, and we have longer
8 feedback on them, this is just a summary.
9 So, the next three topics that were
10 prioritized by the addressing disparities panel
11 were different delivery models for addressing
12 hypertension in minorities, interventions for
13 improving perinatal outcomes, and then
14 interventions to reduce lower extremity amputations
15 in minorities.
16 And then moving onto the last panel,
17 improving health systems that was led by my
18 colleague Chad Boult, so they came up with five
19 topics -- they prioritized five topics. So, models
20 of patient empowering care management, so looking
21 at the effects of care management on patients with
22 chronic or progressive conditions.

1 The second one was models of transitional
2 care, so looking at different models of
3 transitional care on patient safety and patient
4 outcomes. The third one was models of integration
5 of mental health care and primary care, so looking
6 at the effect of collocation of mental health
7 services and primary care.
8 The next were models of perinatal care, so
9 looking at the effects of care management on
10 pregnant and postpartum women. And then the final
11 one was looking at different features of health
12 insurance coverage, so the relative effects of
13 different insurance features, such as benefit
14 designs on chronically ill patients. I am finished
15 with the priority topics, and I just want to make
16 the point that this is informational to the Board,
17 so I will talk about what we're going to do with
18 these topics, but for now it's just letting you
19 know what the outcomes were of the panels.
20 VICE CHAIRMAN LIPSTEIN: So, I just want
21 to add to the information, because this one on
22 improving health systems was the one, in reviewing

1 the advanced materials, that I wanted to speak to
2 because this last one, for example, is one where
3 recently an article got written about BJC
4 Healthcare about changes to our insurance design
5 that we made to encourage wellness and prevention
6 and early detection screening, and we made those
7 changes in 2004 and the article was written based
8 on data from 2005. And we just hadn't changed much
9 in one year, and the article got published in 2013.
10 And so, part of the issue on this
11 particular one is that timing becomes a critical
12 issue in that it will take us a long time before we
13 realize the impact that changes in health insurance
14 design coverage, and I know that PCORI has an idea
15 that by 2017, we will show results. This is one
16 that's really hard to do.
17 There are immediate impacts on cost if
18 you're going to look at cost, but the immediate
19 impacts on health improvement, whether the patients
20 are chronically ill or whether the patients are
21 healthy, is really going to be -- there's a time
22 dimension here that we need to add to that

1 information.
2 So, that was one. And the second one is,
3 in order to get the attention of people who are
4 involved in improving healthcare delivery systems
5 right now, it's hard to get their attention around
6 things that don't have substantial cost attached to
7 them. I know we're not allowed to do that by
8 virtue of our statute on the one hand, on the other
9 hand, given the time that we are in that it's very
10 different from when the law was passed, which is,
11 we are looking at really substantial changes in the
12 financing as well as the delivery of healthcare
13 systems.
14 When we look at high priority topics, if
15 it's possible to look at one that has substantial
16 cost implications, either for the patient, which,
17 you know, we've talked about before, which is out-
18 of-pocket, cost sharing, or financial
19 responsibility after insurance, and the impact that
20 that has on outcomes, or to look at how we actually
21 can maintain outcomes in a more efficient way.
22 And it's just going to be very hard to get

1 the attention of the things that people out in the
2 delivery care sector really care about right now
3 and at the same time ignore dimensions of cost.
4 So, I just wanted to throw that out there.
5 I'm not trying to break the law and I'm hoping
6 nobody's going to come and put me -- are you going
7 to put me in jail? Oh, okay.
8 CHAIRMAN WASHINGTON: Okay. We appreciate
9 those comments. Why don't we, Rachael, if you
10 don't mind, field a few questions?
11 MS. FLEURENCE: Sure.
12 CHAIRMAN WASHINGTON: Starting with Douma
13 and work your way around, Kuntz and Sigal?
14 DR. DOUMA: Yeah, thank you very much,
15 Rachael. Allen Douma, Board. You, in one of your
16 earlier slides, indicated there was research
17 prioritization material that was sort of used as
18 training.
19 I know we've talked about that in the
20 historic past of this ancient organization. It
21 would be nice for me, at least, to be able to take
22 a look at that material.

1 MS. FLEURENCE: Absolutely, and it is
2 actually available on the website as well.
3 DR. DOUMA: Okay, if you could just point
4 me to where to find it.
5 MS. FLEURENCE: I will, yes.
6 DR. DOUMA: That would be great. I
7 appreciate that. You also talked about you gave
8 the group 20 topics to review?
9 MS. FLEURENCE: We gave the assessment of
10 options panel 20 topics.
11 DR. DOUMA: Right. Twenty topics.
12 MS. FLEURENCE: The others did --
13 DR. DOUMA: How did you select those 20
14 topics?
15 MS. FLEURENCE: So, these are the topics
16 that came through a number of sources, including
17 our webpage, including all the questions that were
18 prioritized for the targeted funding announcements,
19 so the questions from the IOM, from the AHRQ future
20 research needs reports --
21 DR. DOUMA: So there are a thousand of
22 them maybe.

1 MS. FLEURENCE: There were close to 1,600.
2 DR. DOUMA: You winnowed those down to 20?
3 MS. FLEURENCE: We winnowed these down to
4 20 using modified versions of our PCORI
5 prioritization criteria.
6 DR. DOUMA: Okay. Yeoman's effort. Then
7 you're going to talk about later about kind of
8 what's next after --
9 MS. FLEURENCE: The next slide is the
10 timeline. Yes.
11 CHAIRMAN WASHINGTON: Rick.
12 DR. KUNTZ: Rick Kuntz, Board member.
13 These are great topics. I kind of wanted to know
14 where in the sequence you are. These are really
15 complicated things to study. They're highly
16 confounded. Whereas picking dimensions like the
17 healthcare system or something and trying to
18 isolate that as a factor when there are a lot of
19 clear confounders associated with the outcomes of
20 patients who are actually in those systems. Are
21 you going to -- if we agree that this is where to
22 go, are you going to drill down to a more

1 methodological question to guide researchers?
2 Because I think this is too broad to ask
3 researchers to answer personally.
4 MS. FLEURENCE: So, the next steps are for
5 our program leads are going to look more in detail
6 at these questions and commission landscape
7 reviews, so do some real homework over the summer
8 on exactly what you're speaking about, and I'll
9 show in the next slide the timeline. Then they'll
10 come back to the Board with the topics that they
11 think are ready for targeted funding announcements.
12 DR. KUNTZ: Well, I was specifically
13 thinking about the fact that this is the most
14 complicated research -- observational research on
15 complicated systems, and there's been a lot of
16 research on this that doesn't get answers. So, are
17 we going to really heavily engage the Methodology
18 Committee to help really direct questions about
19 this? Because I think that's the best way to
20 leverage the Methodology Committee because I just
21 think that the analysis of systems themselves
22 through an observational process, 90 percent of the

1 challenge is the methods.

2 MS. FLEURENCE: Thank you.

3 CHAIRMAN WASHINGTON: Norquist and then

4 Sigal.

5 DR. NORQUIST: [Off microphone.]

6 MS. SIGAL: That's okay. Ellen Sigal,

7 Board. So, Rachael, nice work. So, a question, I

8 think all of these topics are important, a little

9 bit about the process and the -- okay, usually I

10 can be heard.

11 Okay, so a question about the topics and

12 the prioritization. So, a while ago, through the

13 IOM and after the cancer community worked on

14 priority topics, and maybe even Ethan Basch can

15 help me, but the -- and it's not that this topic

16 isn't important, it is important, but it seemed

17 to -- in our ranking it was in the last quartile of

18 feasible projects, and I can't remember exactly

19 why. It could have been because there was a lot

20 going on, on the subject.

21 So, I guess the issue that I'm trying to

22 raise is, it is important, but if we were to get

1 experts in this area or oncologists or people that
2 are really in the field, you perhaps would come up
3 with a different ranking. So, how do we adjust for
4 that, because the legislation calls for advisory
5 panels but it also calls for expert panels and I
6 would bet, if you had given five or ten other
7 priorities in cancer you probably, at this point,
8 may not have come up with this? So, how do we
9 adjust for that?
10 MS. FLEURENCE: This was our first sort of
11 round of working with the questions that we had. I
12 think we're certainly planning on doing more rounds
13 and I think that as we get feedback we will, I
14 think, we'll make changes to the process in order
15 to accommodate comments that you've just made.
16 MS. SIGAL: Well, I just think it's very
17 important, as we get into a specific disease
18 setting, that we start to then go to the people
19 that are really expert in that setting to see
20 what's going on and what the opportunities are.
21 MS. FLEURENCE: So, one thing that we will
22 be doing is commissioning these landscape reviews,

1 but on the topics that have already been chosen,
2 and I think we'll have to have further discussions
3 on how to expand to the expert communities where we
4 feel maybe that we haven't captured exactly all the
5 right questions.
6 MS. SIGAL: So, just one other point and
7 I'll let others speak. The problem with that is we
8 may consume a huge amount of time and then go to
9 the experts and they say there's 25 or 50 studies
10 on this, and there are other opportunities. So,
11 how do we adjust for that, you know, earlier?
12 DR. NORQUIST: Gray Norquist, Board. I'll
13 just follow up on that because this is exactly the
14 thing -- I mean, I looked at the two mental health
15 topics, one of which we supported a research trial
16 when I was at the NIMH on bipolar, I just did -- I
17 can save you the trouble of a landscape review. I
18 just wrote a chapter that reviewed all the research
19 on integration and mental health in primary care,
20 including a recent Cochran review.
21 So, there are topics -- and I agree with
22 Ellen, I think -- I just worry about the process is

1 that if you ask a bunch of people what are the big
2 topics, they'll give you a list, and then you're
3 going to have to -- and I wonder if we go back to
4 kind of what Harlan is thinking is if we have this
5 idea about what do we think are the big ones who
6 are really going to make a change and it's really
7 going to make a difference and then start from that
8 perspective and start to narrow down, then we'll
9 save a lot of work, because I'm afraid you're going
10 to get into a bunch of -- you're going to do a lot
11 of landscape reviews, come back -- I mean, I don't
12 know. Maybe I'm wrong about that, but just another
13 way to kind of look at how to pick the topics here.
14 MS. FLEURENCE: So, as part of the
15 background work that we did do for the panels, we
16 prepared topic briefs using our criteria and one of
17 the criteria is feasibility of implementation,
18 feasibility about what's already known on the
19 topic, so we did do some of the work that you're
20 describing just to sort of make sure, but in the
21 time that we had, we weren't able to do sort of a
22 full systematic review on any of these topics.

1 But I think we're learning as we're going
2 and both your points are well taken that we need to
3 sort of make sure that the process can answer these
4 concerns.
5 CHAIRMAN WASHINGTON: Joe, you want to
6 comment on that question please?
7 DR. SELBY: Yeah, this goes back actually
8 to a bit of a discussion we were having earlier
9 today too, but I think it is really the -- it's an
10 essential question for PCORI and for its identity
11 how we blend this -- these expert advisory groups,
12 and so these are people, researchers, systems
13 leaders, clinicians, patients with special
14 interests in these areas, so it's a remarkable
15 resource, how we blend the questions that come into
16 us through all the channels that we've described
17 with the sudden great idea that may come up in a
18 meeting here or it may come up through an e-mail
19 between Board members or it may come up from one of
20 the advisory panel members, and so that's, I think,
21 what we are working on now.
22 I really like Gray's idea of over time

1 putting more of the landscaping work up before the
2 prioritization process rather than, as we did it
3 this time, a portion of the work up front, but
4 leaving broad questions that we then now go out and
5 do another landscape review on. So, I think that
6 prioritization work actually goes better when the
7 questions are more specific.
8 So, I agree with Gray that doing more of
9 the really -- you know, the honing in on the right
10 question and questions that we feel strongly about,
11 before we get to the prioritization process, and
12 really just picking from refined questions, will be
13 an advance over what we've done the first time even
14 though I think these are compelling topics and the
15 discussions that led to them were quite amazing.
16 CHAIRMAN WASHINGTON: Joe, I think it's a
17 question of sensitivity versus specificity and how
18 much we're willing to pay for that extra
19 sensitivity because there is an argument to be said
20 that, you know, this broader group of experts
21 actually might have, you know, a deeper reservoir
22 of knowledge and more breadth of experience than

1 this small group of us trying to hone it down. So,
2 I understand the question of efficiency, but I
3 would also urge us to weight, you know, what we're
4 giving up when we define what the focus areas are
5 through our landscapes up front before we go out to
6 a broader group, and so I don't think it's as
7 straightforward as jumping from one to the other.
8 DR. SELBY: No, it's a blend, it's
9 blending the strengths of each and recognizing that
10 a great question can, in fact, come from anywhere.
11 CHAIRMAN WASHINGTON: Right. Okay. I'll
12 work around, we have Levine and then we have
13 Weisman and then we have Gabriel.
14 DR. LEVINE: Rachael, yesterday in our
15 joint COC-PDC meeting, we had a fair amount of
16 conversation about what was categorized on that
17 slide as incentives in the system, and one of the
18 things that we've said from the beginning is we're
19 not going to fund research that others are likely
20 to do or are doing, and I think on this issue of
21 health insurance coverage, benefit design, and
22 incentives, there's a tremendous amount of work

1 going on by people who've been doing this work for
2 a long time.
3 So, before we commit to something like
4 this, I think we need to be really careful that
5 it's something unique that we can do that would not
6 come up or come out of research that's already
7 being done given that we're in a period of rapid
8 transition around payment designs, incentives, and
9 benefit design.
10 CHAIRMAN WASHINGTON: Okay. And before I
11 go to Weisman, just a question. When I go back to
12 your -- about PCORI roles and you have advisory
13 panels, the staff, Board of Governors, I mean, it's
14 very clearly laid out, what's the role of the
15 committee structure in this process? I know the
16 committees are committees of PCORI, but in contrast
17 it sounds like you've had experts with the staff
18 and now you're coming to the Board. Understand
19 this is really information and it's much earlier on
20 than where we just were a few minutes ago in terms
21 of recommendation.
22 But in that case, it had benefitted from

1 an in depth discussion, you know, at another level
2 of the Board before it came to this Board, and so,
3 something to think about in terms of us benefitting
4 from that expertise, including Methodology, by the
5 time it comes to the Board.
6 I appreciate that you're coming very early
7 on, but much of this may have sort of -- at least
8 you'd have more to say, well, this is what the PDC
9 or the Methodology thought about these two
10 different approaches.
11 DR. SELBY: And the only -- just as Sharon
12 just offered some cogent comments on that fourth
13 one, I think that kind of input at this stage is
14 useful to us in deciding whether there's a reason
15 maybe not to move forward with the landscape
16 review. And I think actually we do -- I completely
17 agree with you, Gene, we need to work out how we
18 pull the committees in, including the Methodology
19 Committee, and at what point we do what we did this
20 morning, which was approve a topic.
21 MR. BARNETT: So, just clarification, so,
22 to be clear, these aren't recommendations being

1 made to the Board.
2 CHAIRMAN WASHINGTON: No.
3 MR. BARNETT: This is just sort of a
4 report on what we heard from the advisory
5 committees, so there's still a lot of subsequent
6 steps before these turn into any sort of a
7 recommendation.
8 DR. SELBY: Right. Likely some -- most,
9 if not all of these, that we've shown, will get
10 some sort of a landscape assessment, and then the
11 decision would be whether to bring them here.
12 MR. BECKER: So, can I comment on Sharon's
13 -- just build on it for a second?
14 CHAIRMAN WASHINGTON: Okay.
15 MR. BECKER: So, before we did anything,
16 the one other thing I would do if you're going to
17 go after health insurance coverage and benefit
18 design, is I'd link in with somebody by the name of
19 Suzanne Delbanco, who's running the Catalyst for
20 Payment Reform, and I think she's done a whole lot
21 of this landscape reviewing of what's out there and
22 she has lots of people inputting to her.

1 CHAIRMAN WASHINGTON: Okay, thanks.
2 [Off microphone.]
3 DR. WEISMAN: So, you know, I've been
4 reflecting a lot on the day and this specific
5 topic. Gail asked me how I was feeling and I said
6 me, or about the meeting, and she meant about the
7 meeting. But I said, look, I'm unsettled about
8 something and I think what it is, is that some of
9 these issues, to me, don't seem to be issues of
10 facts. I mean, it does seem that -- so, integrated
11 care, in which there's continuity of management,
12 aligned incentives that are in the patient's
13 interest, you know, transitional -- better
14 transitional communication between teams, that's
15 sort of mom and apple pie, and we can do the
16 studies and maybe we discover what people already
17 know about these topics, and somehow we feel that
18 by us doing it, and by us disseminating it, it's
19 going to make it stick.
20 And I just wonder whether we're not going
21 after the underlying causal factors. What I'm
22 saying is true with almost all chronic conditions.

1 Now, seems to me the factual questions are easiest
2 around acute care, you know, whether in somebody
3 who has brain trauma, you know, what type of
4 decompression actually is more effective than
5 another one. That's sort of a factual thing that
6 maybe people don't know, or treatment of a patient
7 with acute myocardial infarction, is it this type
8 of cure versus that type of cure, or is it
9 hypothermia during some types of surgery -- those
10 are factual things that could be determined acutely
11 and fairly short time span.
12 I mean, basically, we have a sort of
13 messed up health system that's fragmented, that
14 doesn't have continuity, that doesn't have a lot of
15 things, and I think people know that -- I mean,
16 some of this is common sense, maybe some of it
17 needs to be tested. I would imagine, just based on
18 what I know about healthcare systems and seeing
19 ones that work very effectively and those that
20 improve their outcomes, they've done their own
21 tests, they've looked at before and after and shown
22 they've had marked improvements of, say, outcomes

1 on delivery and so forth when there's good prenatal
2 care, they've had great improvements in diabetes
3 management when they spend more time engaging the
4 patients using health workers besides
5 endocrinologists involved in some kind of
6 integrated -- we know that, but it's not being
7 done.
8 A lot of the problems, whether it's on the
9 patient's side, the doctor's side, the hospital
10 side, the coverage side, is there are -- it goes
11 back to what I said earlier, there are changes that
12 need to occur that are so deeply engrained that
13 piling more facts and throwing more facts and
14 findings, p-values, I don't think is going to have
15 any more impact than it already has in some of
16 these situations, and I wonder whether it's worth
17 us really seeing what are the true barriers to
18 improvements and is it lack of data about that,
19 about the specific intervention, or is it
20 behavioral impediments, disincentives for doing the
21 right thing? I don't know what it is. I don't
22 know what that problem is. I just worry we're

1 going to have a pile of new data and we're not
2 going to make that much difference unless we pick
3 things where there really is, in a landscape
4 review, no information available and we're really
5 going to add something, and I suspect -- you don't
6 usually ask a patient who's comatose what their --
7 to give their buy in and their opinions about the
8 kind of care and what options they want to choose,
9 because it's acute and you've got to do something.
10 And, you know, sometimes we've got to know more
11 facts there.
12 It's really chronic disease, and I just
13 wonder whether -- how much of it is lack of
14 information versus lack of putting it into effect?
15 And why isn't it? Why are guidelines not followed?
16 We don't need to issue more guidelines. Why isn't
17 it that people aren't doing what we already know
18 they ought to be doing?
19 I love the topics though, but I'm not -- I
20 don't think our approach of getting more -- doing
21 more randomized studies is actually going to answer
22 this -- is going to have the impact we want it to.

1 CHAIRMAN WASHINGTON: Okay, thanks,
2 Harlan. Gabriel and then Norquist. No, he came up
3 later. So, he's on the next round going around.
4 DR. GABRIEL: So, okay. So, you'll be
5 both first and last, Allen, right? Sherine
6 Gabriel, Methodology Committee. This discussion
7 reminds me a little bit of the discussion we had
8 earlier about targeting and really underscores the
9 importance of being both strategic and transparent
10 in those topics that we target for our targeted
11 PFAs because, you know, at the end of the day we're
12 putting all of our eggs in fewer baskets, I guess.
13 So, what I'm going to suggest is that we
14 bring back to the Board, and really to the public,
15 a discussion of the process, because I agree, these
16 are terrific topics, but I'm not sure there aren't
17 six or eight other equally terrific topics out
18 there, and I don't know enough about the process to
19 say, oh yeah, I believe in the process so that I
20 believe in the outcome.
21 So, maybe a full discussion -- full and
22 open discussion of the process of how you get from

1 here to there, generic discussion, might be useful.
2 CHAIRMAN WASHINGTON: And could I suggest
3 that the Methodology Committee, particularly in
4 response to our current deliberations about what
5 new roles and/or activity the committee is going to
6 take on, weigh in on this? Because this is about a
7 method, you know. We use the word process, but
8 it's about method about prioritizing or selecting
9 where we're going to focus going forward.
10 So, Joe and I were agreeing with your
11 comment that we need to find a way to bring it
12 forward.
13 DR. GABRIEL: Yeah, no, I think that's
14 right. And we're going to be working, yay, more
15 closely with Rachael, so that will be a nice tie-
16 in.
17 MS. FLEURENCE: I mean, I do want to say
18 that we do have a description on the website, so
19 it's publically available how we got down to what
20 we did. And so there is some information
21 available, but I'd be happy to report back on it.
22 CHAIRMAN WASHINGTON: Okay. Norquist.

1 DR. NORQUIST: Real quick. I mean, I would
2 second that because there are ways of getting to a
3 number from different ways, and do you narrow down
4 in appropriate ways, because the Methodology, which
5 is very good -- I just want to raise one thing as
6 we think about priorities. One category -- I mean,
7 one criteria we haven't thought about is, given a
8 timeline, how quickly -- because having launched a
9 lot of CER studies myself and seeing them take
10 eight years and whatever, it sure would be nice to
11 think, also, if we've got a high priority topic,
12 something is already -- an infrastructure is in
13 place, if we could add onto that. So, I think at
14 some point we really seriously need to know from a
15 landscape review what exists in a topic area that
16 we might quickly, with some infusions of funds, put
17 into and move something very quickly, and that
18 might put something up a little higher on the
19 priority list than -- it might be the big question,
20 do you know what I mean?
21 MS. FLEURENCE: I do and one of our
22 criteria is duration of information where we take

1 into account sort of how quickly we might be able
2 to produce results, so that would fit into that
3 nicely.
4 DR. NORQUIST: But I'm thinking it's like,
5 go out there to the foundations, NIH, others, and
6 say, what's already in existence? What are you
7 getting ready to shut down but that we might be
8 able to add on to or run on very quickly and get
9 [turned off his microphone mid-sentence].
10 CHAIRMAN WASHINGTON: Hole-Curry and then
11 Zwolak and Douma.
12 MS. HOLE-CURRY: Leah Hole-Curry, Board
13 member. I think Gray's point was the one that I
14 was going to raise, just related to this, and as
15 you move forward with the landscape reviews in
16 really not only identifying the current state of
17 the evidence, but what's in process, and maybe the
18 reach out would be new to certain funders that
19 maybe are getting underway with studies, so CMMI
20 around this last one about health insurance
21 coverage. While there might be a lot of studies,
22 maybe they're mostly focused on what the cost

1 outcomes are versus the outcomes on a patient that
2 we would want to add and fund that component of it,
3 just as an example.
4 So, when you're thinking about the
5 landscape reviews, some additional questions about
6 how we might strategically partner around some of
7 these priority topics.
8 DR. KRUMHOLZ: Can I -- just on top of
9 this?
10 CHAIRMAN WASHINGTON: Please.
11 DR. KRUMHOLZ: Just to say that a lot of
12 people who've received CMMI money, including $10,
13 20, 30 million to do these demonstrations, told me
14 that they've pulled all the evaluation out of the
15 money so that many of them, and I know Joe's aware
16 of this, are desperate for this kind of leverage,
17 and so I think it's a good point that you're
18 making.
19 DR. SELBY: And especially for any look at
20 what we would call patient-centered outcomes,
21 right, I mean, there's a certain amount to look at
22 cost savings and changes in utilization, but

1 nothing about how it affected the patients. And
2 that's from CMMI, they say that.
3 CHAIRMAN WASHINGTON: Zwolak and Douma.
4 DR. ZWOLAK: Bob Zwolak, Board member. My
5 comments build on what just had been said. I think
6 it's treacherous to dive into healthcare system
7 improvement because it's a pretty busy space, but
8 from my perspective, what PCORI could offer is, I
9 think, what a lot of these other evaluations are
10 missing is the patient, what happens to the patient
11 in all of these things, and I think it's a fabulous
12 opportunity, if we really work at it, to apply not
13 just the PCORI sauce, but maybe double sauce or
14 triple sauce, because I think many of these
15 evaluations, the ACO projects and the high value
16 projects, are really potentially overlooking what
17 happens to the person and the patient.
18 CHAIRMAN WASHINGTON: Is that ultra PCORI
19 sauce, the super PCORI sauce?
20 DR. ZWOLAK: [Off microphone.]
21 CHAIRMAN WASHINGTON: Okay. Hot PCORI
22 sauce. Okay, Douma.

1 DR. DOUMA: Thank you. This is really a
2 process question, but I put a little context, and
3 follows on a couple of other folks looking at the
4 topics that were selected, and I'll just pick the
5 one which is models of patient empowering care
6 management.
7 Out there in the world, a lot of study
8 going on in that -- ACOs, medical homes, in Oregon
9 CCOs, we call them, so there's a lot of activity.
10 My question is, was that presented to the Advisory
11 Board, say there's a whole lot of activity going on
12 out here, do you still want to choose it?
13 MS. FLEURENCE: So, we did do some brief
14 homework on each of these topics and able to
15 present ongoing -- and part of the task was to
16 present ongoing research. So, the panels would
17 have received a certain amount of information on
18 ongoing research in each of these topics.
19 DR. DOUMA: But they then had to make a
20 decision to still choose that topic?
21 MS. FLEURENCE: Then they had to decide
22 whether, according to all our criteria, this --

1 they still thought that for PCORI to put money into
2 that topic was still valuable, and in this case
3 they came out saying that they did.
4 DR. DOUMA: Okay. That dynamic is
5 intriguing.
6 CHAIRMAN WASHINGTON: Okay. Thanks,
7 everyone, for your informative comments and
8 suggestions.
9 Rachael, I notice we have the table, but
10 I'd ask you not to spend much time on this. I
11 mean, we pretty much covered it. I do have a
12 question. Landscape reviews in general, what's the
13 cost range, so we have some sense, of what kind of
14 expenditure we're talking about here?
15 MS. FLEURENCE: I'm not sure I know the
16 answer to that.
17 DR. SELBY: Let me just ask if any of the
18 program directors want to weigh in on this from any
19 experience you've had up to this point. Romana?
20 DR. HASNIAN-WYNIA: [Off microphone.]
21 CHAIRMAN WASHINGTON: Okay.
22 DR. HASNIAN-WYNIA: [Off microphone.]

1 So, the cost would go up for additional
2 data [inaudible].
3 CHAIRMAN WASHINGTON: Right, but that
4 gives us -- we're not talking about hundreds of
5 thousands of dollars and we're not talking about a
6 million dollars for a landscape review. Okay,
7 Harlan.
8 DR. WEISMAN: Really, it's just a sense,
9 it's not -- I'm coming out of my funk. To me the
10 question is, if not for us, this difference that
11 needs to occur would not have occurred. And that's
12 what's really not clear to me on any of these. It
13 may be that just because a lot of other
14 organizations are studying something doesn't mean
15 it's going to drive what we believe is needed to
16 get to our vision.
17 So, I would love to know the answer to
18 that. What is it that we're going to do, because
19 we've used the triple sauce or whatever it is, that
20 others aren't doing that will make a big difference
21 that otherwise would not have occurred had it not
22 been for PCORI?

1 CHAIRMAN WASHINGTON: Okay, that's yet
2 another criterion that you will incorporate into
3 your thinking and decision making. Okay, Rachael?
4 MS. FLEURENCE: Okay.
5 CHAIRMAN WASHINGTON: Mr. Vice Chair.
6 VICE CHAIRMAN LIPSTEIN: Gene, one of the
7 things that this brings up when you think about
8 picking one to five topics per program area that
9 come out from the advisory panels is, does the
10 Board -- the Board's never done this, the Board's
11 never, at least to my knowledge, we've never sat
12 there and said, what are the one to five areas that
13 we would like landscape reviews performed on, you
14 know, almost as if we were an advisory panel?
15 Because these advisory panels are advisory to
16 staff, but they're also advisory to us.
17 But it might be useful at a next meeting
18 if we could carve out a couple hours and say, okay,
19 if we were an advisory panel, the Board, what would
20 we want staff to do five landscape reviews -- what
21 topic areas would we want landscape reviews
22 conducted on?

1 And maybe those five areas turn out to be
2 what Dr. Krumholz refers to as a -- as the big
3 rocks, but he's thinking of a different kind of a -
4 - you know, other topics we've yet to get to.
5 I'd kind of think it would be fun for us
6 to be an advisory panel to ourselves for a couple
7 hours.
8 CHAIRMAN WASHINGTON: Okay, I'd have to
9 speak with Larry Becker about the potential
10 conflict of interest there, but we have it on the
11 table now. Kerry?
12 MR. BARNETT: Well, I like that idea, in
13 part, because what it would do is it would help
14 refine the advisory committee process by forcing us
15 to sort of go through it, and so the question that
16 I was actually going to ask Rachael is, now having
17 been through this, not for a complete cycle, but
18 for a significant portion of it, are there things
19 that you would change about the process? Do we
20 have the right people on the advisory panels? You
21 know, when you empanel a body like that, one of the
22 most critical pieces is to make sure that we're

1 getting the assignment right to them, that they're
2 not kind of all approaching it from a different
3 angle.
4 So, as you kind of think about it now
5 having been through this once, are there any
6 adjustments that are worth making?
7 MS. FLEURENCE: Well, I actually think
8 that bringing the different stakeholders together
9 is enriching the process because they do share all
10 the different perspectives and they have a really
11 rich discussion, and the discussion is structured
12 according to our criteria.
13 So, I didn't go over our criteria again,
14 but they are patient-centeredness, they're about
15 what we currently know is -- is it going to be
16 implementable in practice, what's the duration of
17 the study?
18 So, we had them talk about really
19 important criteria to PCORI's mission in a
20 structured way, and that's new about how we do
21 research prioritization.
22 I think part of the improvement to the

1 process is making sure we start off with a good set
2 of questions. So, we don't have the universe of
3 good questions out there yet and I think that's
4 going to be part of the improvement is making sure
5 that we start with a good bucket of questions.
6 I think the process with the panels was a
7 really rich and good process.
8 MR. BARNETT: The only final comment that
9 I'd like to make on this is just a reminder to all
10 of us that what comes out of this process is sort
11 of, I think, a very useful set of new data points
12 for staff and for us to consider, and we have to be
13 careful about treating them as if it's a kind of a
14 set of recommendations that we then jump in and
15 critique. I think we have to think about it as
16 sort of useful input, as all of us figure out the
17 right direction.
18 The fact that the advisory panels told us
19 A, B, and C, isn't something that we want to push
20 back on, it's something that we want to help shape
21 and mold as we move forward.
22 CHAIRMAN WASHINGTON: Okay, this -- again,

1 these have been great comments, and so it
2 underscores the interest that the Board has in
3 this, but I also want to emphasize for the Board
4 that this is not a fixed process, and so Joe and
5 Rachael and the staff will be incorporating this
6 and Steve, we will plan to have some time for the
7 Board to serve in that kind of capacity, really, at
8 the next meeting if not before. I think that's an
9 excellent suggestion.
10 And I would just underscore the last point
11 that was made regarding at the end of the day, one
12 of the screens being, what is PCORI going to add
13 that no one else would have contributed? What
14 really distinguishes what we're doing here from
15 what's being done anywhere else? And what,
16 ultimately, is the impact, in terms of two of the
17 criteria that the other Harlan mentioned earlier
18 regarding how is it going to reshape practice
19 and/or improve outcomes? So, just weigh those as
20 considerations from the Board.
21 And I know -- yeah, there's a question
22 here that we need to vote on.

1 MS. FLEURENCE: That's correct. So, we're
2 requesting a minor modification to the charters of
3 the four advisory panels, and this is simply to
4 include the possibility of having a co-chair on the
5 panels. So, currently the charter only allows for
6 the selection of one chair, and so, if we were to -
7 - if you were to vote to allow for the selection of
8 a co-chair, we'd have to amend the four advisory
9 panel charters, and this is what it would look like
10 in terms of changing the language.
11 So, the changes are in red. There would
12 be two changes. So, one would be saying "a
13 chairperson and a co-chairperson if desired", and
14 then the second amendment would be modifying the --
15 for modifying the stipend, the compensation, where
16 we would add the co-chairperson in there as well.
17 CHAIRMAN WASHINGTON: So I see -- I have
18 one question. Why wouldn't we -- if we vote for a
19 co-chair, why wouldn't we have a co-chair? So, the
20 question is, why would we add the language "if
21 desired"?
22 DR. SELBY: I think we just wanted to

1 leave for future panels the choice.

2 CHAIRMAN WASHINGTON: It's optional.

3 DR. SELBY: Yeah, that's all we meant.

4 The previous charter just called for a chairperson.

5 We didn't feel that we needed to go all the way to

6 requiring a co-chairperson in every case, but we

7 wanted to make it clear that such a person could be

8 appointed.

9 If the Board feels strongly that we should

10 insist on a co-chairperson in every case, I don't

11 think we're opposed to that either, but we thought

12 we'd leave it up to the individual panels.

13 CHAIRMAN WASHINGTON: I'm asking in terms

14 of symmetry across these, and importance, are we,

15 in fact, somehow signifying that when you're on a

16 panel and it's just a chair, that he or she has

17 more authority than a panel that's got a chair and

18 a co-chair?

19 DR. SELBY: No, I think we're only saying

20 that, to some extent, we respect the autonomy of

21 the panel to make that decision. That's all -- it

22 doesn't reflect a value or preference from our

1 point of view.
2 CHAIRMAN WASHINGTON: Okay. Who appoints
3 the chair?
4 DR. SELBY: The Board.
5 CHAIRMAN WASHINGTON: If the Board
6 appoints the chair, then we're not leaving it up to
7 the panel to decide whether or not there's a co-
8 chair. That's all I'm getting at. And so, I'm
9 just trying to understand the circumstances under
10 which we would have a chair versus a co-chair, and
11 if we don't have those kind of circumstance -- I'm
12 just raising, why do we set up the latitude? We're
13 appointing the chair and we're appointing the
14 leadership.
15 DR. SELBY: I think the Board can vote to
16 go that direction. In point of fact, all four
17 committees concluded that they wanted a co-chair as
18 well, so there could never --
19 MS. FLEURENCE: There will be more panels,
20 though, set up.
21 DR. SELBY: There will be future advisory
22 panels. So, I don't see a big -- any constraint.

1 MR. BARNETT: I think the only reason why
2 we're discussing this is because the charters
3 themselves used the word "chair" instead of "co-
4 chair."
5 DR. SELBY: No, there was a chair, now
6 we're saying there will be a chair and a co-chair.
7 MR. BARNETT: Not two co-chairs.
8 DR. SELBY: There may be a co-chair along
9 with the chair. It's not two co-chairs, it's a
10 chairperson and, if desired, a co-chairperson. But
11 one person is the chair.
12 MR. BARNETT: And the co-chair is somehow
13 less than the chair?
14 DR. SELBY: It's quite a bit like the
15 Board of Governors of the Patient-Centered Outcomes
16 Research Institute or the Methodology Committee.
17 MR. BARNETT: We don't have co-chairs.
18 DR. SELBY: We have chair --
19 MR. BARNETT: We have a chair and a vice
20 chair.
21 DR. SELBY: Okay, well, I think we're
22 using the word --

1 MR. BARNETT: Is that what we're talking
2 about?
3 DR. SELBY: We're using the word co-chair
4 like vice chair, but we're saying chair and co-
5 chair.
6 CHAIRMAN WASHINGTON: No, no, no. If you
7 look in the Institute of Medicine reports and our
8 many, many governing bodies, there's a chair and a
9 co-chair and it's clear what that means, that's
10 right, it's a PI and a co-PI, and what it says --
11 really, what you're doing is giving the second
12 person a little higher order title and it really
13 promotes more engagement than being just a vice.
14 But it's a big difference between the
15 chair and the co-chair, and so --
16 UNIDENTIFIED BOARD MEMBER: [Off
17 microphone.]
18 DR. SELBY: No, but I can imagine that
19 there could be a panel who just, considering the
20 people who were on the panel, they felt that there
21 was an obvious chair and there was not an obvious
22 co-chair, so they didn't vote to appoint one.

1 Imagine a five- or six-person panel. I
2 think it's unlikely. I think most, when faced with
3 the choice, would probably say yes to the type of
4 co-chair.
5 CHAIRMAN WASHINGTON: Except for the only
6 part I'm not understanding, Joe, is we're
7 appointing the chair.
8 DR. SELBY: Yes.
9 CHAIRMAN WASHINGTON: So, the co-chair
10 would be appointed at the same time?
11 DR. SELBY: Yes.
12 CHAIRMAN WASHINGTON: But the panel
13 wouldn't be weighing in on it.
14 DR. SELBY: Well, the panel is sending us
15 suggestions. You'll see in closed session
16 tomorrow, because this is a personnel issue, you
17 will see that the panel is forwarding to us
18 nominations that actually come from, among other
19 things, polling panel members or soliciting
20 nominations from panel members.
21 And from those panels came nominations for
22 chair and a request for co-chairs as well.

1 CHAIRMAN WASHINGTON: Okay. By the way,
2 I'm okay with the language. I was just -- no, I
3 wanted to understand why.
4 So, is there a motion?
5 MS. SIGAL: A quick question please. So,
6 I really would like to have a vote and I'm okay
7 with it, but I don't understand the 1,500 to 2,000.
8 How many -- that's -- if they're meeting a lot and
9 putting a lot of time and energy in it, it seems
10 that that may not be enough. I don't know. I
11 mean, I don't know how we decided on that, but if
12 they're meeting multiple times a year and spending
13 a huge amount of time on it, I don't know how -- I
14 can't remember how we came up with that number.
15 CHAIRMAN WASHINGTON: It's a stipend.
16 MS. SIGAL: It's a stipend, but it's a
17 stipend for, what, five days? Eight days? Ten
18 days?
19 DR. SELBY: The exact number of days
20 hasn't been nailed down yet, but it looks like
21 they'll meet three, conceivably four, but probably
22 more like three times a year, like every four

1 months, and I think most of the meetings will be a
2 day now. The first one was basically two days.
3 MS. SIGAL: I mean, I know people are not
4 doing this for money, but there may, if there's a
5 lot of work between meetings and a lot of stuff
6 they have to do, it may not be sufficient. So, I
7 don't know.
8 I think, for me, if there's a lot of work
9 for people --
10 DR. EPSTEIN: [Off microphone.]
11 CHAIRMAN WASHINGTON: That's a good point.
12 Is there a suggestion?
13 DR. CLANCY: Arnie, could you repeat that
14 comment. I'm sorry. Too many concerts over here.
15 DR. EPSTEIN: I don't know we would not
16 want to pay on the high side of reasonable.
17 DR. SELBY: So, I'd ask -- I'd ask the
18 Board maybe to go with this at the moment and let
19 us judge over time whether the number of days or
20 comments or complaints from -- or suggestions from
21 advisory panel members call for a higher fee. We
22 talked about a daily rate and decided that we

1 rather wanted an annual rate, and this seemed very
2 fair at the moment, but we're not wed to this
3 number long-term, we just think it's the best
4 number to start with.
5 CHAIRMAN WASHINGTON: Is there a motion?
6 UNIDENTIFIED BOARD MEMBER: So moved.
7 CHAIRMAN WASHINGTON: Second?
8 UNIDENTIFIED BOARD MEMBER: Second.
9 CHAIRMAN WASHINGTON: Okay, language is
10 there if you go back to the other slide, but all in
11 favor?
12 [Chorus of Ayes.]
13 CHAIRMAN WASHINGTON: All opposed?
14 [No response.]
15 CHAIRMAN WASHINGTON: Any abstentions?
16 [No response.]
17 CHAIRMAN WASHINGTON: The motion carries.
18 Thank you, Rachael. A very efficient
19 group, tough group, but very efficient.
20 Okay. We're ready. I think 2:30 --
21 DR. GABRIEL: [Off microphone.]
22 CHAIRMAN WASHINGTON: Okay, Joe. It's up

1 to you then.

2 DR. SELBY: I guess it really doesn't

3 matter, so why don't we stay in order?

4 CHAIRMAN WASHINGTON: Okay.

5 DR. SELBY: Which would be --

6 CHAIRMAN WASHINGTON: Active portfolio

7 management.

8 DR. SELBY: Yes.

9 CHAIRMAN WASHINGTON: Joe and David.

10 DR. SELBY: Yes.

11 CHAIRMAN WASHINGTON: [Off microphone.]

12 DR. SELBY: We really think they will be

13 onsite for three days a year. Yes, three times a

14 year. It generally is not entirely worked out. It

15 could differ by panel. It could be more work on

16 one panel than another and there will be some work

17 at home. There will be.

18 UNIDENTIFIED BOARD MEMBER: [Off

19 microphone.]

20 DR. SELBY: Okay, I think this is probably

21 not the forum -- this is not the forum to debate

22 this.

1 UNIDENTIFIED BOARD MEMBER: [Off
2 microphone.]
3 DR. SELBY: Right. And you could even ask
4 me to survey the panelists for their level of
5 satisfaction with the compensation.
6 [Off microphone discussion.]
7 VICE CHAIRMAN LIPSTEIN: Joe let's push
8 on.
9 DR. SELBY: Okay, so I want to welcome Dr.
10 Lori Frank and Dr. David Hickam. At the last
11 meeting we had some beginnings of a conversation,
12 some questions about how PCORI manages its research
13 portfolio now that we've got one and the notion of
14 active portfolio management took off and has
15 actually worked its way into our strategic plan and
16 certainly into our daily dialog at PCORI.
17 And so, we have two presenters that are
18 going to talk about active portfolio management on
19 two different sets of projects, but we really, you
20 know, intend this almost in a sense as a manifesto
21 that in fact PCORI does intend to be very actively
22 engaged with those we fund and we really look

1 forward to your suggestions about how we might
2 refine that and make it as effective as possible.
3 So, thanks. You guys know who is going first, I'm
4 sure.
5 MS. FRANK: Thanks Joe. David's going
6 first.
7 DR. HICKAM: Thanks very much. It's a
8 pleasure to be here and to interact with you for a
9 few minutes about how we're thinking as a staff
10 about managing the portfolio of projects at PCORI.
11 So, our goals today is to review with you
12 the status of the PCORI portfolio management plan,
13 to review insights gained from work with the PCORI
14 Pilot Project Program. As you all know, that was
15 the first batch of projects funded by PCORI. Those
16 projects are now underway, so there's an
17 opportunity to gaining experience that we can apply
18 to our more programmatic groups of projects that
19 are sort of coming along about six months behind
20 the Pilot Projects.
21 And then, to seek input from you on the
22 key priorities of these management efforts. So, we

1 just might stop for a minute and consider why do
2 this. Why should be actively manage a funding
3 portfolio? I mean, we could take a very
4 conventional sort of grant-based model and just
5 make decision and turn money over to projects. So,
6 what might you gain by this?
7 And the first point we wanted to make was
8 this is an opportunity to optimize the knowledge
9 that we gain from the projects that are funded and
10 especially to start thinking at an early stage
11 about where there is important knowledge that's
12 provided by the projects and how a dissemination
13 strategy might build out of the information from
14 the projects.
15 Secondly, to realize that all research
16 projects have barriers and some are more successful
17 than others, and so, to basically have an active
18 process by which we can identify problems with
19 funded projects and make any kind of corrections or
20 modifications that might optimize the probability
21 that the project will deliver useful results. And
22 so, we kind of think of this as a risk management

1 strategy.
2 Third, to really try to get insights from
3 our experience with our early projects, about how
4 we can design our future funding initiatives and so
5 to really use the lessons learned as projects are
6 underway to make plans for future.
7 Fourth=, to facilitate the ability of
8 individual investigators and groups of
9 investigators to learn from others that are also
10 part of the PCORI program and possibly to
11 facilitate collaboration among those groups.
12 And finally, to sort of build up the
13 infrastructure, to build up the base of
14 investigators who can perform patient-centered
15 outcomes research.
16 VICE CHAIRMAN LIPSTEIN: Can we hold off
17 on the questions for the Board until you go through
18 the whole presentation, because you have the same
19 questions coming at the end and nobody --
20 MS. FRANK: Right.
21 DR. HICKAM: Yeah.
22 MS. FRANK: So --

1 VICE CHAIRMAN LIPSTEIN: -- more
2 efficient.
3 MS. FRANK: I agree. We wanted to orient
4 you to the questions we have for you, so you can be
5 thinking about them over the next few minutes as we
6 --
7 VICE CHAIRMAN LIPSTEIN: These guys are
8 always thinking. I promise you. Go ahead.
9 MS. FRANK: Okay, so the questions that we
10 do have for the Board are these and you will see
11 them again at the end. So we do ask that we not
12 discuss this until David and I are through
13 presenting the vision for active portfolio
14 management at PCORI.
15 [Off microphone discussion.]
16 MS. FRANK: First, we're asking if the
17 goals that we're presenting are the right goals and
18 should any be added. Second, we ask whether the
19 Board has specific examples for us from other
20 funding agencies. For example, that could be
21 incorporated into PCORI's practices. Third, we
22 want to ask for suggestions for ways in which we

1 can be nimble and flexible with our portfolio. We
2 want to steer the portfolio, so we're interested in
3 a discussion about how we can take promising areas
4 based on our own surveillance of our portfolio and
5 invest in them in different ways. And the finally,
6 we welcome you input on how PCORI can best measure
7 success. That last one is a big area.
8 So, I wanted to just share with you that
9 this is connected to the strategic plan that Joe
10 presented this morning. So by all means active
11 portfolio management is intended to increase the
12 quantity, quality and timeliness of relevant
13 research and it's most definitely intended to
14 accelerate dissemination and implementation of
15 findings. By actively driving our results into
16 implementation, we should influence the field.
17 A priority activity for this year is to
18 implement portfolio planning, management, and
19 evaluation, so that's right out of those priority
20 activities that Joe shared with you as part of the
21 strategic plan.
22 DR. HICKAM: So I'm trying to sort of

1 think through to what the kind of -- the blueprint
2 for portfolio management looks like. We found it
3 useful to divide it into three categories. Really
4 only two of which we're going to talk about today.
5 No surprises here, it's the pre-award
6 phase in which we essentially design our funding
7 programs. We identify key gaps within each of our
8 priority programmatic areas, as has been shared
9 with you already to identify the potential for
10 collaborative opportunities. We heard an example
11 of that with the work between PCORI and NIA this
12 morning. To identify co-funding opportunities
13 where there might actually be sharing of resources
14 or contributions of research funding for more than
15 one organization. And then, to sort of flow all of
16 this through to Program Funding Announcements to
17 build upon the plans for designing the portfolio.
18 And I think as I had mentioned before,
19 there's a certain amount of feedback into this
20 process where as we gain more and more experience
21 with the projects that are funded by PCORI that's
22 in the future going to affect the planning for, you

1 know, building our portfolio plans.
2 Then there's the next step in which people
3 actually submit applications and a peer-review is
4 performed and projects are selected. We're really
5 not going to talk about that today, but we do
6 acknowledge that that's a really important part of
7 the overall portfolio planning activity. And then,
8 once decisions are made for which projects are
9 likely to be funded then there's a series of steps
10 that we can use to ensure that the research is as
11 successful as possible.
12 First of all, is to do an evaluation of
13 each project and then do follow up of the issues
14 that are identified through a monitoring plan. And
15 I'll speak a little bit more to that issue in the
16 slide after this one. But the other sort of post-
17 award activities include identifying and being
18 aware of early findings from projects that would
19 guide portfolio planning, but it also would guide
20 possible avenues of dissemination so that the
21 dissemination strategies that don't apply
22 necessarily just to single projects but to apply

1 across the portfolio, sometimes to multiple
2 projects, can start to be kind of thought about and
3 sort of put on the plans for future work.
4 Third, we can also identify opportunities
5 for collaboration among the funded investigators
6 and Lori is going to speak more to than in a few
7 minutes. And then also, to look for situations
8 where some very targeted supplemental funding might
9 really increase the output of particular studies,
10 and so, to be adaptable as we develop the work --
11 as we monitor the work on the individual projects.
12 So just to speak more to this kind of risk
13 management aspect of managing individual projects,
14 the various things we want to look at. First of
15 all we want to look at the team of investigators,
16 identify any areas where -- not that they're
17 incompetent, but where they make lack in experience
18 and that we just need to sort of keep in touch with
19 them and, you know, see if there are situations
20 where some very, very targeted consultation might
21 be useful.
22 Second, might be to understand the setting

1 in which the study is being conducted and the
2 requirements for developing the datasets that will
3 be used in the study and so, this I think all of
4 you would be very familiar with a clinical trial
5 scenario where you need to be concerned about
6 recruitment rates into the trial. But this can
7 also apply to observational studies in which there
8 may be barriers to access to data that are being
9 used to develop registries and this sort of thing.
10 So, we just need to try to identify those kinds of
11 barriers and monitor the projects.
12 To look at any sort of institutional
13 barriers, procedural barriers, IRB issues that
14 might be applicable to an individual project, to
15 look at the limitations of the methodologies and
16 the methods that they plan to use. And there was a
17 really nice discussion at your meeting last night
18 involving both the Board of Governors and the
19 Methodology Committee about one way that we might
20 be able to augment the work, to really identify
21 important improvements and consultations that can
22 be applied to projects at the front end. To make

1 sure they're using the best methodologies for
2 achieving the aims and objectives of each study.
3 Also, a few other things we can identify
4 barriers to disseminations so we can at least start
5 developing strategies for dissemination, realizing
6 that we really can't make decisions about
7 dissemination until projects are all through. And
8 then, since all PCORI projects involve patient and
9 stakeholder engagement to try to help individual
10 groups of investigators the may not have very much
11 experience with engagement to use the rich
12 expertise of PCORI to help them with those
13 activities.
14 And I think we went backwards.
15 MS. FRANK: You did. Okay, so what David
16 was just alluding to was managing the risk, the
17 potential risk within the portfolio but our
18 internal discussions are about balancing risk and
19 reward. And so, we obviously see a lot of
20 opportunities to optimize the portfolio by
21 considering risk, but also considering the reward
22 side of the equation. So how is this PCORI unique

1 and what's the potential impact?
2 So, for us we're taking an active
3 portfolio management approach with our Pilot
4 Projects as David mentioned and from that we're
5 finding ways to bring together information across
6 different projects and communicate that information
7 to the intended end-users.
8 We considered this a pilot for active
9 portfolio management for PCORI going forward then.
10 We're using different forms of dissemination to
11 communicate with our awardees, including
12 professional presentations and having meetings
13 among the awardees, which I'll talk about more in
14 just a moment.
15 We've particularly pleased with what we
16 have learned about the cross-cutting themes,
17 including how to identify the relevant themes. And
18 while each individual research team has thoughts
19 about how to disseminate and implement their own
20 findings, by working across projects we can
21 identify enhanced opportunities for dissemination
22 and implementation, so we're taking advantage of

1 the bird's eye view we have of the portfolio as a
2 funder.
3 Academy Health is assisting PCORI with
4 actively managing the Pilot Projects and
5 establishing an active learning network. It's
6 actually quite vibrant and we're very excited about
7 this. We have a lot of people involved in this
8 work, so Alison Rhyne, Laura Esmail, Raj Sabharwal,
9 and Emily Moore and Veronica Thomas from Academy
10 Health. And from PCORI, Kara Walker, Natalie
11 Wegener, Rochelle Bent, and Laura Forsythe have all
12 been involved in this.
13 Academy Health completed a qualitative
14 content analysis and form that content analysis we
15 created thematic groupings as one way to identify
16 potential cross-collaborative opportunities. Four
17 different groups formed based on these thematic
18 groupings and most communications now between the
19 research teams is happening within these smaller
20 groups.
21 We've established different channels for
22 the awardees to communicate with one another,

1 including teleconferences, webinars, and an online
2 collaborative tool. And each group determines
3 their own desired outputs for collaboration. So
4 PCORI is facilitating the communication and
5 collaboration, along with Academy Health. We see
6 that the Pilot Projects are gaining experience with
7 active portfolio management themselves, and PCORI's
8 gaining that experience, too so we can apply it as
9 I said, moving forward.
10 With Academy Health's assistance, the
11 Pilot Project awardees have initiated some cross-
12 collaboration already. As Joe mentioned this
13 morning, several awardees have already joined
14 together to submit abstracts to professional
15 meetings. Right now, we're in the midst of share
16 and tell webinars, where a couple of awardees from
17 each of the thematic groupings presents a brief
18 overview of their work and the group discusses it
19 and identifies crosscutting issues, including those
20 that can be work shopped in follow up. Common
21 challenges are being identified and then we get the
22 benefit of suggestions from across multiple

1 research teams.
2 So, this is really an example of the whole
3 being greater than the sum of the parts. And it's
4 a very exciting aspect for us, the portfolio
5 management.
6 So, with that here we are at the end with
7 the questions.
8 VICE CHAIRMAN LIPSTEIN: Gene, what we
9 agreed to do was hold the questions for the end and
10 I guess before we open it up for questions, is
11 there anybody on the Board that doesn't feeling
12 like active portfolio management is a good idea?
13 UNIDENTIFIED BOARD MEMBER: [Off
14 microphone.]
15 DR. WEISMAN: I raised this, I think in an
16 earlier conversation. I think personally, I think
17 this is a good idea, but there's another -- this is
18 what portfolio management of what operationally
19 managing the projects that we've agreed to fund.
20 The other aspect of portfolio management, the way
21 it's used, is to decide on the distribution of the
22 types of projects you want and what their returns

1 are going to be. Similar to the way you do
2 investment portfolio management and decide on your
3 risk tolerance and decide on your timeframe, you
4 decide on the kind of returns you want.
5 And so, we have a portfolio -- as we're
6 currently doing, which may or may not be a great
7 fit for eventually what we want to achieve and we
8 need to -- it's about grouping and sequencing the
9 types of things we're doing and making sure that
10 it's maintaining the balance that PCORI wants.
11 That isn't what I heard here. This sounded like
12 once you have a portfolio, how do we manage it?
13 It's a type of project management of projects. So
14 you have project management of individual projects
15 and you have project management of the family of
16 projects. That's a very good thing to do from a
17 management standpoint. From a strategic standpoint
18 it gets not close to what Harlan K. was talking
19 about earlier, what should be in your portfolio and
20 what's the right balance of the types of -- maybe
21 it's the size of the rocks, I don't know.
22 VICE CHAIRMAN LIPSTEIN: Lori, were you

1 going to say something?
2 MS. FRANK: Yeah I am. The reason why the
3 emphasis was on the post-award with this was
4 because we were using some examples out of the
5 Pilot Projects and all of you are deeply familiar
6 with --
7 UNIDENTIFIED OVER PHONE: Talk into the
8 phone, please.
9 MS. FRANK: All of you are familiar with
10 what went on with the pre-award phase.
11 [Discussion over microphone.]
12 MS. FRANK: Okay, this one's on. We can
13 all tell.
14 So I was saying, everyone here is aware of
15 all of the pre-award active portfolio management
16 that you all engaged in. And so, we were given
17 examples then from the post-award side. but I went
18 back to the slide, because David did talk through
19 some of the pre-award activities and absolutely,
20 perhaps it's not broken out in sub-bullets there,
21 but it's part of our ongoing discussion. The gaps
22 within each priority area and how best to emphasize

1 different areas within each of the five priority
2 areas, in each of the programs also.
3 So, we very much have incorporated that
4 aspect into our discussions about portfolio
5 management. We just aren't giving examples of that
6 quite yet, because it's in an early stage for the
7 actual PFA program.
8 DR. WEISMAN: What I heard today though
9 was some -- not using this terminology, but some
10 challenges to our portfolio from a strategic
11 aspect. One of them came from Gail earlier, which
12 was about we don't have enough short-term stuff or
13 low hanging fruit stuff, like work that's already
14 going on that we could bring about, disseminate and
15 implement, help implement it very quickly. So,
16 that's a time-kind of portfolio decision.
17 What I heard Harlan talking about, there
18 are some strategic opportunities that would, you
19 know, leverage our efforts in a much greater way
20 than perhaps we're thinking. We're not having that
21 discussion. So even your pre- is more about given
22 about what we already decided and how are we doing

1 against it?
2 I heard some sort of more fundamental
3 questions about does our portfolio today match our
4 aspirations of what we want to achieve and what do
5 we need to do about it? That's more of a strategic
6 question. It's like what your investment profile.
7 MS. FRANK: Yeah, so that definitely has
8 been part of the discussion.
9 VICE CHAIRMAN LIPSTEIN: Christine.
10 MS. GOERTZ: Yeah, Christine Goertz, Board
11 member. Thank you.
12 I'm a huge advocate of active portfolio
13 management. I think that's really critical,
14 especially pre-award. I mean, I really want to get
15 to the point where somebody can==who has a question
16 is able to call up a real person and have a
17 discussion with them while they're putting their
18 grant application together about whether what they
19 want to do fits within our priorities. You know,
20 how will we advise them on being patient-centered
21 and all of that. I think that that's really
22 critical.

1 I think what we've done with the Pilot
2 Projects is, you know, that level of monitoring and
3 involvement is what we plan to do because we
4 consider the Pilot projects to be a learning
5 laboratory and we wanted to make sure that we
6 learned as much as we could from that experience.
7 But I feel a little bit this is pounding in a tack
8 with a sledgehammer with some of this. It's just
9 too much. And I think some of these things,
10 perhaps, you know, like qualifications of the team
11 of investigators and the steady settings and data
12 requirements, I hope we're handling all of that in
13 peer review and that applications that we actually
14 fund are, you know, that we already know the
15 qualifications of the investigators.
16 I mean, on average I'm not saying that
17 might not be true of some projects that for
18 whatever reason we accept out of order, but I think
19 most projects that we would fund I would hope the
20 qualifications of the investigator and their
21 construction of data files would be something that
22 we would just be able to assume. Now, I do -- you

1 know, we have had some talk about having a
2 methodological review of some or all our
3 applications, I think that could be very important
4 and very helpful. And I've been on both sides of
5 this, as a program officer who was managing
6 cooperative agreements, sometimes multi-million
7 dollar cooperative agreements as well as smaller
8 projects, and also as an investigator who is being
9 managed by another program officer. And I can tell
10 you that there is a line at which its helpful and
11 then there is a line beyond which it's not
12 particularly helpful. And, in fact, it can be
13 really difficult especially if the program
14 director-manager is not a content expert in what
15 you're trying to do.
16 So, I just think we have to be really
17 careful about what it is that we're trying to do
18 here and make sure that -- first of all, we have
19 the staff to do this. Because Lori, you mentioned
20 all of the people involved with managing the 50,
21 you know, Pilot Projects. I mean, as we're scaling
22 up, I don't know what the costs, you know, would be

1 to manage at that level. Though, I think some of
2 the stuff you're talking about with going across
3 portfolios and providing opportunities for people
4 to get together and share ideas and such could be
5 extremely helpful. It's really whether we can
6 balance it or not.
7 So I just think -- I think this is a
8 really good concept, I think we're definitely
9 moving in the right direction but I think we need
10 to think a little bit more about where to draw that
11 line.
12 VICE CHAIRMAN LIPSTEIN: Carol.
13 DR. CLANCY: So the answer to the question
14 we offer active portfolio management is of course.
15 I mean, we owe that to the taxpayers. Period.
16 Now, what I think I'm finding confusing
17 about this conversation is where you're new to an
18 area, starting up a research entity, trying to put
19 processes in place, what I'm seeing is a mix of
20 stuff that I think of as SOP. And stuff where
21 PCORI could actually make a unique contribution,
22 okay?

1 The follow on study area for selected
2 areas and disparities immediately comes to mind
3 because studies haven't been powered enough in some
4 areas. But that I think is what I would be
5 focusing on. I can't believe that anyone funds
6 research without some hope and aspiration and lots
7 of cheerleading, that the grantees will want to
8 play together nicely. And you know what? Some do,
9 some don't. That's all I'm going to say.
10 And I think some of this will also will
11 ultimately need to be linked back to what is in a
12 PFA or the front materials, you know, how do I
13 apply for my grant? So, this all feels a little
14 bit confused to me. You know, some of this is just
15 standard stuff. The other thing I would be a
16 little bit leery of, and I have to think about how
17 to say this diplomatically, so I'll use a little
18 parable.
19 We had an evaluator once. in fact, we
20 still have this evaluation team under contract and
21 one would think by the way they wrote the
22 evaluation that they got paid by the word. So, I'm

1 not sure I would be looking to the entity who is
2 managing grants for us necessarily as the only
3 source of input in terms of what might be done. Am
4 I being clear enough? Okay. Thanks.
5 VICE CHAIRMAN LIPSTEIN: Ellen and then
6 we're going to pause for a minute, because we have
7 another segment on our agenda coming up that can't
8 be delayed.
9 MS. SIGAL: I didn't have a question.
10 VICE CHAIRMAN LIPSTEIN: Your thing is up.
11 CHAIMAN WASHINGTON: Your card is up.
12 VICE CHAIRMAN LIPSTEIN: Okay, that's
13 good. Now we have accelerated.
14 I think as I summarize some of the
15 comments and the thought is that there is
16 bureaucracy that you could put on this process pre-
17 award and there is bureaucracy post-award and it
18 can involve methodological review, it could involve
19 active portfolio management. I think the challenge
20 for staff to think about is how much bureaucracy
21 both pre- and post- added value and when do you get
22 to diminishing returns. And so, I think you've got

1 some good insight, some good input from the Board
2 and I think it would be good if you take that input
3 back and then figure out how best to act on it.
4 Gene, we have a little bit of time before
5 the Public Comment session. I don't know exactly
6 what you want to do with it, so I'm glad you're
7 back.
8 CHAIRMAN WASHINGTON: Okay. Joe any
9 additional comments at this point before we thank
10 Lori?
11 DR. SELBY: No, let me ask David a Lori if
12 you have any closing comments. I think this is an
13 ongoing process, the notion of risk management was
14 something we got as we sort of did a survey of
15 other funding organizations to see how they
16 approach a portfolio. I think Christine's and
17 Carolyn's point about not getting overly
18 bureaucratic. I'm not too worried about that at
19 this point, but it's just because of the time we
20 really don't have time to be too bureaucratic yet.
21 Certainly, it is an important point to
22 keep in mind.

1 Lori.
2 MS. FRANK: yeah, I just wanted to add
3 that the Pilot Projects having a methods focus for
4 us is part of the impetus behind how far we've gone
5 with this. But we're mindful of not being
6 intrusive, so it really now is up to each of those
7 teams if they want to pursue things we'll support
8 it, but if not, of course that's fine.
9 DR. SELBY: David? Good. Thank you both.
10 CHAIRMAN WASHINGTON: Thank you Lori,
11 thank you David.
12 Okay, we have a couple of minutes before
13 the Public Comment period and to ensure that we're
14 on time for the Public Comment period you will not
15 be recessed from this room. There is a guard at
16 the door. However, I want to in my role as Chair
17 take a moment to recognize an individual in the
18 public health world who is going to be recognized
19 tomorrow at three o'clock. Someone named Toni
20 Yancey. Some of you may know the name.
21 She popularized the notion of instant
22 exercise, where it was sort of the idea if you sat

1 60 minutes, you should get up and stretch at least
2 three. Regrettably, Toni died last week at the age
3 of 55 after a battle with cancer and nationally
4 tomorrow at three o'clock when we will be gone,
5 around the country organizations have banded
6 together. We were going to do it, but we're not
7 going to be together. To just at 3:00 p.m., is it
8 East Coast?
9 DR. SELBY: It's 1:00 Pacific, so it's
10 3:00 here.
11 CHAIRMAN WASHINGTON: Three here but we're
12 going to do it today. And so, just instant
13 exercise means you just stand up in place and
14 often, what Toni used to do it there was somebody
15 leading you in it and she could have you doing some
16 really goofy things. But you're just going to do
17 whatever exercise you want to do, stretch --
18 UNIDENTIFIED BOARD MEMBER: [Off
19 microphone.]
20 CHAIRMAN WASHINGTON: This is good, this
21 is still live.
22 [Laughter.]

1 UNIDENTIFIED BOARD MEMBER: It will
2 CHAIRMAN WASHINGTON: It will be a hit on
3 YouTube, that's for sure.
4 UNIDENTIFIED BOARD MEMBER: How long are
5 we supposed to do this?
6 CHAIRMAN WASHINGTON: Three minutes.
7 [Off record discussion.]
8 CHAIRMAN WASHINGTON: Can we cut the
9 cameras for seven minutes? We're okay, and then
10 we're going to reconvene in seven minutes for the
11 public comment period.
12 [Recess.]
13 CHAIRMAN WASHINGTON: Welcome back to this
14 meeting of the Board of Governors of the Patient-
15 Centered Outcomes Research Institute. And this
16 next session we're going to hear from members of
17 our public who are going to provide us with some
18 comments. And so, I turn it over to Sue Sheridan.
19 MS. SHERIDAN: Great, thank you, Dr.
20 Washington.
21 First, we're going to take comments from
22 those commenters in the audience who have

1 registered. We have two right now, and then after
2 everyone has spoken, we’ll see if there's any
3 comments by phone, and from what I understand from
4 our operator, Nikki [phonetic] we have three people
5 on the line. And then individuals offering public
6 comment must limit their remarks to no more than 3
7 minutes and I apologize for that but we want to
8 make sure we get through everybody’s comments and
9 I’ll give you a 10-second warning when you're
10 getting close to your 3 minutes.
11 Your written testimony should be submitted
12 to PCORI via e-mail to info@pcori.org. And all
13 testimony and additional materials submitted to
14 PCORI will be provided to appropriate Board
15 members, Methodology Committee members, and staff
16 for review and consideration in our work that we do
17 at PCORI.
18 So, I’d like to first welcome Mary Alice
19 Lawless from the Foundation for HealthSMART
20 Consumers. You can just come join me up here next
21 to me and provide your statement.
22 MS. LAWLESS: Thank you, Sue. Thank you,

1 everybody. I wanted to just take a few moments
2 just to come up and say hello and also to thank
3 you. Hello. Thank you for the really great work
4 you're doing.
5 I am with an organization called the
6 Foundation for HealthSMART Consumers, and we were
7 actually founded in 2009 to just take a little tiny
8 step toward this. We've done much more modest
9 work, but we have done a lot of really interesting
10 work in terms of I would say our work is not on the
11 research side per se, but much more on the
12 communications and dissemination aspect of this.
13 So, we've taken a lot of what you've discussed
14 here, which is fantastic research that does exist.
15 A lot of good clinical best practices, a lot of
16 evidence-based medicine, and we've tried to
17 reorient it in some cases for clinicians based upon
18 the types of care they provide and where they work
19 and also to reorient it in ways that real people
20 can just sort of understand, even some of the most
21 basic elements because medicine is so very
22 mysterious and how it works is so very mysterious

1 for so many people.
2 So, I'll just tell you a little bit about
3 one project that we're working on right now which
4 is really neat and it happens to be in conjunction
5 with the University of California San Francisco and
6 the Smoking Cessation Leadership Center and the
7 Convenient Care Association, which is the
8 association that organizes all of the retail
9 clinics like MinuteClinic and Walgreen's Take Care,
10 organizations like that.
11 What we've done is we've taken -- you can
12 imagine the body of work that's been done on
13 smoking intervention, but we've reorganized it and
14 reoriented it for that particular point of care,
15 which is a very quick visit, people that are sort
16 of shopping in Wal-Mart and stop in for health
17 care. So, it's gone very, very well. It's
18 actually launching at the Retail Clinic Education
19 Congress. We've had a number of clinical practice
20 leadership in that domain working with us on this
21 just to make sure that this becomes really usable
22 material for that patient provider interaction and

1 we’ll hopefully have outcomes data coming forth
2 shortly, as these things are disseminated out
3 through the networks of retail clinics. These
4 are run, as I mentioned, some are run by those
5 larger organizers like a CVS or Walgreen’s. Others
6 are run by hospital systems where they sort of have
7 their nurse practitioners coming and working there.
8 So, we hope to see a little bit of reverse
9 migration of some of this practice even maybe back
10 into other points of care where those NPs are
11 cycling.
12 In terms of what you're doing, obviously,
13 we’d really love an opportunity to explore a whole
14 bunch of different ideas that perhaps some of which
15 we may have had as we’ve done our work, but perhaps
16 haven't gotten off the ground just due to our own
17 size. We also get a lot of feedback in the work we
18 have done with public entities and patient groups
19 in terms of any information is good information.
20 So, I do ask that you not think in terms
21 of only being able to put forth the best packaged
22 final product, but maybe to let people in on even

1 just the good work that's going on here right now.
2 This feels a little bit -- my first time, I'm a
3 brand-new first-timer. I met one of your
4 colleagues at the World Health Care Congress and
5 heard about the work you're doing and decided to
6 participate in today's session as a result.
7 This almost has the makings of a reality
8 TV kind of approach where whatever steps are being
9 taken, the conversations you're having here, we
10 used to say this after the World Health Care
11 Congress, if only people out on the street could
12 hear what's being discussed in here. It's actually
13 not really above their heads. So, whatever we can
14 do to help you with that, we certainly will look at
15 communications and disseminations. That's probably
16 our domain opportunities, but look to other
17 exploratory collaboration opportunities with you,
18 as well.
19 CHAIRMAN WASHINGTON: Thank you very much
20 for your comments and for that invitation.
21 MS. LAWLESS: Okay, thank you so much.
22 CHAIRMAN WASHINGTON: Okay.

1 MS. SHERIDAN: I'd like to welcome Regina
2 Greer-Smith to share her comments.
3 MS. GREER-SMITH: Thank you, Sue, and I
4 want to welcome everyone to the Board and Dr. Selby
5 to Chicago, home of the Chicago Bulls. We are
6 happy that you decided to have your Board of
7 Governors' meeting here. I think it's energizing
8 not only the city, but all of us patient advocates
9 who have been really dreaming of an opportunity
10 like PCORI to finally appear.
11 First, I'd like to congratulate you and
12 encourage you on the PPRN, the Patient-Powered
13 Research Networks. I find this very encouraging
14 because it'll ensure patient-centeredness of
15 research by empowering and providing opportunities
16 for networks and collaborations of patients to be
17 involved with research. This is the actual
18 patient-centeredness that we've been dreaming of
19 for decades. The PSA also encourages and addresses
20 the requirements of targeting underserved and hard-
21 to-reach and high-risk communities. Very important
22 for us.

1 I'm also extremely encouraged by the use
2 of technology and the recognition of mobile
3 applications to reach underserved and minority
4 communities. We know research shows us that
5 minorities, especially African-American women and
6 Hispanic women are higher users of mobile
7 technology. You have that in the PFA and that's
8 just perfect. So, we're very happy of that.
9 Finally, and my comments are short, I do
10 have an ask. We're looking for opportunities from
11 PCORI that will enable patient-initiated research
12 where patients and stakeholders can identify and
13 orientate researchers to the topics and questions
14 that impact the health outcomes and quality of our
15 life. So, we want to have the opportunity of
16 identifying researchers who can work with us, as
17 well. We want to initiate research. We do have
18 topics that we are sending to PCORI and we want to
19 develop questions from those topics, but we want to
20 grow our own researchers or identify those
21 researchers who can work with our uniqueness and
22 our health incomes and disparities.

1 So, with that, I want to thank you for the
2 opportunity and thank you Sue.
3 CHAIRMAN WASHINGTON: Thank you very much,
4 Ms. Smith. Although we're in Chicago, we do have
5 some New York City-based Board members, so be
6 careful about the Bulls.
7 [Laughter.]
8 CHAIRMAN WASHINGTON: Thank you for that
9 suggestion and, Sue, we will follow-up to make sure
10 we have that request in writing.
11 MS. SHERIDAN: Absolutely.
12 CHAIRMAN WASHINGTON: So it can be passed
13 up.
14 MS. SHERIDAN: I do want to acknowledge
15 that Regina is on our Inaugural Patient Engagement
16 Advisory Panel.
17 CHAIRMAN WASHINGTON: Oh, great.
18 MS. SHERIDAN: So, she brings a wealth of
19 information and passion to PCORI.
20 Now I'd like to ask Nikki, I think we have
21 our operator online, and, Nikki, if you could
22 introduce our next commenter and could you please

1 introduce their names, as well?
2 OPERATOR: If you'd like to make a
3 comment, you may press star one to be placed into
4 queue. Again, we ask that you press star one to be
5 placed into queue.
6 Please give me one moment while they queue
7 up.
8 We do have Andrew Auerbach. Your line is
9 live.
10 MR. AUERBACH: Thank you. My name is
11 Andrew Auerbach. I know a few of you on the panel,
12 but I want to introduce myself to you all. I'm a
13 professor of medicine at University of California,
14 San Francisco, and a hospitalist here. For those
15 of you who don't know what a hospitalist is, we are
16 a specialty of general internal medicine that is
17 now caring for more than 65 percent of hospitalized
18 patients in the U.S.
19 One of my other jobs here at UCSF is
20 general hospital medicine, which gives me a good
21 overview of the field of hospital medicine and
22 what's going on in the hospital medicine world.

1 And relevant to this phone call in my time here
2 with you today, the cofounder along with my friend
3 Peter Lindenauer at Baystate Medical Center in
4 Springfield, Massachusetts, of a research network
5 called HOMERUN, the Hospital Medicine Reengineering
6 Network.
7 So, let me take a minute to introduce
8 HOMERUN to you. We are a 13-hospital network of
9 nontraditional academic medical centers, two safety
10 net hospitals and two community-based teaching
11 centers that are taking advantage of the role of
12 hospitalists in their hospitals to understand the
13 opportunities for improvement, affect meaningful
14 change, and create generalizable evidence in that
15 process.
16 In contrast to some research networks
17 though, the central tenant for how we operate, we
18 seek engagement from all of our stakeholders,
19 patients, frontline caregivers, and our health
20 systems in a variant of community-based
21 participatory research we call hospital-based
22 participatory research.

1 The reason I'm talking to you today is we
2 represent one of many different research networks
3 that we think are [inaudible]-ready research
4 networks that can link research discoveries to
5 implementation, shorten the time from discovery to
6 widespread health impact.
7 So, as an example of our project, with
8 support from the AAMC, the Association of American
9 Medical Colleges and our hospitals, we've just
10 undertaken the first U.S.-based study of why
11 patients are readmitted from the hospital, but
12 using the patients' viewpoint as the central source
13 of information.
14 We're now finishing our first resource
15 phase which will result in the largest study of its
16 type and we're prototyping interventions which I
17 think will make really fundamental changes in the
18 way, at least our hospitals kind of work with
19 discharging patients and educating their patients
20 and families in how to take care of themselves when
21 they go home.
22 Let me stop here for a second and be very

1 clear. HOMERUN is not necessarily unique. We're
2 aware of several other research networks that have
3 similar features. There's one that's focused on
4 pediatric acute care, emergency medical care,
5 critical care, pneumonia, COPD, those are the ones
6 that just I'm aware of and Peter is aware of.
7 There are probably dozens of other ones. Each have
8 patient outcomes as the central focus, they engage
9 patients directly. They have outstanding frontline
10 engagement with their health systems and their
11 providers. These clinical data and research
12 observations then turn those into interventions to
13 improve care.
14 The reason I asked to be allowed to
15 comment to you today is I think networks like
16 HOMERUN provide at least two major opportunities
17 for PCORI to extend its impact. The first is we
18 view PCORI as a natural partner, but we have had
19 some challenges in identifying ways other than this
20 phone call where we might become more engaged in
21 your work. As PCORI continues to grow, I encourage
22 you to consider a systematic and broad engagement

1 of clinicians and researchers whose interest in
2 infrastructure while at the same time it works to
3 understand the goals of patients. I think you just
4 heard this from the previous speaker.
5 I really believe this will shorten the
6 time it takes to develop knowledge and forward to
7 all stakeholders. For example, our network, we
8 could provide a ready group of providers,
9 researchers, and patients focused on our case,
10 acute care and general medicine. Groups such as
11 ours would be well-suited to co-develop programs
12 that meet high priorities in these areas.
13 Second, available RFAs have been a
14 necessary [inaudible] but may have been missing an
15 opportunity to take advantage of existing networks
16 of patients, health systems, and researchers poised
17 to make the widespread change I think you want.
18 As you develop your portfolio RFAs, we
19 encourage you to consider mechanisms that support
20 the development of networks that can answer
21 multiple questions simultaneously and which produce
22 evidence that can be translated to practice.

1 Quickly, these networks that you're
2 envisioning and ones that I’m mentioning here are
3 somewhat different than the networks that you're
4 developing currently and that they would collect
5 data specifically tailored to patients involved in
6 the study. It’s been our experience, certainly
7 with the work we’ve been doing at this point that
8 even the best administrative databases lack the
9 best patient-centered outcomes making us have to
10 spend lots of money to develop infrastructure to
11 collect data from patient surveys, cellphones, and
12 the like.
13 Networks like HOMERUN and our brethren can
14 simultaneously support studies that focus on risk
15 readmissions, methods for preventing hospital
16 [inaudible] methods for improving functional
17 status, but what we need is the support for the
18 data systems as well as the people who are needed
19 to carry out the studies in a model that in some
20 ways is akin to what we would we call the
21 [inaudible] Program Project, but there are lots of
22 other ways to achieve that same operational goal.

1 It's possible and even likely you've
2 thought about these issues, so, I hope my comments
3 encourage you to consider ways to excel your
4 efforts and certainly to engage clinical-proven
5 networks and my colleagues who are doing research
6 in conjunction with their patients more directly.
7 So, I'll end by thanking you for your time
8 and I'll speak for my colleagues in HOMERUN when I
9 say we welcome the opportunity to raise these
10 issues and to contributing to the conversation in
11 the future.
12 CHAIRMAN WASHINGTON: Thank you, Andrew,
13 and good to hear your voice. We appreciate your
14 comments and they certainly will be incorporated
15 into our thinking and deliberations.
16 MS. SHERIDAN: Thank you.
17 Nikki, could you invite the next person in
18 queue to provide their comments?
19 OPERATOR: We have no one at this time,
20 but as a reminder, you may press star one to make
21 your comment. Once again, star one.
22 [Pause.]

1 CHAIRMAN WASHINGTON: Okay.
2 OPERATOR: I have no one in queue at this
3 time.
4 CHAIRMAN WASHINGTON: Well, Sue, as we
5 have done in the past, if there's someone in the
6 audience who has not signed up but would like an
7 opportunity to speak, we invite you to come forth.
8 And if not, we will ensure that the time is
9 available if someone shows up in the next 15
10 minutes, but we'd like to proceed with agenda for
11 this afternoon.
12 And, Dr. Gabriel, we have Methodology
13 Committee up next, correct, Joe?
14 DR. SELBY: That's right.
15 DR. GABRIEL: So, thank you very much.
16 CHAIRMAN WASHINGTON: And before you --
17 again, I want to emphasize to all of our
18 presenters, commentators that we greatly appreciate
19 and highly value your input. So, please continue
20 to share with us your thoughts and suggestions for
21 how we might improve and then ultimately be more
22 effective in achieving our mission.

1 DR. GABRIEL: Okay. Thank you very much.
2 If I could have my slides up, please. It was
3 scheduled to be just prior to the public comment
4 period. Thank you.
5 Okay, so, it's late in the afternoon and
6 the good news is I'm not asking the Board for
7 anything today. So, this is really just an update
8 for your information to give you a sense of what
9 we've been up to. And we'll be presenting and I
10 think both David and Robin will be commenting and a
11 number of our Methodology Committee members.
12 Actually the plan to stay until the first part of
13 the afternoon, but I see that a number of them had
14 to catch flights. So, we don't have too many of
15 our members here yet. So, we'll try and muddle
16 through without them.
17 What I'd like to do is give you a bit of
18 an update in four areas. One, the methodology
19 standards, the recommended actions, what we're
20 doing to finalize the actual report, which sort of
21 is the wrapper around both of those and some other
22 things and then just some additional initiatives

1 that we're working on.
2 First with respect to the standards, as
3 you know and as you heard from us previously, the
4 goal here is not to provide methodological
5 standards to cover the entire waterfront of
6 clinical research, but really just to focus on
7 standards, creating standards where standards do
8 not currently exist, and where a revised or
9 improved standard would really advance patient-
10 centered outcomes research. So, we're trying to be
11 fairly specific there.
12 Of course, in December of 2010, this Board
13 approved our first set of methodological standards
14 and they've been on the Web since then and we're
15 working to ensure that our reviewers are familiar
16 with them and our folks submitting grants are
17 ensuring that their grants align with those
18 standards, but we're also looking to develop new
19 standards and perhaps even improve on the current
20 ones. And to do that, the Methodology Committee
21 reviewed again the work that we did for the draft
22 reports that you saw back in December, went back

1 and reviewed in detail the public comments, looked
2 at all kinds of other sources of input that we've
3 received over the years and began to have a
4 discussion about new standards development. We
5 haven't completed that.
6 As you'll see I think on an upcoming
7 slide, we expect to bring that to you in September,
8 but just to give you a sense of the areas we're
9 talking about and it's probably not completely by
10 luck, but some of the areas we are talking about
11 creating new methodologic standards for align very
12 nicely with this morning's discussion on falls and
13 some of the other priorities that Rachael discussed
14 because we're looking, for example, to develop
15 methodologic standards to evaluate system
16 interventions, to develop methodologic standards to
17 evaluate those contextual factors that impact
18 outcome in addition to things like cluster
19 randomized trials and research prioritization and
20 others.
21 So, we'll put all of that information
22 together. We hope to share that with the

1 PDC for their input and then we'll propose at the
2 next board meeting the next set of standards we
3 will work on from the Methodology Committee.
4 Concurrently with that, however, because
5 that process is a little less ad hoc than the first
6 one, but still too ad hoc for the Methodology
7 Committee, we're going to develop a more systematic
8 process for synthetizing and soliciting very broad
9 stakeholder input for the subsequent set of
10 standards we'll work on and we're going to be
11 relying a little bit on Gene and others to look at
12 what other organizations have done. So, put out
13 RFIs and really cast a pretty wide net in terms of
14 what else should we be looking at, what other kinds
15 of methodological standards are needed in this
16 domain? So, that's what we're doing with respect
17 to standards and Robin will stop me if I miss
18 anything here important.
19 With respect to recommended actions, you
20 remember that back in December, we brought forward
21 the set of methodologic standards as we are
22 required to do by the statute and the other

1 requirement of the statute was for the Methodology
2 Committee to draft what they call recommended
3 actions, I'm not going to remember the language
4 exactly, that facilitate adoption of the standards
5 or something like that.
6 So, other things we should be working on.
7 They're not methodologic standards, but other
8 activities we should be working on that would
9 facilitate the adoption and implementation of the
10 standards. And we had a long list of those. And
11 we were asked by the Board -- these were not things
12 that needed to be voted on. That was made clear.
13 That's what the legislation says. But we were
14 asked by the Board to sort of prioritize them, put
15 them in categories because it was a really long
16 laundry list that we presented at the time. So, we
17 did that.
18 We categorized those activities into four
19 topic areas and they kind of fit nicely into four
20 topic areas and assign four workgroups to look at
21 those areas, look at the recommended actions within
22 each, and if not exactly prioritize, at least stage

1 them. In other words, what things need to be done
2 sooner, what things can wait a year or later. So,
3 to try and stage the activity and these were the
4 four areas that they fell into and this is a bit
5 dangerous, but I did hand out -- it's a bit
6 dangerous because it's got a lot of information on
7 it and we can talk about it for a long, long time,
8 but I did hand out because we weren't quite sure
9 how to summarize it in a reasonable way in a slide
10 a handout that really talks through what each of
11 those categories contain, what kind of recommended
12 actions are contained in each category.
13 So, you can see on the first page is our
14 first category, which is methodological research
15 gaps and evaluation and then if you go on, I think
16 the second page is a category of training. The
17 third page is category of infrastructure, support
18 for applicants, and then on the very last page
19 policies and procedures. So, all of the
20 recommended actions fit into those topics and
21 they're summarized there and we summarized them
22 this way. So, you've got the action. In some

1 cases, we did a little tweaking of the language to
2 clarify things and then we identified the timeline
3 associated with that particular activity. And then
4 we also have a category, a column here for
5 responsibility.
6 So, you can see that in some cases, these
7 are things that we need the Board's help with. In
8 some cases, it's Methodology Committee, in some
9 cases, it's staff or a combination thereof, and in
10 some cases we thought we could contract or
11 outsource to accomplish the activity.
12 The other good piece of news that as we
13 looked at these recommended actions, we determined
14 that about one-third of these, a couple of dozen
15 things we're already moving forward on. And so,
16 the bottom of each one of these pages are those
17 efforts, those recommended actions where there's
18 already progress. So, we determined we're already
19 working on those areas and not a lot more needs to
20 be done except to complete that work.
21 So, this is sort of my brief summary of
22 the recommended actions, responding to what the

1 Board asked us to do, which is to categorize them,
2 figure out what we're doing and what needs to be
3 done by whom and when.
4 The third category just to provide an
5 update is the Methodology Report, the actual
6 report. So, this board has approved the
7 methodological standards, which is really kind of
8 the core content of the report, and the actions,
9 the recommended actions that you can see here, but
10 really what we thought was important to do and we
11 started to do in the draft report that I realized
12 it wasn't complete or probably adequate back in
13 December was that there needed to be what we call a
14 demystification or just more explanation to make
15 the standards more accessible. And I'm just
16 reflecting last night on a couple of comments I
17 think Leah and Ellen both made comments about
18 having not taking as full advantage of standards as
19 perhaps we could.
20 And so, this is the goal of the report
21 which at least in paper copy will be completed by
22 the end of May to demystify the standards using

1 explanatory stories. And, again, if you remember
2 back in December, we tried to do that kind of on
3 our own within the Methodology Committee, but what
4 we've done since then is pull in real experts, so,
5 people with medical journalism backgrounds and so
6 on to help us and relying on stories that are
7 already in the public domain, but and pulled
8 patient stories, so, it's kind of not standard by
9 standard, but category by category, used patient
10 stories to really illustrate the centrality of the
11 patients' voice in PCOR methods and for each group
12 of standards. We also had some research stories or
13 what we called research and practice stories which
14 are real-world examples of research that's ongoing,
15 demonstrating how these methodological principles
16 can be applied and have been applied successfully.
17 So, again, the hope through these stories
18 is to demystify the standards, make them more
19 accessible to a broader community of investigators
20 and other stakeholders and really get more from our
21 report than we currently have.
22 So, that's the content and the content

1 piece I think is essentially completed. We've been
2 working on that since December. In terms of the
3 delivery piece, we will have, as I said, the actual
4 report and it's very pretty, there are lots of
5 pictures and things. We'll have the paper report
6 completed by the end of this month. But we're also
7 working with other groups to help us make sure that
8 the information is available in a number of other
9 ways.
10 So, we're going to create an eBook with
11 some interactivity where we have a patient story
12 written in words, and then in an eBook, you might
13 be able to click and the patient could actually
14 tell you her story, Web versions and so on. So,
15 we're going to be looking at that probably shortly
16 after May and then a number of derivative projects.
17 So, PowerPoints.
18 So, for example, there are lots of groups
19 around the country that want to talk about PCORI or
20 the PCORI Methodology Standards. We do as much as
21 we can, but if we put a PowerPoint out there, we
22 can have many more ambassadors talking about the

1 standards, again, to help explicate the standards,
2 continuing education modules, and other kinds of
3 training vehicles. So, that’s basically the work
4 that is ongoing around the report and, again, the
5 actual content and the paper version will be
6 completed by the end of this month and hopefully
7 the team that we have on our staff plus some
8 outsourcing, we’ll be able to move forward with the
9 other activities, the online activities also.
10 So, my last topic, other initiatives. The
11 Methodology Guidance Panel, we had a discussion
12 about that last night and I won't go into that, but
13 that’s kind of a new idea that we’re launching and
14 we’re very happy that we were able to share that to
15 Steve Goodman and this really comes from Steve
16 Goodman and Clyde Yancy and it was an idea that
17 really germinated just a month or so ago from the
18 Methodology Committee how we can work more closely
19 in partnership with investigators to help improve
20 the methods of their studies with funded
21 investigators. And we’ll be working more on that
22 with members of the Board and the PDC.

1 We’ve also been active in a number of
2 workshops, methodological workshops, the IOM
3 workshop, and observational studies. Not only had
4 a number of Methodology Committee members actively
5 involved, but Larry Becker was there the whole
6 time.
7 MR. BECKER: Yes.
8 DR. GABRIEL: We’re recruiting him to the
9 Methodology Committee soon.
10 MR. BECKER: Thank you.
11 DR. GABRIEL: The Academy Health Workshop
12 on Implementation of Methodology Standards, that’s
13 coming up in June and a PCORI workshop on PROs
14 coming up in 2013 and we’re considering some others
15 that you'll hear about.
16 Also, dissemination implementation of
17 methodology standards, again, that's something that
18 we really need to work harder on. It’s not just a
19 matter of creating the standards, but making sure
20 they're out there and accessible and usable and
21 it’s really unfortunate that Brian had to leave
22 because this is really his effort and he has a

1 proposal with a number of tools for more easily
2 assessing and applying the standards and he expects
3 that by the end of 2013 we'll have some of those
4 tools actually developed, David, and as I said, a
5 comprehensive implementation dissemination plan of
6 course working. He works very closely with the
7 COEC and some targeted conferences. So,
8 dissemination implementation is really sort of in
9 full swing at this point now that the standards
10 have been completed or at least the first set.
11 And then we're working with Rachel and
12 others on the staff to figure out how the
13 Methodology Committee can participate in the review
14 of the research projects consistent with our COI
15 guidelines, the Methodology Research Projects just
16 to ensure that the projects that we consider for
17 funding are in alignment with what we initially
18 anticipated as the goals. And, again, we're very
19 much aware of the COI guidelines and they're
20 working with in those.
21 So, that's a very quick overview and I'm
22 happy to, maybe I'll ask Robin or David if I may if

1 they had other comments --
2 CHAIRMAN WASHINGTON: Please.
3 DR. GABRIEL: And then we're happy to take
4 questions.
5 MS. NEWHOUSE: No, the other only comment
6 I have is it was --
7 CHAIRMAN WASHINGTON: Robin, would you
8 state your name, for the record.
9 MS. NEWHOUSE: Oh, excuse me, Robin
10 Newhouse, Methodology Committee.
11 In reviewing the recommended actions, it
12 was amazing to think this was a year ago that the
13 report was recommended and the 28 recommendations,
14 how much forward progress we've made without even
15 thinking. I mean, we just have kept on moving in a
16 direction that's so strategic and thoughtful.
17 The other thing, I just wanted to
18 reinforce this whole discussion about methods and
19 complex interventions and system complexities and
20 systematic reviews of system interventions. Were
21 certainly topics that we talked about in terms of
22 needed standards. Those of us that work in systems

1 really struggle with what evidence one can adopt.
2 So, this whole discussion, it just added to what we
3 had discussed yesterday about the need for this
4 kind of standard to help clarify standards for
5 implementation, standards for context, standards
6 for systematic review of complex intervention. So,
7 this was a wonderful discussion, much appreciated.
8 CHAIRMAN WASHINGTON: David, anything to
9 add?
10 Thank you, Robin.
11 DR. HICKAM: No, no, nothing to add.
12 CHAIRMAN WASHINGTON: Okay. Well, I see a
13 few cards. I'd like to first express my
14 appreciation and our appreciation to Sherine and
15 Robin for their leadership and to all the
16 Methodology Committee members along with all of our
17 PCORI staff members who work in this area. We
18 continue to see your group as making a significant
19 contribution to our overall efforts and
20 specifically to improve in all the research that's
21 conducted not just at PCORI, but across the nation.
22 One question I have, when I look at the

1 list of recommendations here, and this came up when
2 it was first presented is which of these have we
3 sort of adopted as priorities and you don't need to
4 answer this today. I think we need a metric system
5 to measure progress in the same way that we have
6 for other areas and particularly something very
7 similar to what Joe presented this morning.
8 Remember when he put up the legislative mandates
9 where they have the statute, the institute shell,
10 then he had the status red light, yellow light,
11 green light, and then a progress report. So,
12 something as simple as that as it relates to these
13 recommendations would be very helpful.
14 DR. GABRIEL: Yes, and we would love to
15 sort of hook into the staff to help us do that --
16 CHAIRMAN WASHINGTON: Oh, absolutely. I
17 would expect that.
18 DR. GABRIEL: -- in the same way that
19 they've done it for the Strategic Plan. That would
20 be great.
21 CHAIRMAN WASHINGTON: Okay.
22 DR. HICKAM: Could I comment on that for a

1 minute?
2 CHAIRMAN WASHINGTON: Please, David.
3 DR. HICKAM: So, some of these recommended
4 actions do have resource implications. So, we
5 thought it was a good idea for the Board to sort of
6 re-familiarize themselves with those and we've
7 tried to make some estimates both about timetable
8 and resource needs.
9 CHAIRMAN WASHINGTON: Okay, go on.
10 UNIDENTIFIED BOARD MEMBER: Resource
11 implications over what timeframe? Are you talking
12 about next year, next cycle, or now?
13 DR. HICKAM: Well, whenever you want to
14 start carrying through with the recommendations.
15 CHAIRMAN WASHINGTON: But, I mean, that's
16 actually my question here is to the group. So, the
17 long list, which ones are we already sort of quasi,
18 unofficially or officially adopting and we're
19 moving forward?
20 DR. GABRIEL: Right.
21 CHAIRMAN WASHINGTON: And which ones or --
22 DR. GABRIEL: So, on the bottom of each of

1 these sections, it says "efforts already underway,"
2 and you can see that they're underway -- some of
3 the things that are already in place and for each
4 of these, as I said, we have a timeline and a
5 responsibility. Now, of course there are resources
6 associated with everything. We have a budget and
7 much of this I think can move forward if we had the
8 support within our current budget, but I think you
9 make a very good point. This needs to be part of
10 the strategy of the institute and needs to be woven
11 right into that and we'd be happy to do that.
12 CHAIRMAN WASHINGTON: Okay, sounds good.
13 Okay, I'm going to start here with Zwolak and make
14 our way around. Hunt, Levine, and Krumholz.
15 DR. ZWOLAK: Bob Zwolak, Board member.
16 I'd like to acknowledge your great
17 progress and efforts and my brief comment here is
18 simply that on the PCORI Web site under "Research
19 Plan," our directions still say "Applicants are
20 encouraged to refer to the contents of the PCORI
21 Draft Methodology Report in developing their
22 research plan." It seems like we should be fed up

1 in terms of “refer to.” It seems to me it needs
2 stronger wording. I think we should be following -
3 -
4 DR. GABRIEL: So, yes, if I could just
5 comment. Yes, we’d be delighted to see that and we
6 talked even yesterday about creating a checklist or
7 whatever makes it easier for reviewers to ensure
8 that the work that we’re funding is aligned, but I
9 think that would have to come from the Board rather
10 than the Methodology Committee.
11 DR. SELBY: So, if I may, Bob. There's a
12 reason why the instructions haven't said that yet
13 and it’s because as we implemented the Methodology
14 Committee standards for purposes of eliminating any
15 advanced knowledge advantage, we put in a six-month
16 lag between the actual publication of the standards
17 in November, in late November after our Boston
18 meeting and their actual applicability. So, when
19 the applications guidelines go up, next week,
20 Martin, on the 15th, there will be that change.
21 You will now see that applicants are in fact
22 expected to adhere to the methodology standards and

1 absolutely, Sherine, Robin, and David, we need to
2 work on aids for our peer reviewers to know how to
3 apply them best.
4 David, you may have something to add to
5 that.
6 DR. HICKAM: So, the initiative that
7 Sherine described in her presentation was to
8 develop those tools specifically for reviewers, and
9 so, that's on the launching pad to get done in
10 2013. To get completed.
11 UNIDENTIFIED BOARD MEMBER: Sooner.
12 DR. HICKAM: Well, again, so, the
13 viewpoint here is that these are tools to help
14 reviewers apply the standards to the evaluation of
15 individual research applications. Now, again,
16 we'll have to see how well the reviewers sort of
17 take that to heart.
18 CHAIRMAN WASHINGTON: Hunt.
19 MS. HUNT: Gail Hunt, Board.
20 I was just asking what happened to the
21 translational table that we talked about a whole
22 bunch, but maybe I haven't seen it.

1 DR. GABRIEL: Well, the reason we haven't
2 presented it is frankly because Sebastian was away
3 yesterday. So, the plan now is to -- and I think
4 we talked about this the last time we were here --
5 is to put forth an RFA to develop the translation
6 table according to the specifications that we've
7 discussed and we don't have those specs, I think,
8 completed to share with the Board yet.
9 DR. HICKAM: I'd be happy to speak to
10 that. As you probably remember, there was a
11 description of the concept for the translation
12 table in the Draft Methodology Report that was
13 posted last summer. In the revised Methodology
14 support that. That has been changed. And so,
15 there's sort of a new description of or an updated
16 description of the concepts for the translation
17 table. And so, that's going to be coming out with
18 our final report, which is going to be coming out
19 within the next month or so.
20 And so, our thinking was to sort of use
21 that then as kind of the launch to move forward
22 with further activities associated with the

1 translation table. And I think that one of the
2 things maybe just for consideration is that it
3 might not be the case that it’s really a cable or
4 an algorithm, that it’s a more comprehensive
5 approach to applying the standards. We do feel
6 that there's a close link between the standards
7 themselves and a translation table activity.
8 CHAIRMAN WASHINGTON: Okay, Levine and
9 Krumholz --
10 DR. HICKAM: And you're looking very
11 puzzled there.
12 DR. WASHINGTON: -- and I’ll work my way
13 back down.
14 MS. HUNT: [Off microphone.]
15 I just thought we actually were going to
16 get that a while back. That’s the only reason I
17 was asking.
18 DR. LEVINE: Sherine, you may have already
19 have this in the works or thinking about it, but
20 from a consumer perspective, we’re in the biggest
21 areas of the confusion and frustration around
22 research is the very real ongoing cycle of

1 findings, refuted findings, new findings, changing
2 findings, and one of the areas, the why methods
3 matter piece could actually I think in lay terms
4 bring a lot of clarity to the issue of why
5 different studies delivered different results and
6 why translating the work of the Methodology
7 Standards into a vehicle to enable consumers to
8 understand that all research isn't the same, that
9 methods do matter, and linking it to what is
10 massive ongoing investment now in electronic health
11 records that many people believe will deliver us
12 into a world where you push a button and answers
13 come out. And I think there are lots of areas of
14 hope and expectation that the consumer version of
15 this work could really help to bring some
16 understanding and some clarity about how to fit
17 research findings into the universe of information
18 about health.
19 DR. GABRIEL: Yes, and so, thank you for
20 that. I mean, I couldn't agree with you more.
21 That's why I'm excited about the patient stories
22 that are now going to be part of the report and I

1 think that will be the start, perhaps, of a
2 communication that would be more broadly acceptable
3 to the public and I really hope it is just the
4 beginning of that kind of communication. I mean,
5 is that what you were talking about? I think those
6 patient stories are meant to illustrate why the
7 methods are important and in a way that might be
8 more meaningful to patients.
9 DR. LEVINE: I know one of the things that
10 many people have struggled with is this issue of
11 communicating risk and probability to a lay
12 audience and I include physicians --
13 DR. GABRIEL: Yes.
14 DR. LEVINE: -- in terms of the lay
15 audience. At least many physicians. And there is
16 a group at Stony Brook University in Long Island.
17 It's the center for communicating science to the
18 public that has been working in this area for a
19 number of years and there may be some learnings
20 there about translating complex ideas into simple
21 or accessible information for consumers and I think
22 this is a ripe area for that.

1 CHAIRMAN WASHINGTON: Okay, thank you,
2 Levine.
3 Krumholz.
4 DR. KRUMHOLZ: Hi, Harlan Krumholz.
5 Four quick things. One, on last night, I
6 just wanted to at least follow-up. There was a
7 suggestion that this be layered on top of the peer
8 review. What I asked Steve to do yesterday was to
9 see if they could go through a sample of grants
10 that we have funded and see what percentage of them
11 have major methodologic flaws that he thinks would
12 undermine their competitiveness for journal-like
13 annals because I think it would give us a good
14 indication of the potential value of this extra
15 review plus it would also be able to feedback into
16 our current review process in order to strengthen
17 it and I felt getting some data on that might be a
18 very useful thing to do and would demonstrate -- I
19 told him I thought if he had opened his
20 presentation with that saying 20 percent of what we
21 funded have methodologic issues that would have
22 precluded publication in a high-tier journal, that

1 would be very useful for us in terms of if -- or if
2 they weren't remedial, then it's a different remedy
3 for the future, yes. So, you either fix those or
4 they never should have gotten through if they
5 weren't remedial. Remedial, so.
6 UNIDENTIFIED BOARD MEMBER: [Off
7 microphone.]
8 DR. KRUMHOLZ: But, anyway, just one thing
9 is to try to get some data on that.
10 The second thing is as I've been
11 reflecting on the Methodology Committee's great
12 work and thinking, Michelle, about the logic model
13 and trying to figure out where does it fit in that
14 model because what we're talking about there, we
15 don't actually have in the model as far as I can
16 see better research and we want to increase
17 information, speed implementation influence
18 research, we want better informed decisions to
19 improve health incomes, better health care, the
20 better research somehow all fills into that, but we
21 just need to be clear, I think, where this fits in
22 that model and how that's feeding in.

1 Because when I first started listening to
2 you, I starting thinking gosh, we need a logic
3 model for the methodology group because what are
4 their outputs? And then I thought well, we don't
5 actually want to create a parallel logic model, it
6 needs to be in our organizational logic model, and
7 I'm sure you already have this in your thoughts,
8 and I'm probably looking in the wrong place when
9 I'm thinking about what we create, but, anyway, I
10 think it just needs to be firmly integrated so that
11 our success is dependent on funneling in the
12 products of the work that the Methodology Committee
13 -- because it fits so well with what we're trying
14 to do on the ultimate outputs that we do.
15 Two other things. One is as I think about
16 this, the major problem that I would want to solve
17 is the poor quality of much of the methodology
18 that's embedded in studies people want to do or the
19 lack of access that so many people have to high-
20 quality methodologic consultation. And I think if
21 we said those of us who are fortunate enough to be
22 surrounded by exquisitely talented methodologist

1 are spoiled, we can go back and forth so much with
2 people who are so talented so that by the time we
3 submit something, we have the benefit of being told
4 why we were wrong about 100 times before we finally
5 get it right.
6 There are precious few of those places
7 that have such easy access plus if we're trying to
8 reach out to atypical investigators, investigators
9 who aren't necessarily in the usual places but have
10 good ideas, then we need to find ways to assist
11 them and I just wonder why PCORI wouldn't want to
12 say well, we're going to allocate $20 million a
13 year to creating a national resource, a
14 clearinghouse where people can get consultation and
15 somehow we need to figure out what is it that gets
16 people in, but that people could have an hour where
17 they sit down with people who know what they're
18 doing and can give them feedback.
19 Now, some of that feedback may be you do
20 not have the -- where you are, you're not going to
21 be able to get to where you need to be because we
22 can't serve the role of being your methodologist,

1 but we can tell you you're too far away, you need
2 to find a partner who can provide this for you. In
3 other cases, they may at the margin be able to
4 point them to places in the Methodology Report and
5 give that kind of consultation.
6 But to create a clearinghouse, there is no
7 place that most -- if a non-profit says we want to
8 do a project and we're doing this in New Haven
9 because our scholars program is working with non-
10 profits, they can't write grants without help on
11 the methodology section. And we're helping them
12 now, but before that, that part was just a deal-
13 breaker for any application because they didn't
14 have the background in order to do it even though
15 they had great ideas.
16 So, I just wanted to at least put this on
17 the table because I know we're thinking about how
18 we can improve the grants that are submitted, but
19 I'm more concerned with trying to get out into the
20 environment and provide the kind of support that
21 people need in order to know what can I do, how do
22 I use the Methodology Report and in many cases the

1 urge to find a partner, go to your universities or
2 find somebody who can help you do this, you got a
3 great idea, but this is just not going to work
4 unless you get that done.
5 The final piece is we've talked about
6 this, and I bring it up at about every other
7 meeting, is our own capacity building and the
8 degree to which we're going to provide funds to
9 expand the group of people who are qualified to
10 engage in this kind of research and I don't just
11 mean physicians, although physicians are part of
12 that. I don't just mean nurses; I know the nurses
13 are a part of that. I mean a whole wide range of
14 people who are committed to putting careers in PCOR
15 and I still think we should have PCORI scholars who
16 are being trained around the country who then will
17 eventually expand our capacity.
18 So, anyway, those are the four points I
19 wanted to make.
20 CHAIRMAN WASHINGTON: Okay, thank you --
21 DR. GABRIEL: Oh, pardon me, a very quick
22 comment on two of them. This is Sherine Gabriel

1 again.

2 With the motivation that you described

3 regarding pulling in nontraditional investigators

4 with great ideas who need methods support is

5 exactly what led us to the discussion last night

6 and I guess our hope is that if we can develop a

7 pathway working with the peer review process where

8 the PCORI peer review process helps identify great

9 ideas with what they perceive as solvable, fixable

10 methodologic gaps and we can move that forward,

11 that can be a first step in doing exactly what you

12 say, but it’s challenging and we have to do it in a

13 way that’s integrated with the current peer review

14 process.

15 And then training, I just wanted to

16 underscore that. If there's something we can do,

17 and training was one of the categories of

18 recommended actions, if there's something we can do

19 to move that forward, the idea of PCORI scholars I

20 think is important. It’s a big piece of

21 sustainability.

22 CHAIRMAN WASHINGTON: Joe, did you want to

1 comment --

2 DR. SELBY: Yes.

3 DR. WASHINGTON: -- because Douma is next.

4 Well, go on, please.

5 DR. SELBY: I just wanted to say that I

6 think from the staff's point of view, we're open to

7 discussing the issues of training again. We have a

8 number of plans underway, including the engagement

9 awards, which provides certain kinds of

10 opportunities to train. We have a training RFP.

11 We have stayed away from formal fellowships, for

12 example, K-like awards and because AHRQ funds those

13 -- they have one out right now, as a matter of

14 fact.

15 UNIDENTIFIED BOARD MEMBER: [Off

16 microphone.]

17 DR. SELBY: So, Gene is here, and I don't

18 want that we need to discuss this right now, but I

19 think, for example, the PDC would be a great forum

20 and maybe the PDC in concert with the Methodology

21 Committee would be a great forum to continue

22 discussing this.

1 And I just wanted to say also just this
2 notion of the awards that we give in attention to
3 or our desire to optimize them methodologically, I
4 think it's very safe to say that the awards that we
5 funded have met a high standard of methodologic
6 rigor already, but that is never to say with any
7 funding agency that the opportunity to collaborate
8 with, as you say, Tom, not just methodologists,
9 couldn't make it a bit better in some cases. So,
10 that's I think what we're looking for there.
11 And this notion about identifying
12 nontraditional researchers and bringing them to the
13 level of competiveness for funding is yet a third
14 idea and I think that's one that I'd have to
15 understand more how this fits in with the
16 Methodology Committee's proposal, but it's
17 certainly something that we'd love to see, in other
18 words the ability to extend PCORI primary research
19 funding to nontraditional research teams.
20 CHAIRMAN WASHINGTON: Okay. Becker and
21 Norquist and Hole-Curry.
22 DR. DOUMA: Allen Douma, Board.

1 Let me start off by saying, Sharon, I
2 don't think you can say that loudly enough the need
3 for us to be able to communicate to consumers and
4 particularly to be able to communicate research,
5 what is research? I think that should be a core
6 goal of PCORI and, in fact, it will sustain us or
7 make us sustainable if you want to pull up the
8 perspective 2019. And so, we ought to focus on
9 that and the methodology folks a great resource to
10 do that or at least being engaged in that.
11 Gene, I also want to reference back. I
12 think it is critical for us given all of the great
13 stuff, and I had no idea how much you've been
14 doing, Sherine, and balancing all those balls and
15 if you look at the stuff that's being recommended
16 to do, put that on the same plate. It's huge to be
17 able to track it and monitor it and measure it and
18 to show it off is going to require some kind of
19 strategic planning and operational plan that we can
20 all watch and look at.
21 And apropos to that, I know, Sherine, you
22 reflected back saying if you want us to do that, we

1 need help. We need help. My question is: Because
2 of the importance of what you do, what the
3 Methodology Committee does, and I think we need to
4 make sure you have enough help and that this board
5 needs to be supportive above and beyond just the
6 routine reflex to make sure that you have staffing
7 that's dedicated and focused on providing what
8 you're doing to leverage because so many of the
9 programs you're working on are leverageable as
10 compare that to spending a few million dollars on a
11 single study as compared to some of your stuff,
12 which will reflect in every study. So, I think we
13 need to make sure that staff understands that the
14 Board is very supportive and if you have any issues
15 with that or with them, just remind them.
16 CHAIRMAN WASHINGTON: Well, just to pick
17 up on Allen's point that it's really a very good
18 point that you also made, Sherine, and that is,
19 going forward, we really expect that everything
20 that you just presented would be incorporated into
21 the PCORI Strategic Plan. And so, Joe, the idea
22 here is that when you get to -- I was looking for

1 the diagram, but the section that talks about
2 advancing research methods, essentially at the high
3 level, there's a dashboard and then as you push the
4 button and go deeper and deeper, you get down into
5 the very recommendations that Sherine has laid.
6 So, it’s not something separate, and so, in the
7 future, we’d expect that we would see this as part
8 of the PCORI Strategic Plan and I suspect you're
9 already seeing it that way, but it’s coming through
10 very clearly that it’s that’s what it is.
11 DR. SELBY: Yes, I couldn’t agree more. I
12 think that starting with the pillar of rigorous
13 research methods --
14 CHAIRMAN WASHINGTON: Right.
15 DR. SELBY: It leads to just about every
16 output and all three goals.
17 CHAIRMAN WASHINGTON: Okay. And Norquist.
18 MR. BECKER: So, I’d like to hear from
19 somebody who’s smarter than I on this topic, but I
20 thought in response to Arnie’s question about the
21 use of methods adopted by the Methodology Committee
22 the response was we’ll see whether the reviewers

1 take it to heart. I think that's what I heard.
2 So, that's one.
3 And then the second question is: What are
4 we doing to leverage the inflow and so, the use of
5 the methods for research not PCORI-funded? Because
6 I thought the whole point of this was this was a
7 national effort, PCORI, we set up this Methodology
8 Committee and we're going to disseminate these
9 methods so that we change practices so patients can
10 rely on the information that comes from research?
11 DR. GABRIEL: Everyone's afraid to talk
12 because there's nobody smarter than Larry.
13 [Laughter.]
14 CHAIRMAN WASHINGTON: Well, Larry's put a
15 question on the table and Joe reflect on it and
16 respond at some point in the near future.
17 DR. HICKAM: So, I think I was the one who
18 made that comment, so, maybe I should reply. So,
19 you remember that PCORI recruits reviewers from a
20 wide range of disciplines. We have a large group
21 of reviewers that sit on the individual merit
22 review committees. Of course, we want them to be

1 aware of and adhere to the methodology standards in
2 conducting their reviews. We want to give them
3 tools that will make it as easy as possible and as
4 successful as possible and those applying them. I
5 just meant to acknowledge that this a diverse group
6 of reviewers and that we're going to see some
7 variability in the way they interpret and apply the
8 methodology standards to individual projects.
9 CHAIRMAN WASHINGTON: Okay, Norquist.
10 DR. NORQUIST: Yes. I'll just add, that
11 wasn't what I was going to say, but it's very easy
12 how -- what, you want to say something?
13 DR. GABRIEL: Oh, I just wanted to respond
14 to your second question --
15 DR. NORQUIST: Okay.
16 DR. GABRIEL: -- which had to do with I
17 think it was how did the Methodology Standards help
18 people who aren't submitting grants or who are
19 unsuccessful, and in our recommended actions, there
20 are under the training section we hope to create
21 some training modules that would be widely
22 available so that anybody can learn about what the

1 PCORI Methodology Standards are all about, whether
2 they want to apply or not. So, hopefully, that can
3 be built into some of the educational modules that
4 we build in as part of the report and even beyond
5 that.
6 CHAIRMAN WASHINGTON: But, Sherine, I
7 thought I heard Larry asking, which I think is an
8 excellent question, us as an board, an
9 organization, what are we going to do to
10 proactively promote these? And, I mean, that's a
11 step in the right direction, but that's a rather
12 passive way of advancing the methods, and so, it's
13 a question, Larry, that's on the table. Joe's
14 going to get back --
15 MS. NEWHOUSE: No, I just want to mention
16 that we have an active implementation plan. So,
17 this is a piece of our work. Beyond these
18 recommended actions, there's a whole group of work
19 that's also occurring that we're moving forward
20 with, and one of which is the implementation plan
21 that Sherine mentioned. Part of that
22 implementation plan is active strategies. So,

1 training is part of it.

2 The Institute of Medicine project that we

3 just completed is part of training that had a

4 diverse group of stakeholders. The Academy of

5 Health is a diverse group of stakeholders. That's

6 on strategy. But in addition to training, there

7 are other kinds of communications that will need to

8 occur, the tools are a piece of that, but it's part

9 of the bigger implementation plan.

10 CHAIRMAN WASHINGTON: Okay, Norquist,

11 Sigal, Hole-Curry, and Epstein.

12 DR. NORQUIST: So, I would just add that

13 you can tell people all day long to do something

14 and they won't do it, and I deal in this every day.

15 [Laughter.]

16 DR. NORQUIST: And there are strategies

17 like don't fund them and they will learn very

18 quickly that they have to come back. So, we have

19 some leverage in that way in our active portfolio

20 management and do that. Influencing other funders

21 is a whole different issue that will take some time

22 and some strategy to get them, but once that

1 message gets out, you can change behavior pretty
2 quickly.
3 That wasn't what I want -- but first, I
4 want to thank you. I mean, I just can't imagine
5 what this is like to do this all day long and have
6 another 150 percent job. So, I really appreciate
7 all the work that you're doing and all of your
8 group is doing.
9 Just a couple of concrete things. One is
10 you, Sherine, and myself and Christine talked about
11 at one point picking topics. So, one of the topics
12 might be like exactly what Sharon is talking about
13 is how do you really take these methods and educate
14 and even what Harlan is saying, what I worry about
15 are the people who don't have these high resources,
16 living in an area where you don't have is and how
17 do you really help bring these people up to speed?
18 So, it's one of those things that as a group, we
19 talked about COEC, PDC, and the Methodology
20 Committee working on a specific issue with kind of
21 a timeline on some kind of thought about how you
22 might move forward in that. So, I would suggest

1 that might be one area and one kind of concrete
2 thing we could do as a board and with staff also to
3 take on.
4 The other thing that I haven't seen and
5 just want you to think about at some point is as we
6 move to larger CER-type trials and stuff, we got to
7 think about some other big-time methodology issues
8 and like DSMVs, are we going to have that in house,
9 are we going to contract these out? Some of these
10 big issues that I haven't heard. We've been
11 focusing on methodology for smaller, but when we
12 think about big-time trials, those are big issues
13 and we better start thinking about however we're
14 going to handle that or when we run into stopping a
15 study or somebody looks at something, what are we
16 going to do, like early looking at data. I mean,
17 what are going to be our methods issues on that?
18 So, at some point, that would be important, too.
19 MS. NEWHOUSE: No, I just wanted to --
20 CHAIRMAN WASHINGTON: Robin.
21 MS. NEWHOUSE: -- respond by saying we had
22 a discussion just yesterday about the same topic,

1 about the additional kinds of oversight and input
2 that we might need to prepare ourselves for.
3 CHAIRMAN WASHINGTON: Okay. Sigal, then
4 Hole-Curry and Epstein.
5 MS. SIGAL: Ellen Sigal.
6 CHAIRMAN WASHINGTON: Krumholz.
7 MS. SIGAL: So, Sherine, again, I want to
8 thank you for all your amazing work on this.
9 I do think that there are certain core
10 values that PCORI has, patient-centeredness, and
11 this Methodology Report. The Methodology Report is
12 a core value, as I see it, and we have an
13 obligation to integrate this now that it’s final
14 into all of the research and we’re just going to
15 have to figure out how to do it and I agree with
16 what Gray said earlier. If it’s not, we don’t
17 fund. I mean, there can be some teeth. We can't
18 make others and other professional societies or NIH
19 adopt it, but we certainly can for our own research
20 and I think we have to be really rigorous about it.
21 If we believe in it, it has to be a core value and
22 it has to be part of everything we do and you're

1 right, there are different people that may
2 interpret it. I deal with statisticians all the
3 time. They drive me crazy, but the truth of the
4 matter is --
5 UNIDENTIFIED BOARD MEMBER: I can help you
6 with that.
7 MS. SIGAL: Well, I think there are other
8 things on the list that I'm crazy about, too, but
9 if you can help, it would be great, but it is
10 really as the Board I think and I see it or all of
11 us see it is a core value for PCORI and there
12 should be no excuse for why it's not adopted in our
13 research that we fund.
14 CHAIRMAN WASHINGTON: Okay, thank you,
15 Ellen.
16 Hole-Curry.
17 MS. HOLE-CURRY: Leah Hole-Curry, Board
18 member.
19 I think that I'm just going to add because
20 I really care deeply about this issue. I think the
21 tradeoff of conflict of interest even for
22 methodology members versus enforcing this right off

1 the bat was a compromise that we should have voted
2 on here. But --
3 UNIDENTIFIED BOARD MEMBER: [Off
4 microphone.]
5 MS. HOLE-CURRY: Well, basically, the
6 reason that we haven't enforced these standards to
7 date is due to our conflict of interest policies
8 that we wanted to make sure that no methodology
9 member would be prohibited from bidding on the
10 first couple of rounds. And I just think that's a
11 compromise of our core values and I think we should
12 have voted on it here, but we didn't.
13 But what I'd point out is that we had a
14 briefing that says we're in the green for the
15 conditions of our contract for the statute and it's
16 required that we comply with the Methodology Report
17 as a condition of the contract for funding. So, I
18 don't believe we can be in the green right now
19 based on my personal feeling about this issue, but
20 also it's a core requirement. So, I think that
21 status needs to change and it really should be in
22 front of the Board if we have a review process

1 that’s I hear what you're saying, I know that the
2 standards are not necessarily only black and white,
3 so, there will be debate about it, but those are
4 things that we have to address if we care about it
5 deeply. They're not barriers to saying we can
6 comply with is in my view.
7 So, add another layer for the methodology
8 compliance if we need to. The discussion that we
9 had yesterday might help. There's a lot of ways to
10 get at it. I just think it’s just we’re a research
11 institute and if we can't even follow our own
12 standards, I think that’s a core failing. So, I
13 really feel like this needs to be front and center.
14 DR. GABRIEL: So, I think we agree with
15 that, but maybe a minor correction. I think one of
16 the reasons that it’s written a little fuzzy right
17 now was more of a timing issue I think than a COI
18 issue. The standards weren't completely ready to
19 give investigators really enough time to write
20 their proposals to be fully compliant, but now we
21 don’t have that excuse and I completely agree with
22 you. If we believe in the standards, we need to

1 require them. There's certainly no hope of other
2 organizations adopting our standards if we don't --
3 or fix them if there's an issue with them.
4 MS. HOLE-CURRY: So, that was mostly an
5 ask of the Board, not of you. My ask of the
6 Methodology Committee would be to consider whether
7 the actions that are identified here help us with
8 that piece or if there's some additional ones that
9 you all could help us with to consider.
10 And then the other thing was just specific
11 to the standards. There's a new set of standards
12 you're working on because the first Methodology
13 Report did not address all areas. There was also
14 controversy around some of the standards that were
15 adopted and some folks felt like they were more
16 minimum standards and we could move to aspirational
17 areas.
18 Is there work on the core set? Let me put
19 it that way, the currently adopted set of -- there
20 was consensus that these are core. Are we leaving
21 those in place or is there also work on those
22 related to moving to an aspirational level or

1 adjusting?

2 DR. GABRIEL: Yes, I think our feeling is,

3 and I'll have my colleagues chime in, is that the

4 standards need to remain as minimal standards

5 because we're going to require them of everybody.

6 Okay, aspirational piece is really what we

7 tried to speak to last night because that almost

8 needs to be individualized to a study or to an

9 investigator group, and so, that was the piece that

10 we talked about last night, yes.

11 MS. HOLE-CURRY: Okay.

12 DR. GABRIEL: The standards are minimal,

13 everybody, it's sort of a must do, but beyond that,

14 how do we help investigators and teams ensure that

15 they have the best methodological approach that

16 could be imagined? Well, that almost requires

17 mentoring and interaction with the right kind of

18 methodologists and that's the kind of thing that we

19 were describing last night.

20 MS. NEWHOUSE: The only thing I would add

21 would be -- Robin Newhouse -- is that these aren't

22 static standards and we know that they outdate and

1 we don’t know the time that it outdates, but like
2 systematic reviews every three years. So, there
3 has to be some kind of plan that they're regularly
4 reviewed and regularly updated and we absolutely
5 have to do that.
6 CHAIRMAN WASHINGTON: We have two more
7 comments and/or questions and suggestions and then
8 we’re going to take a 10-minute break. It’s 3:56;
9 I expect we’re going to break by 4:00.
10 So, Dr. Epstein and then Dr. Krumholz,
11 you’ve got the last word.
12 DR. EPSTEIN: Arnie Epstein, Board.
13 I thought I’d take just a couple minutes
14 to establish myself as a softie. Yes, after years
15 of that tough veneer.
16 So, I think of the job of a reviewer as
17 analogist closely to a job of an editor. And the
18 editor gets in a paper and he gets a bunch of
19 reviews or she gets a bunch of reviews and the
20 reviews talk about the merits of the paper usually
21 and the ways that the paper is not working very
22 well and often in reviews, the way they could even

1 make it better. And the editor’s job is not to
2 make a decision on the basis of what's come in the
3 door; the editor’s job is really to make a decision
4 on the basis of what could come in the door if the
5 people on the other end of the telephone heard what
6 the editor had to say and the reviewers had to say
7 and made a good-faith effort to get it back the
8 right way. So, the editor is always thinking ahead
9 and what makes a good editor often is enough
10 experience to know what a good paper writer can do
11 or not and make the decision on that basis.
12 And we’re doing the same thing with
13 grants. I think the standards that are in the
14 report, and I’ve spent a lot of time reading it
15 come a year ago, were reasonable and good common
16 denominators and pretty basic and I think in the
17 kinds of people that Harlan was talking about
18 before who’ve spent a lot of time at this, they're
19 going to get this except in a rare case and they’ll
20 be others who won't and I think our posture
21 shouldn’t be you did, you son of a gun, here's the
22 formed rejection and get to our Web site. I think

1 it can be something much gentler than that like you
2 didn't do a power analysis. In fact, we had our
3 fancy statistician do one for you and it looks like
4 your numbers are good, so, you got it right even
5 though you didn't tell us. Please though do the
6 formal work putting in the power analysis or some
7 variant on that for a different standard.
8 So, it's a little bit softer than why
9 aren't you listening, go to our Web site, because
10 people frankly, they're not going to go to the Web
11 site and read that that way. Most of them think
12 they're pretty good, some of those who think
13 they're pretty good could be dead wrong, and we'll
14 educate them, but I think we can do it in a way
15 that moves the field over time. That's my bias.
16 I get the alternative to that, which is
17 let's get the word out that we're tough and mean
18 and be out at Dodge without their weapons, but I
19 don't think so.
20 CHAIRMAN WASHINGTON: Okay.
21 DR. EPSTEIN: I'm a softie.
22 UNIDENTIFIED BOARD MEMBER: [Off

1 microphone.]

2 [Laughter.]

3 DR. GABRIEL: So, I think --

4 DR. EPSTEIN: I'll be quiet now.

5 DR. GABRIEL: No.

6 CHAIRMAN WASHINGTON: Dr. Gabriel and then

7 --

8 DR. GABRIEL: In the spirit of being a

9 softie, I think the message isn't you didn't do it,

10 you're out, it is providing every opportunity for

11 that group to improve and then if they don't step

12 up and take those opportunities, then we do have to

13 say that's --

14 DR. EPSTEIN: I took an example where they

15 committed the grievous law, they didn't put in a

16 power analysis, that's one of your standards, but

17 they had plenty of power. So, just dot the damn I,

18 would you, please?

19 CHAIRMAN WASHINGTON: Thank you, Arnie.

20 Last word, Dr. Krumholz.

21 DR. KRUMHOLZ: In making four points, I

22 think I maybe I obscured one suggestion that may be

1 better made with clarity. If an applicant gets
2 through the Letter of Intent process, we approve
3 it, I would like to be able to give them two hours
4 of methodologic consulting time in the period where
5 they're preparing their application. I would even
6 like to consider giving one hour of patient
7 engagement consulting time and then that’s just
8 going to be up to us to create the army of people
9 who can provide that kind of information back to
10 them.
11 As it stands now, investigators have
12 trouble talking to someone at PCORI. A person from
13 my institution could not get anyone on the phone at
14 PCORI and I think that if we want to get these
15 people out before, then we find -- I don't care if
16 we have to outsource it, I don't care where these
17 people come from, we go around the globe and we pay
18 for it, by the way. And not everyone will want it,
19 but some people who want it, you’ve gotten through
20 the Letter of Intent process. Then you say we’re
21 going to give you two hours of consulting, here are
22 the people, we’ll help you schedule it, and you get

1 two hours on the phone. And some of that might be
2 you need to find some people locally, that this
3 thing is such a mess that you need help. It’s not
4 to fix it; it’s not to write it for them, it’s to
5 give them consultation on it. And the two hours
6 might be one hour of preparation for the call, one
7 hour of talking on the call, and that I think would
8 be of enormous help to people who are applying. I
9 know it’s going to be logistically challenging, but
10 I think it would send in a very important message
11 and then it would also mean people could send in
12 Letter of Intents without having any frigging idea
13 exactly how they're going to do it, but they want
14 to get in the door in order to be able to start
15 engaging. Just a suggestion.
16 DR. EPSTEIN: [Off microphone.]
17 DR. KRUMHOLZ: We would have to train a
18 cadre of people who could give the advice on the
19 phone about what we mean when we say “patient
20 engagement,” what represents best practice. That’s
21 why I added both. But I think this would be very
22 helpful to people who were applying.

1 CHAIRMAN WASHINGTON: Okay, thank you, Dr.
2 Krumholz and everyone for that robust discussion
3 and I think we've heard, Joe, some valuable ideas
4 and suggestions that we'll take back to consider.
5 And, again, Dr. Gabriel, would you convey our
6 gratitude to all members of the Methodology
7 Committee and likewise, David, to all of our
8 colleagues on the staff for the great work that you
9 continue to do? And the message is clearly, at
10 least for me, is that we've got to incorporate this
11 and integrate it as though it's just a part of the
12 everyday activities and one way we may do that is
13 to rethink about the presentation here actually.
14 You're the only committee chair that literally does
15 most of the presentation and it's maybe a
16 reflection of what Allen was getting to. We have
17 to make sure you have the right staff in terms of
18 level, and this is no slam on David in any kind of
19 way, but he may also be overwhelmed, but we want to
20 ensure that the activities are no different from
21 the activities related to patient engagement or
22 related to dissemination or research as it relates

1 to methodology. So, thank you again.
2 DR. GABRIEL: Thank you for the input.
3 Thank you for the support.
4 CHAIRMAN WASHINGTON: Okay, we're going
5 to reconvene [off microphone].
6 [Pause.]
7 CHAIRMAN WASHINGTON: We're live. Welcome
8 back to this last session of the afternoon for the
9 Board of Governors' meeting for the Patient-
10 Centered Outcomes Research Institute.
11 And now we're going to have a couple of
12 announcements from Executive Director Dr. Selby
13 before we move to the next item on the agenda.
14 DR. SELBY: So, this is about dinner
15 tonight. We do have guests from the community
16 tonight for dinner. We have representatives from
17 Access Community Health Network, which is Chicago's
18 largest private provider of primary health care.
19 It's a network of more than 40 community health
20 centers in the greater Chicago area and surrounding
21 suburbs. So, they'll be here. We have a reception
22 at 6:00, dinner at 7:00.

1 CHAIRMAN WASHINGTON: Okay. We look to
2 see all Board members at the reception and dinner
3 this evening. Thank you.
4 Dr. Norquist.
5 DR. NORQUIST: Thank you. So, for this, I
6 got a bottle of wine, but anyway. That's an inside
7 thing.
8 So, what we're going to do, and I think
9 this is our little plan of keeping the audience
10 with us for the day because I'm sure there are a
11 lot of people who want to hear whether or not
12 they've been funded at this point. So, what we're
13 talking about here is Cycle II Applications.
14 Now, I chair the Selection Committee, and
15 let me say who else was on this. You see here
16 myself, Arnie Epstein, Kerry Barnett, and Gail Hunt
17 from the Board. From the Methodology Committee
18 Robin and Michael were on there and very helpful,
19 and then the staff is you see Joe, Romana, David,
20 and Chad. These are their programs that they see.
21 Stanley and Martin have also been
22 incredibly helpful, and I would say particularly

1 because we really had to work hard at trying to get
2 people together, and so, I want to apologize. I
3 hope all the Board members who are on this have
4 seen the final slides. I just saw them last night
5 and we sent them around because we had to hurriedly
6 go through this.
7 So, what we started with, and this is the
8 overall issue is that the PCORI staff, you'll see
9 there are four different funding announcements,
10 remember, and that the PCORI staff is recommending
11 a funding line of responsive applications. What we
12 mean are those who made it to the review and came
13 out with a score which ranged between -- so, it
14 depends on the funding announcement; we'll get to
15 that in just a minute, hang on -- 9.8 to the 14.7
16 percentile.
17 All right, so, of each of these, and we'll
18 detail those in just a second and maybe I should
19 just go on with that because that's what the last
20 thing says. So, here they are quickly. So, we
21 have four programs are, right? Assessing options,
22 that's David's program.

1 Now, we didn't ask them all to come up
2 here because that would take more time, but if
3 there are specific questions, you can ask him.
4 So, in the assessing options, the program
5 is proposing, which we went over with them, 20 of
6 these successfully-scored applications which
7 represents 11.5 percent of the total. Now, what do
8 we mean by the "total?" You can see down there in
9 the small print that the percent of total is of
10 those who were successfully scored. Not all
11 applications that came in, okay, the ones that came
12 in. All right, that totals an average budget --
13 well, the average budget for those 20 is around
14 $1.6 million with a total budget for all 20
15 applications over the 3 years of $33,648,774,
16 depending on how they contract with them.
17 All right, for the Improving Health Care
18 System, 13 successful applications. We're going to
19 say a little bit more about this; I want to say
20 something about the numbers here in just a second,
21 but let me get through each. You can read the
22 average budget for those for a total of

1 $24,000,500, and then there were 8 of the
2 applications in the Communication Dissemination
3 Research Program, which actually I forgot to say
4 that Chad runs the Improving Health Care Systems.
5 Joe was actually I guess in charge of the
6 Communication Dissemination Research. He presented
7 those for us, which he selected 8 for 9.8
8 percentile. And then Romana's program in
9 addressing disparities, she went with 10 of the
10 successful applications and that's a 14.7 percent
11 success rate there. And so, the total average
12 success rate is about 12.3 percent. It varies,
13 obviously, so, I wouldn't pay much attention to the
14 average. It gives us a total of 51 total grants
15 for a total of $88,600,000 over 3 years. That's
16 close to what we had allocated about what was it $6
17 million, yes. Okay.
18 So, let me just say also that what we did
19 in our Selection Committee, and I'll get to this in
20 the next slide. Well, actually, let me go to the
21 next slide and we can come back if people have a
22 question about the numbers.

1 Here are the steps because everybody wants
2 to know the process, how did we get to this? We
3 didn't just randomly pick these and stuff. So,
4 what happened is the PCORI program directors and
5 the senior staff reviewed the applications after
6 the review panels. So, they went through peer
7 review. Then then established an initial pay line.
8 So, they said let's draw it at the 10 percentile
9 and let's look and we asked to look above that pay
10 line, meaning a worse score and below the pay line
11 to say if you look at the group of grants that
12 you're proposing within that 10 percentile, how do
13 you feel about them? Do they really add value to
14 your portfolio? Do they address high priority
15 areas and these kinds of things and they felt
16 pretty comfortable to a program.
17 I mean, I think we went over this with
18 them again and again and we said now, look above
19 that line and just in a kind of active portfolio
20 way look at some grants above that and tell us do
21 you see any in your judgment that you feel meet a
22 high priority topic, it's an innovative thing that

1 might be successful, adds value to your portfolio.
2 So, they did that and you can see and they had
3 these a priori criteria they use, high priority
4 topics, studies of priority population and fits
5 within the vision of the program, meaning adds
6 value to the program.
7 So, let me go back and point out that in
8 the assessing options, David actually picked up --
9 and, David, you'll have to correct me -- if was
10 either another two or three grants that he pulled
11 right above the -- David's not there. Martine, was
12 it three? Yes, so, originally.
13 So, he actually went back with a little
14 bit of active portfolio management picked up some
15 right above the pay line because he felt they met
16 these criteria. I think Romana picked up an extra
17 one in the addressing disparities one and Joe
18 didn't see that there were any above that that he
19 felt comfortable with an I don't think in improving
20 health care, unless I'm wrong, that we picked up
21 any others in that one. Is that right? So, in
22 essence, we added another about four above what the

1 initial pay line was as a kind of active portfolio
2 management.
3 Did you want to say something, Joe?
4 DR. SELBY: Well, just looking at the
5 percent of Chad's, it suggests that they did. He
6 picked up five.
7 DR. NORQUIST: He picked up five.
8 DR. SELBY: Five.
9 DR. NORQUIST: Okay, so, I was wrong about
10 that.
11 DR. SELBY: Yes.
12 DR. NORQUIST: So, he started out with
13 eight and he went forward, picked up five that were
14 right above that pay line. So, thank you. I had
15 forgotten that one. Okay.
16 So, then that was discussed and I would
17 say it wasn't just Chad sat down and picked, we
18 wanted to be clear that they vetted this with other
19 program staff, went over them, felt comfortable
20 with the fact that these did meet some kind of --
21 so, it was kind of a group process and then the
22 Board Selection Committee and the methodology group

1 that was on that with us went over that to some
2 degree, but we then blessed basically in going with
3 the recommendations that they're making without
4 going into too much detail on the grants
5 themselves.
6 So, here it is. The next four slides are
7 the grants with their titles that are being funded,
8 and so, we -- oh, I'm sorry, I got to say this,
9 this just gives you an outline of the priority
10 population. So, you'll get a sense about the range
11 of, for example, rural children, elderly, racial
12 and ethnic disparities and a variety of other
13 points here by each one. So, you can see there's a
14 pretty good range across that.
15 Distribution, again, we’re distributed.
16 We missed Texas and my state and some others here.
17 So, you can see we -- we hope to do more outreach
18 in some of these to get some of the states that
19 don’t have green in them.
20 Now, this is for this round. If we put
21 this right, Joe, if we match it with our other one,
22 we might fill in some of these, right? Because

1 this is just this round. Okay.
2 DR. SELBY: It’s done particularly east of
3 the Mississippi.
4 DR. NORQUIST: East of the Mississippi.
5 Yes, we might fill in more there, okay.
6 All right, here we go. So, this is the
7 lead into the project titles, which I’m sure the
8 people on the phone and otherwise want to know
9 whether they’ve been funded, and so, the first one
10 is the assessing options and I’m not going to sit
11 here and read every one of them. You guys can
12 read, but this gives you an idea of the topical
13 areas of the grants. So, these are the actual
14 literal titles of the grants. I’ll give you a
15 minute to look at that. So, everything from the
16 first one there and these are not in any particular
17 order, generating critical patient-centered
18 information for decision-making in localized
19 prostate cancer. There are actually, Ellen, you'll
20 see there are a couple or two or three there on
21 prostate cancer.
22 MS. SIGAL: [Off microphone.]

1 DR. NORQUIST: Sitting next to --
2 MS. SIGAL: [Off microphone.]
3 DR. NORQUIST: Yes, and you can see a
4 number of others there, which we will post
5 immediately I think on our Web site.
6 DR. KRUMHOLZ: Do we fund grants that have
7 surrogate outcomes as their outcomes or do we
8 require that they have patient outcomes?
9 DR. NORQUIST: Good question. I think,
10 Joe, you want to answer?
11 DR. SELBY: I mean, I can't honestly say
12 that I know this for everyone, but I think just
13 based on the review criteria, it'll be unlikely to
14 have a study that had surrogate outcomes and no --
15 DR. KRUMHOLZ: Like glucose control or
16 something.
17 DR. SELBY: Yes, we always beat up on
18 glucose control.
19 DR. KRUMHOLZ: We would avoid that, right?
20 DR. SELBY: But yes.
21 DR. NORQUIST: Yes, be careful about
22 reading titles and we don't know the whole grant

1 here. So, that’s the thing that I --
2 UNIDENTIFIED BOARD MEMBER: [Off
3 microphone.]
4 DR. NORQUIST: Yes, you'll see one at the
5 end that I’ll show you the title and I was like
6 this doesn't give me any information. So, you'll
7 see in a minute. These are the grants that are
8 recommended still in assessing options. Remember,
9 there were 20. So, there are two pages here, so,
10 there are 10 on each page. So, this continues on
11 the same program.
12 You will see one at the end here,
13 “Comparing Patient-Centered Outcomes after
14 Treatment for Uterine Fibroids.” And so, the
15 question came up points of adding that to the
16 portfolio, in fact, that we might be doing a
17 targeted announcement, but the feeling by the
18 program staff was that this would give us a head
19 start and would be an important addition to their
20 portfolio.
21 Improving health care systems, I hope 13
22 grants if that’s the number, correct? You will see

1 there a range of different things, including,
2 Ellen, evaluating cancer survivorship care models.
3 So, there are a range of different --
4 MS. SIGAL: Is there a printout of this
5 anyplace?
6 DR. NORQUIST: I'm sorry, what?
7 MS. SIGAL: [Off microphone] -- a
8 printout.
9 DR. NORQUIST: We'll have a printout as
10 quickly as we get this up. The point was to share
11 this with everyone at exactly the same time.
12 And then under the communication
13 dissemination, there are only eight awards. So,
14 these are the awards out of -- Joe, that's your
15 program. So, if you want to comment on anything
16 about that program.
17 DR. SELBY: No.
18 DR. NORQUIST: Okay.
19 DR. SELBY: As you said, we followed the
20 scores.
21 DR. NORQUIST: He followed the scores
22 directly up to the line.

1 And then the last but not least is the
2 Addressing Disparities Program. So, these in
3 Romana’s program were the grants. You can see the
4 first title was originally “Ms. A and Mr. B,” and
5 that didn’t tell you much information about what --
6 the actual literal title, I was like this is very
7 interesting and then Romana filled in some other
8 things about what the grant is actually about. So,
9 that’s not the real title of the grant.
10 UNIDENTIFIED BOARD MEMBER: [Off
11 microphone.]
12 DR. NORQUIST: Back to the previous slide,
13 yes.
14 Oh, okay, I'm sorry, Communication
15 Dissemination we’re back to.
16 DR. DOUMA: Gray.
17 DR. NORQUIST: Yes.
18 DR. DOUMA: [Off microphone] summary of
19 it.
20 DR. NORQUIST: Yes, as we’re looking at
21 these, let me just tell you a couple other things
22 that came up in our discussion with the Selection

1 Committee. So, we had advised that at least the
2 abstracts certainly be quickly put up and then I
3 guess the issue about the rest of the grant at some
4 point. Then remember they have to do some
5 discussions with the applicant and things like
6 that, but we felt it was important to at least get
7 the abstracts up also so we at least know. Now,
8 sometimes abstracts don't tell you everything, and
9 so, it would nice to know the whole grant.
10 And let me just say the other thing that
11 we had a discussion about is this idea of kind of
12 active portfolio management when we're doing the
13 selection and what's the role of the Board in that
14 or some sub segment of the Board as we help the
15 program staff make these decisions about going
16 above a certain line, coming below, whatever, and
17 we didn't -- Arnie actually chimed in on this one
18 in a big way, too, and we never came to any
19 complete conclusion, but something we may want to
20 have more discussion about as we talk in general
21 about active portfolio management is what is the
22 Board's role when we do the selection? We did

1 better this time instead of before, we were
2 completely masked. We didn't know the names of
3 anybody, anything else.
4 This time, at least we knew a little bit
5 more about what the topical areas were and stuff.
6 We felt more comfortable about actually serving a
7 role than just drawing a line and I think we would
8 like to see that we have that kind of role and I
9 think as I pointed out to Joe and them that when I
10 was at the institute, we had these advisory
11 councils and advisory councils serves that purpose
12 kind of like the Board when the staff want to pick
13 something, it's above a line or really pick
14 something innovative, it's a good role for the
15 Board to have to be able to step in and say yes,
16 this adds value, whatever, and we agree with you or
17 something. But we don't want to get to
18 micromanagement into the program staff as they
19 build a portfolio.
20 All right, we'll go on to the final one
21 here.
22 DR. WEISMAN: Well, like with the duration

1 of --
2 UNIDENTIFIED BOARD MEMBER: Turn your mic
3 on.
4 DR. NORQUIST: Turn your microphone --
5 DR. WEISMAN: It is. It’s Harlan Weisman.
6 What the median or average or range of
7 durations of these trials are and including the
8 fact that there's going to be a startup period,
9 there's going to be notification, contracts, all
10 the stuff. So, it takes a while to get any study
11 up and running and then there's the initial inertia
12 of any study before it actually starts enrolling
13 and there's a time course for which the enrollment
14 has to occur and then there's the analysis and
15 interpretation phases.
16 So, I guess what I’m asking is when would
17 any of them produce results? When would we expect
18 to start seeing the results of these? And then on
19 top of that, I’d like to --
20 DR. NORQUIST: Yes, so, let me -- let’s
21 address the first issue. So, first, you're right.
22 They’ve got to negotiate with the potential

1 grantees, get them started. So, let’s say the
2 earliest start date might be the fall or something
3 and then you're looking at I think almost all of
4 them were three-year grants, maybe one or two were
5 one-year grants. So, you're looking three years,
6 you're looking at 2016, the end of 2016 or maybe a
7 little before, depending on how soon they can get
8 it. I think on average is your average question.
9 DR. WEISMAN: Now I understand what's been
10 bothering me all day, it’s that clock ticking that
11 I’ve been hearing and we’re basically at Joe’s 2017
12 right now and I think not now, because I love the
13 grants, love the titles, I think it’s a real issue
14 for this board, not for the institute, for the
15 institute, too, to take ownership of the fact that
16 this is basically a work product as far as our plan
17 horizon of when we’re going to start doing things
18 to have impact.
19 Now, I may be exaggerating, but I think
20 it’s a big issue and I think that we’ve got to do
21 some things with a sense of urgency beyond this
22 because I’m not sure we’re going to have a lot to

1 show for what we’ve been doing. I'm sorry. I
2 mean, we’ve got to think about it.
3 The next round is going to be going into
4 2017 and then the next round after is that is
5 really outside of our funding horizon. That’s a
6 big deal and I’m not sure we’ve really been facing
7 it from a portfolio standpoint. Our portfolio
8 isn't producing something that’s going to deliver
9 what we’ve committed to ourselves to deliver what
10 we’ve committed to the public to deliver. I’m not
11 blaming anybody; I just think it’s a reality that
12 we’ve got to face.
13 DR. NORQUIST: So, yes, I mean, it’s a
14 reality of where we are that makes the targeted
15 announcements even more critical to get them out
16 very quickly if you want to get some other results
17 out because the next round, I don't know when those
18 will be reviewed, but then you're looking at not
19 getting --
20 DR. WEISMAN: We’re doing something else.
21 DR. NORQUIST: Yes or doing something
22 else, you're right. I mean, but that brings up the

1 bigger question, not the question about the
2 specific issue.
3 DR. WEISMAN: Right.
4 DR. NORQUIST: So, before we get into some
5 of those bigger questions, can we take specific
6 questions about this funding, about these grants,
7 because what we're going to ask is that the Board
8 approve what has been recommended for funding.
9 Yes.
10 DR. WEISMAN: Okay.
11 DR. NORQUIST: I'm sorry, Sharon.
12 DR. LEVINE: Sharon Levine. If you could
13 go back to the prior slide, so, I thought, and
14 maybe it's my error, the communication and
15 dissemination research was going to be researched
16 into the communication and dissemination of
17 research results. So, and maybe the problem is all
18 I can see is the titles, but I'm not sure how some
19 of these fit into that mindset.
20 DR. SELBY: So, the Communication and
21 Dissemination Funding Announcement calls for
22 research, as you say, on among other things

1 patient-clinician communication, shared decision-
2 making, tools for decision support, those kind of
3 activities are called for in that, as well as work-
4 related to dissemination. So, a lot of what comes
5 out is decision support in patient and clinician
6 interaction and tools to support that. And always
7 comparative studies with patient-centered outcomes.
8 So, not just the development. It's not
9 methodologic in the sense that it's the development
10 of a new decision aid or shared decision tool.
11 It's a trial or observational comparison of two
12 approaches.
13 DR. NORQUIST: Kerry.
14 MR. BARNETT: Just remind me, the total
15 amount of all these grants combined is $88.6
16 million and that's against an original budget of
17 what when the PFAs were first released?
18 DR. NORQUIST: This particular round, 96 I
19 think they planned on.
20 UNIDENTIFIED BOARD MEMBER: Up to 96.
21 MR. BARNETT: Up to 96.
22 DR. NORQUIST: So, we're off by $8 million

1 here.
2 MR. BARNETT: But we were reasonably
3 close. So, what do we draw down from that? Why
4 are at $88 million instead of closer to the $96
5 million? Is there something process-wise that we
6 would want to tweak or something about the way we
7 handled the announcements that would have gotten us
8 to the full amount? I mean, we're prepared to give
9 away 96 --
10 DR. SELBY: Yes.
11 MR. BARNETT: And we wind up giving away
12 88.
13 DR. SELBY: This is a little --
14 MR. BARNETT: I'm just trying to
15 understand the dynamic there.
16 DR. SELBY: I have to get a little bit
17 technical here, but we're used to the scores that
18 come in from -- many of us, we've seen scores from
19 study sections at NIH and AHRQ and we're used to
20 scores actually carrying names like exceptional and
21 outstanding and when we see the distribution of
22 scores that come from these reviews, they are

1 higher. They're substantially higher, I think,
2 than the distribution of scores from the typical
3 NIH or AHRQ study section and given that this is a
4 brand-new process, new review panels, we have
5 several options for why that is.
6 One option is hey, these are just not as
7 good as the average application coming in to NIH
8 and AHRQ. The second is that the review criteria
9 are somewhat different here and we’re incorporating
10 the criteria of patient-centeredness and patient
11 engagement and that’s what's bringing these scores
12 down. And the third I think is a variant of that,
13 which is that people are just learning to do
14 patient engagement and patient-centeredness and
15 it’s tough to distinguish, it’s impossible I think
16 really to distinguish between them.
17 So, we’re faced with actually funding
18 applications that score pretty high when you just
19 look at the absolute scores versus NIH, but on the
20 other hand, percentile-wise, it’s not very
21 different in what NIH is funding. So, then we take
22 a look at the applications that are above the pay

1 line and we think that the peer reviewers pretty
2 much got it right, that it looks like the pay line
3 is about where it ought to be.
4 DR. NORQUIST: So, and let me just say,
5 Kerry, I think one thing you need to address here
6 is the 96 was a guess. We had no idea. I mean,
7 that was just a guesstimate amount that we thought
8 we should spend after we looked at how much money
9 we had.
10 What we ended up with after we did peer
11 review and then a certain line that we ended up
12 with applications and I wouldn't say these are bad
13 applications, they are actually high-quality
14 applications and we cut our line at a point that we
15 didn't feel comfortable going up another $8 million
16 just to solve for X because we got into some other
17 issues, methodological problems, some others, but
18 we did ask. I mean, if we had not asked the staff
19 to go back and so some as we would say a little bit
20 more active portfolio management, the number would
21 actually have been lower.
22 MR. BARNETT: Right, and that's really my

1 point.
2 DR. NORQUIST: Yes.
3 MR. BARNETT: I'm certainly not suggesting
4 lowering the bar in order to spend more money.
5 It's more a question of is there something we can
6 and should be doing that will increase the quality,
7 the relative quality of the grants such that we're
8 going to want to come back next time and not spend
9 $96 million, but really want to spend $106 million.
10 DR. NORQUIST: Right, so, that's part of
11 what we've been talking about today, the training
12 of folks to have them understand what it is we want
13 to do and then I think -- remember, these people
14 can come back. I mean, it would be very unusual
15 for NIH, I mean, in many times to pay first-time
16 grants without them expecting them to come back
17 revised and that's what we need to do a good job
18 of, right?
19 All right, let me --
20 CHAIRMAN WASHINGTON: Okay, we have a few.
21 DR. NORQUIST: -- go on this side because
22 you guys were already up first. Christine, we'll

1 just come down this way.
2 MS. GOERTZ: Yes, thank you. Christine
3 Goertz.
4 Can you tell us what was approximately the
5 cutoff for scores?
6 DR. NORQUIST: Yes, the actual priority
7 score.
8 MS. GOERTZ: The actual priority score.
9 What range were the priority scores --
10 DR. NORQUIST: Yes, so, we're up around
11 the 3.5 here, but I don't remember. So --
12 DR. SELBY: Three point --
13 DR. NORQUIST: David, do you remember? Is
14 David in here?
15 UNIDENTIFIED BOARD MEMBER: No.
16 MS. GOERTZ: Thirty-five.
17 DR. NORQUIST: Three point five. All
18 right, 35. That was in assessing options in the
19 Improving Health Care System.
20 DR. SELBY: It's all pretty because the --
21 DR. NORQUIST: I think it was pretty close
22 to 3.5. It just happened the percentile was --

1 DR. SELBY: Yes, it was close to 3.5.
2 MS. GOERTZ: It's not bad.
3 DR. NORQUIST: Yes, no, it's not bad.
4 DR. SELBY: Another point Martin just
5 points out that if you compare from Cycle I to
6 Cycle II, things got better. It looks like things
7 did get better, and so, we're hopeful that with a
8 bit more time, scores will come down some and we'll
9 find it easier to fund everything --
10 DR. NORQUIST: Yes, we're paying a little
11 bit higher priority score this time. We were
12 paying close --
13 MS. GOERTZ: Round 1 was closer to three,
14 right?
15 DR. NORQUIST: -- to three, now we're at
16 3.5. Yes, yes, that's right, exactly.
17 MS. GOERTZ: Yes.
18 DR. NORQUIST: Exactly.
19 UNIDENTIFIED BOARD MEMBER: Gray, on a
20 scale of what?
21 DR. NORQUIST: On a scale from one to
22 nine.

1 UNIDENTIFIED BOARD MEMBER: One to nine.
2 DR. NORQUIST: So, you get a one to nine,
3 and so --
4 DR. SELBY: It was good.
5 DR. NORQUIST: Once you get above a three,
6 the review group is judging it. There are one or
7 two kind of moderate problems and that starts to
8 get into an issue. So, but a 3.5, I mean, NIH and
9 them are paying at the two or 2.5. You're lucky if
10 you get there. So, three and 3.5, those are still
11 solid, very good applications.
12 CHAIRMAN WASHINGTON: We're going to move
13 around.
14 DR. NORQUIST: Yes, moving.
15 CHAIRMAN WASHINGTON: So, Douma, Allen,
16 then Gabriel, Hole-Curry. So, we'll just go this
17 way.
18 DR. DOUMA: Allen Douma, Board.
19 I just want to follow-up on Harlan
20 Weisman's question, concern. Can you just talk
21 about what would happen if we decided if a certain
22 number, significant number of our next grants had

1 to be two years or less?

2 DR. NORQUIST: Well, I don't know until I

3 saw those grants what they would be. I mean, I

4 think that's a bigger issue. But to me, let me

5 just --

6 DR. DOUMA: But if we put it out there and

7 we acquired, what if we're only granting it two

8 years?

9 DR. NORQUIST: Let me say my own

10 perspective on that, and everybody can else can be

11 -- I don't want to just have a bunch of two-year

12 grants just so we meet some deadline or something.

13 What we want is quality research that is going to

14 answer the questions and do the kind of things that

15 we want to do as opposed to moving sure we've got

16 5,000 reports to issue in 2017. I mean, that's a

17 bigger, to me, an issue about what are we really

18 trying to do?

19 DR. DOUMA: Yes, I was just adding to the

20 discussion because four-year grants are going to be

21 better than three, also, but we choose three. So -

22 -

1 DR. NORQUIST: It depends on what the
2 question is. I mean, if you're really trying, I
3 mean, this is where the methodology -- I mean, if
4 you really want to answer a hard CER-type question
5 and for what you're comparing and over a period of
6 time, it may take you three or four years to answer
7 that question. You can't do it in two years, you
8 know what I mean, if that's the thing --
9 DR. DOUMA: I understand, but there are
10 some things you can't, right?
11 DR. NORQUIST: No, that's true.
12 CHAIRMAN WASHINGTON: Gabriel.
13 MS. GOERTZ: So, just to Kerry's question
14 of we had budgeted more funds and we couldn't fund
15 as many grants as we had budget for, presumably
16 because the quality just didn't meet the bar, do
17 you have a sense of what it was, what the big
18 issues were? I mean, were they grants, and I'm
19 thinking again of the Methodology Guidance Panels
20 and the discussion from the last section. Were
21 they projects or research questions that were
22 really on the mark and they were the kinds of

1 things that we want answered, but the group just
2 didn’t have the wherewithal to answer it properly,
3 they didn’t have the methods, or were they just
4 totally off the market?
5 DR. NORQUIST: So, in most things, it’s
6 all of the above. So, there were some that were
7 like that, but a lot of them just didn’t add
8 something else, we would say a value to the
9 portfolio in PCORI kind of terms, if you will. We
10 ask this to them, we ask their program staff about
11 that very question and we asked them to look at it
12 hard and to make a decision about that and they
13 just felt it didn’t add something more, there were
14 some methodological problems in some of them that
15 they felt they could work with them and address and
16 have them come back. So, it would depend on the
17 grant, I think, in general.
18 Joe, did you have --
19 MS. GOERTZ: So, some of these were
20 salvageable --
21 DR. NORQUIST: Absolutely.
22 DR. GOERTZ: -- if we had the right

1 mechanism?
2 DR. NORQUIST: Oh, no, I think there's
3 some of them that we were led to believe by the
4 staff were quite salvageable, yes.
5 CHAIRMAN WASHINGTON: Okay, Hole-Curry and
6 the Zwolak.
7 MS. HOLE-CURRY: Leah Hole-Curry, Board.
8 And I think with our earlier round and it
9 may just be you haven't had time to do this yet,
10 but we did a little bit of analytics around
11 geographic distribution and distribution by major
12 conditions and distribution by populations. So, I
13 guess the biggest one I was looking at was by
14 condition, which we did before.
15 DR. NORQUIST: No, we had that slide, and
16 if you saw it, you would be so -- I mean, it has
17 like so many bars in how you write those.
18 MS. HOLE-CURRY: Okay.
19 DR. NORQUIST: So, we have it. We
20 actually have it, but if you see it, it doesn't
21 give you much information to be honest. It’s all
22 over the place.

1 MS. HOLE-CURRY: Okay, so, maybe for this
2 type for the Board by individual slate isn't as
3 important as overall portfolio?
4 DR. NORQUIST: So, you do have on the
5 right --
6 MS. HOLE-CURRY: It would be less busy?
7 DR. NORQUIST: -- there on the population.
8 MS. HOLE-CURRY: Right.
9 DR. NORQUIST: You see by the individual
10 slate. We didn't here because of the numbers just
11 to show you this on geographic, but you --
12 MS. HOLE-CURRY: Right, no, that's great.
13 DR. NORQUIST: I'm sure they could pull
14 that.
15 MS. HOLE-CURRY: No, no, I think if it was
16 too busy to represent the other way --
17 DR. NORQUIST: Right.
18 MS. HOLE-CURRY: It may be just at a high
19 level for us to get some mental images of the
20 slate. As I think somebody else mentioned as we
21 went through it, the first one had three on
22 prostate cancer. So, just going back to Harlan's

1 comments about active management, I think that's
2 something for us to try to figure out as we move
3 forward how we address something like that. It may
4 be these are all studies that are important and
5 there are lots of unanswered patient-centered
6 questions or it may be some other clustering and we
7 want to make sure that that's not clustering
8 specific to PCORI. So, I'm not sure how you do
9 that going forward, I just think it needs some
10 discussion.
11 DR. NORQUIST: Well, no, let me just say
12 that gets back to what is the role of the Board --
13 MS. HOLE-CURRY: Right.
14 DR. NORQUIST: -- and the active portfolio
15 management. We relied on the staff to make that
16 decision as they do let's say at NIH. I mean, when
17 I was there, that's what we did. But what is the
18 role of the Board at some point and how much of a
19 micromanagement we want to get into, that gets
20 difficult at some point when we start second-
21 guessing. So, but it is a discussion we should
22 have at some point.

1 MS. HOLE-CURRY: Right, and it may not be
2 that the Board looks at those individual ones, but
3 now that we have some history and we can combine
4 those with our other 60 or so and start to look
5 across it, maybe we say we have a slate for this
6 specific condition or this specific population and
7 encourage staff to take that into consideration as
8 they make the recommendations. I'm not saying that
9 we have to pick, I'm just saying that triggers a
10 discussion point.
11 DR. NORQUIST: Right. And I think one of
12 the things we could do is like we did yesterday,
13 where we had the staff present their portfolio to
14 the joint session of the PDC and the COEC, and
15 that's another option where we could have that kind
16 of a discussion with them as what's in their
17 portfolio because it helps to do it a priori. You
18 don't want to tell a grantee afterwards oh, we
19 don't like your area.
20 MS. HOLE-CURRY: Correct.
21 MR. NORQUIST: Yes.
22 CHAIRMAN WASHINGTON: Okay, Zwolak and

1 then Epstein and then Weisman, and we'll move
2 around.
3 DR. ZWOLAK: Bob Zwolak, Board.
4 Congratulations for getting these done.
5 That's great news.
6 This is Cycle II, and as the way I try to
7 look at the calendar, we still are on target, I
8 guess, to get Cycles III and IV announced,
9 recruited and announced during calendar 2013, with
10 the last one being in November.
11 DR. SELBY: Cycle III is already in.
12 DR. ZWOLAK: Right.
13 DR. SELBY: The deadline is closed and
14 Cycle IV opens. August 15th we're going from the
15 year forward which reflects the due date. It opens
16 May 15th. So, that's the one that will be
17 announced in December.
18 DR. ZWOLAK: In December. So, if --
19 DR. SELBY: Just like last year.
20 DR. ZWOLAK: If the scores were hurt a
21 little bit by the patient involvement, which is
22 what people are having trouble with, is the staff

1 looking at those grants that may have been really
2 good otherwise say for the patient involvement
3 piece and not just assuming that people may dive
4 back into the pool, but potentially encouraging
5 people to look at and maybe help them a little bit
6 with the patient involvement piece and to dive back
7 in the pool so we can make sure we get high-quality
8 spend for as much as we hope to in these last two
9 cycles.
10 DR. SELBY: One thing we know is that a
11 number of applications are being resubmitted to
12 cycle for really the first time, and so, we're
13 excited by that. I think we actually do have the
14 capacity at this point to analyze the data to some
15 extent in terms of what scores may have influenced
16 the overall score. We only get those scores before
17 the discussion, so, it's again technical, but there
18 may be some work that we can do in that area, as
19 well.
20 DR. EPSTEIN: Three quick things. First,
21 the Selection Committee met by teleconference three
22 times in the last two weeks. I found it arduous

1 myself, but I do want to congratulate the staff for
2 putting together a lot of information, for
3 responding coherently, and Gray did a terrific job
4 of sharing the meeting in what was pretty
5 directive. So, I really want to put that forth.
6 Second, I think we may have some
7 advantages and a challenge here with what's
8 happening with resubmitting grants. The goods news
9 here is I think we'll see the scores go up, God
10 willing, and they separate higher and that'll maybe
11 address some of the concerns that Kerry raised.
12 Joe, what are you planning to do about
13 giving reviewers copies of past reviews and
14 especially holding people blameless? And the issue
15 that comes up here all the time is someone gets
16 advice, they listen to the advice, and a new
17 reviewer comes out of left field and says I don't
18 really like those [inaudible]. So, and I think we
19 have to make a decision about that and you could
20 tell where I fall out on that, but --
21 DR. SELBY: I will make a comment and I'll
22 also add Martin to add comments if there's

1 something else, and the comment I'll make is I know
2 because I just asked Martin the other day about
3 this. We are working hard to get reviewers back if
4 reviewers reviewed the application the first time.
5 We're working hard to get at least some of those
6 back this time on the basis of what we know about
7 who has resubmitted.
8 DR. EPSTEIN: I guess the question is:
9 Can we enforce essentially a contract and the
10 contract is if they make a change in their proposal
11 to address what we told them to do, we're not going
12 to criticize them again for it.
13 DR. SELBY: That sounds good. I think we
14 actually do have some work to do in prepping the
15 SROs and the reviewers for these resubmissions.
16 DR. EPSTEIN: Yes. And the third issue I
17 want to raise, this is going to be -- Gray made a
18 faint at this -- I want to underscore it because I
19 think it's important and put it out for a little
20 bit of discussion, which is how does the Board want
21 to relate to actual applications? I'll give you
22 how I was feeling, but that's not meant to say that

1 we all want to do this.
2 I was feeling that I did not want to
3 second-guess staff. They made some judgments. We
4 gave them pretty clear direction and license to go
5 back, actively manage at both ends of the spectrum,
6 ones that were scored highly to say I don't think
7 so and ones that were on the opposite direction.
8 They say again and again that their own views
9 correlated very highly with the viewer views.
10 I should say that's not my own personal
11 experience in life, but they did it. And then for
12 myself, I found myself wanting to get not to
13 double-guess the staff, but to understand better
14 what I was dealing with. And I talked and Gray
15 will remember this and I think he had some
16 interest, as well, at least for us, but maybe for
17 everybody spending some period of time from each of
18 the major sections, let me blow an hour, let me
19 blow an hour-and-a-half, tell me a five minute's
20 piece about two of the grants that you really
21 liked, describe it, why you liked it, what's the
22 information that you hoped to get from this and how

1 it will change what patients and doctors are doing
2 or not and then go above the cut line, just above
3 it, where you said no and tell me what was driving
4 you. Not with the sense that I was going to say
5 how could you do that, but for that. But the
6 bigger issue is also how much the Board wants on
7 that, and so, it’s really with that spirit that I
8 bring this forth here.
9 DR. NORQUIST: Yes, and I just want to
10 second that Arnie and I felt very strongly about
11 this and that it also means that we need some
12 consistency across time and who’s doing the
13 selection and stuff if we’re going to have the
14 Board involved in that, which requires some work,
15 but I know that Arnie and I, I don't know how the
16 others felt, but we felt fairly strongly that that
17 is an option.
18 DR. SELBY: Well, first of all, I want to
19 say from the staff’s point of view that the
20 Selection Committee and the Board and the
21 Methodology Committee’s participation in it was
22 extremely constructive. I think we learned a lot.

1 This was the first time that we really did any of
2 what we might call “active portfolio management” to
3 speak of and my hunch is that we’re going to get
4 more active with your encouragement over time. So,
5 we’ll just get more facile at it.
6 I think there are advantages to the Board
7 not actually digging into individual applications.
8 One of the immediate advantages I can think of is
9 that we don’t have to worry about recusals and
10 conflicts of interest and you can review this one,
11 but you can't review that one because it’s from
12 your institution. And so, that’s huge.
13 And, Gray, your comment about consistency,
14 did you mean consistency from the staff or did you
15 specifically mean consistency on the Selection
16 Committee?
17 DR. NORQUIST: I’m talking about both. I
18 assume the staff would be consistent.
19 DR. SELBY: Yes, I assume, too.
20 DR. NORQUIST: It’s the same program. I’m
21 not sure it’s planning on --
22 DR. SELBY: Yes.

1 DR. NORQUIST: -- getting rid of someone,
2 but --
3 DR. EPSTEIN: And you get rid of the
4 recusal issue by showing this last year’s
5 applications. In other words, the issue here for
6 me is to get a little bit more familiar about
7 what's under the hood, what are we really funding,
8 what goes into people’s thinking when they think
9 it’s really good? How do they relate to the fact
10 that this will really yes or no change what a
11 patient gets in this world, because that’s what we
12 care about and one way to have done it would be the
13 applications that just came in now, but if you want
14 to do it in three months or two months from now
15 with the applications that came in and are already
16 funded --
17 DR. SELBY: Right.
18 DR. EPSTEIN: -- it’d be just as useful to
19 me.
20 DR. SELBY: Yes, that makes sense.
21 DR. EPSTEIN: I just want to learn a
22 little.

1 DR. SELBY: Some on either side.
2 DR. EPSTEIN: It will make me wiser in how
3 I relate to --
4 DR. SELBY: Yes.
5 DR. NORQUIST: And let me just say it's
6 not a problem with recusal. I mean, NIH does this
7 all the time in the advisory group. People walk
8 out when they have an actual grant or something.
9 So, it's possible to address that.
10 CHAIRMAN WASHINGTON: Okay, Wiseman and
11 then Goertz and Douma and Kuntz.
12 DR. WEISMAN: Harlan Weisman, Board
13 member.
14 Again, I'll just reiterate what I said
15 earlier. I think these all seem like very good
16 projects and I would not second-guess. I mean, I
17 think as far as I can tell, you followed everything
18 we said we were going to do and we have some
19 research projects that are exciting and worthy of
20 funding.
21 However, I do feel that we're in a bit of
22 a crisis in terms of what we want to accomplish and

1 what we can accomplish in a finite period of time,
2 which is dictated by legislation and also the
3 patients of the multiple stakeholders that we have
4 in terms of what will be done. How many of these
5 studies, although they're really worthy, will move
6 the need the way we want to move the needle? And
7 certainly in isolation, it’s unlikely that that
8 many of them really will do that because that’s
9 just the nature of things. And we don’t have the
10 luxury of time to really expand on these.
11 The nature of any startup organization
12 like we were and I guess still are, we’re
13 transitioning out of it, that moves quickly, that’s
14 innovative is that you try things and not
15 everything works the way you expect it. I mean, we
16 went out and we set about setting up a structure
17 that was going to accomplish things that we wanted
18 it to accomplish. I think what we’re learning is
19 that things that we didn’t know about are
20 conspiring against us a little bit in terms of
21 estimating how difficult it is to get patients
22 truly involved in meaningful ways or not the

1 typical set of researchers able to complete our
2 applications and do high-quality grants and the
3 ability of very experienced researchers to be able
4 to reach out to the community and engage patients
5 and clinicians who are outside of the academic
6 realm.
7 And that's led to things that we're
8 learning, but I think we got to just really take a
9 good look at what we're doing now. I don't think
10 it's accomplishing what we wanted to accomplish.
11 It doesn't mean we're not doing things well.
12 Please understand that. To me, it's a question of
13 understanding the difference between precision and
14 accuracy. We have good precision here, we're doing
15 things very well, but accuracy means just because
16 you can hit a target over and over again very close
17 to what it is, it may not be the target you want to
18 hit.
19 The target we want to hit may be somewhere
20 else and I suspect that if we look at our vision
21 and our mission that we are unlikely to hit the
22 target we've said is ours if we keep going about it

1 and I hope that we reflect in an honest way, say
2 what's working really well for us and what things
3 aren't working the way we wanted them to or things
4 aren't rolling out the way we expected and it may
5 mean after reflection that we have to make an
6 adjustment of not our goals, but the way we're
7 going about trying to achieve our goals.
8 And Harlan Krumholz has come up with some
9 ideas; I think a lot of people have ideas. Gail
10 suggested the ability to take what's known because
11 on top of all this, we've got to figure out not
12 only what the research results are, but somehow we
13 have the idea that unlike others who have done all
14 this stuff before and, Gray, you've mentioned a few
15 times you were doing CER a few years ago and
16 everyone has been on it.
17 Nobody has really gotten the stuff to
18 stick and I think without really understanding how,
19 one, the research we're funding isn't ahead of
20 things when we want it to. And two, that we really
21 have the knowledge once it starts coming at us in
22 2015 through 2017, well, once we'll have the time

1 and two, we'll have the ability to really not only
2 disseminate it, just throw it out there, but really
3 get it to stick.
4 And that's why I say I think this is a
5 crisis, there's a sense of urgency. I don't blame
6 anyone. I think the institute's staff is doing
7 exactly what we asked them to do and they're doing
8 it very well. And I think the Board had good
9 intentions, but I don't think we're doing what we
10 need to do in terms of making the adjustments if
11 we're serious in delivering on the promise of
12 Patient-Centered Outcomes Research in the timeframe
13 we're given.
14 CHAIRMAN WASHINGTON: Okay. Thanks,
15 Harlan. Goertz.
16 MS. GOERTZ: Thank you, Christine Goertz,
17 Board member.
18 Two things. First of all, I want to pick
19 up on the comment that Leah had made about noticing
20 that there were several applications in particular
21 topic areas and leading back to the discussion that
22 we had earlier today about to what extent our

1 portfolio made the switching from more broad
2 funding announcements to more target. I think part
3 of becoming more targeted is not only have targeted
4 PFAs, but also being able to assess our portfolios
5 and to say we have at least for right now enough
6 applications in this particular area, so, you would
7 need to really talk to us first or before you would
8 be advised to submit an application in this
9 particular area because we more or less have that
10 covered. So, I hope that that's something we're
11 considering as we're also looking at more
12 aggressive portfolio management.
13 And second of all, I would just like to
14 thank all of that applicants who have put in the
15 huge time and effort to submit these applications
16 to us and to congratulate all of the investigative
17 teams that are represented in these applications
18 that are being proposed to the Board for approval
19 today.
20 CHAIRMAN WASHINGTON: Okay. Thank you,
21 Dr. Goertz.
22 Dr. Kuntz.

1 DR. KUNTZ: Yes, just a real quick
2 comment. First of all, I think this is great. I'm
3 looking at the very small sample distribution in
4 the states, and we mentioned this earlier, and the
5 grants fall where they can, but are you planning on
6 looking back at the geography again because I
7 remember that a lot of the motivations that we had
8 about PCORI early on was about the nurse in
9 Mississippi who had the idea that nobody would else
10 would think about, and when I look here, there's a
11 big missing part in the South and I'm especially
12 surprised by Texas, which is like number four in
13 the NIH and number two in the CDC. So, they
14 clearly have world-class, outstanding researchers
15 all through that state and got zero. And I don't
16 know if it was just a sample issue or not, but it'd
17 be kind of fun to look back to see can we do some
18 maybe more projected analysis of why that happened.
19 DR. NORQUIST: Yes, I think one thing,
20 thanks to my own state, where I know there were
21 applications, I think one thing to do is look back
22 and look at the applications that were from these

1 states and see if there were particular issues
2 around that. I mean, I think that may be some of
3 the issue which would be interesting to see, also.
4 CHAIRMAN WASHINGTON: Okay, Mr. Becker.
5 Larry.
6 MR. BECKER: Larry Becker, Board.
7 So, we've spend a lot of time getting
8 input from patients, clinicians, and researchers
9 about the questions and if others agree, it would
10 seem to me that in simple math, we've had two
11 cycles and we had the Pilots Projects and we
12 probably had 1,100 not successful grants,
13 applications, and it might be interesting to look
14 back at those 1,100 and see if there are questions
15 that our clinicians, the researchers, the patients
16 really wanted answered. They may not have met
17 muster, right, they may not have hit the line, but
18 there may be some themes in there that would say
19 but the customer really wants the answers to these
20 questions. So, we might learn something from the
21 other 1,100.
22 CHAIRMAN WASHINGTON: Okay. Gray.

1 DR. NORQUIST: I want to say one final
2 thing. Thanks to the group who really put in a lot
3 of time and the staff and I just want to say I
4 agree with Christine about making clear that
5 there's certain areas we no longer may want, but
6 please do it quickly because one of the biggest
7 nightmares I ever had when I was at NIMH was where
8 we did this where we cut off one area and somebody
9 had a grant coming in for the next review and we
10 ended up with a congressional inquiry about why we
11 didn't fund that one grant. So, I think it's not
12 fair to the field if you decide to cut off some
13 area, cut if off, be very clear about it right now
14 so that people who are out there thinking about
15 submitting to us will stop and go down some other
16 path, okay?
17 CHAIRMAN WASHINGTON: Okay, well, I also
18 want to -- Hunt.
19 MS. HUNT: Yes, real quick.
20 CHAIRMAN WASHINGTON: Ms. Hunt.
21 MS. HUNT: Gail Hunt, Board.
22 I just want to reiterate the fact that if

1 there's any way we could figure out how to foster
2 innovation more in these proposals, that's
3 something that we really need to do and I know it's
4 hard, but when you talked about the nurse in
5 Mississippi that has the great idea, that's exactly
6 -- I'm not sure we're getting to that, so, it would
7 be great. Thanks.
8 CHAIRMAN WASHINGTON: Okay. Sharon.
9 DR. LEVINE: And this is just a question
10 for Christine and Gray in light of the comments
11 that were just made, I mean, would you really want
12 to cut out something that had prostate cancer in
13 the title before you even looked at it? I mean,
14 perhaps it's looking at or answering a question
15 that is applicable across conditions and I'm
16 wondering how you make the judgment that sorry,
17 we're full up on prostate cancer research or
18 hypertension research without looking at the
19 question --
20 DR. NORQUIST: I agree with you. I mean,
21 I think you have to be very careful about what
22 you're saying, but if it were the same test of some

1 very specific intervention --

2 DR. LEVINE: Okay.

3 DR. NORQUIST: -- in prostate cancer,

4 that’s what I was talking about. That’s where we

5 got in trouble. It was about chronic depression

6 and somebody had a similar kind of intervention.

7 DR. LEVINE: Okay.

8 DR. NORQUIST: And we cut that off.

9 DR. LEVINE: Yes.

10 DR. NORQUIST: But I think yes, you're

11 right. And we didn’t look at this and I think in

12 fairness to the grantees, those particular grants

13 may have relevance across a number of cancer

14 conditions, for example.

15 MS. GOERTZ: Right, and again, what I had

16 said was that they would talk to us before they

17 would submit just to make sure that there wasn’t

18 any overlap. So, I don't think we would ever say

19 absolutely no, but with some, we might come to the

20 point where we would say talk to us first.

21 CHAIRMAN WASHINGTON: I have Sigal and

22 Hole-Curry.

1 MS. SIGAL: Ellen Sigal. So, I agree. I
2 think it’s very hard for us to cut off conditions
3 to say no more on prostate, because there's a
4 compelling need and we don’t absolutely have a clue
5 on how to treat it is an example, I looked at
6 these.
7 The proposals, and I’m sure they're all
8 good, they're not going to give us the answers. On
9 the other hand, we do have to do some management
10 and do priority-setting and I must say that I agree
11 with Harlan Weisman. And it may be Harlan
12 Krumholz, too. The big rocks, the big things that
13 are really going to be transformative for PCORI are
14 not in this group. There may be some really nice,
15 important things we do and we have to think about
16 what we want to do about those big things because
17 money and resources and time are starting to run
18 out.
19 CHAIRMAN WASHINGTON: Okay. Hole-Curry.
20 This is the last comment.
21 MS. HOLE-CURRY: Thanks. So, just to
22 respond, I mean, you could weight it and not

1 everybody has access to the grants that we've
2 already funded and I don't know the exact solution,
3 but you could say for every novel condition we
4 haven't yet funded, if you wanted to encourage
5 that, you get some percent additional point for
6 every -- I mean, there's a lot of ways to do it
7 without saying no, never and given current
8 information, just like there's a lot of ways to say
9 what we really want right now is good applications
10 that can be completed in a year. You could bump
11 those scores up if people actually met other
12 methodological standards because when we say the
13 basics is $2 million in three years, that's what we
14 get.
15 So, that's a reality. That doesn't
16 necessarily mean we couldn't encourage something
17 else, even within the structure we already have
18 here. And I hear a lot of resistance to active
19 management, which is all of these ideas. It
20 doesn't mean a specific one is right, but we have
21 to start talking about it and I don't know how else
22 to get out that --

1 CHAIRMAN WASHINGTON: Right.
2 MS. HOLE-CURRY: -- in our meetings.
3 CHAIRMAN WASHINGTON: Okay, I want to --
4 Harlan, if it's something new.
5 DR. WEISMAN: [Off microphone.]
6 CHAIRMAN WASHINGTON: Okay, because I am
7 really hearing the same things over and over again
8 now, so --
9 DR. WEISMAN: Well, I agree with what Leah
10 just said and what we choose to fund should have
11 less to do with what the topic is specifically or
12 how many we funded before and more to do with what
13 we want to accomplish. The research in many ways
14 is a means to an end, and so, if the means, meaning
15 a specific research topic, advances us toward the
16 end we want to achieve, then we should do it, and
17 if it doesn't, I would say no matter what the
18 quality, we may not want to fund it because it
19 doesn't advance us toward what we're trying to
20 achieve. Thank you.
21 CHAIRMAN WASHINGTON: Okay, thank you.
22 Well, Gray and Christine and all the Board

1 members involved, along with Martin and other staff
2 and this selection process, thank you. We are
3 going to ask for a vote in a minute, but there are
4 two themes that I heard I just want to underscore
5 and let everyone know we heard you very clearly.
6 One is, Larry, I took what you said and
7 some degree what Harlan W. said is in my mind it’s
8 equivalent of an impact analysis, only you have us
9 a very specific way to go about it. Take the last
10 set of grants, take this set of grants, and we’re
11 here to define what we mean by impact and that
12 impact, the process indicators, but there's also
13 the indicators of some expectation that it’s going
14 to reach a care, so to speak, or it’s going to
15 improve outcome, and we may have to get outside
16 help to help us define that. But we need that kind
17 of framework going forward because I think that
18 also helps us to understand a little bit more
19 clearly whether or not we are moving closer to the
20 goal, even though I like what we’ve laid out in
21 terms of the metrics, but those are different
22 pieces. We’ve got to have measure of impact.

1 That's one thing.
2 Two, the other is I've heard three
3 different definitions of "active portfolio
4 management," and that's good, that's good. Okay,
5 at one level, what I've heard is we want to
6 actively manage a process of soliciting grants.
7 And that means we want to be proactive, it means we
8 want to have training in place, want to have
9 certain criteria to drive us toward our goals. We
10 may want to look at a timeframe, whether it's one-
11 year, two-year, but active management in that case
12 is more akin to what I think the two Harlans were
13 referring to earlier in stepping back and thinking
14 about exactly where we want to be and proactively
15 generating those kinds of proposals and/or grants.
16 So, that is sort of active management in terms of
17 soliciting proposal.
18 The second one would be what I just also
19 heard is active management and selecting actual
20 projects because we just did that. That's what you
21 did. We got a set of projects in, you had a cut
22 line, but you actively looked above and you looked

1 below. And that was active management and we want
2 to continue to do that. We want to make sure that
3 its objective in how we approach it, but that's
4 another component.
5 And then the third one, which is where we
6 actually started and where I was when I was hearing
7 active management is essentially management of
8 projects. We funded projects, now we're managing
9 them to make connections and ensure that we're
10 optimizing the return on the investment in those
11 projects.
12 I would suggest, Joe, that we develop --
13 it should be a one-pager that sort of lays out what
14 we mean by "active portfolio management," and if we
15 are serious about this as sort of a core activity,
16 then we ought to also have a metric around active
17 management, which says there are a set of
18 activities related to it and instead of outcomes in
19 some kind of way where we also have a dashboard
20 related to -- I know we have you on dashboards
21 today. But I like what I'm hearing about active
22 management and we should be a little bit more

1 explicit on a sheet of paper and use it as a guide
2 in all of these areas of our activities.
3 Okay.
4 DR. SELBY: I think we agree and we're
5 actually quite close to having that and we think of
6 it just that same way in the three compartments
7 that you mentioned.
8 CHAIRMAN WASHINGTON: Great, thank you.
9 Kerry.
10 MR. BARNETT: [Off microphone.]
11 CHAIRMAN WASHINGTON: Oh, we need to vote.
12 Vote, it's been a long day. Okay, would you put a
13 motion on the table?
14 DR. NORQUIST: Yes.
15 CHAIRMAN WASHINGTON: Can you, Kerry?
16 MR. BARNETT: I move that we approve the
17 slate of applications that were listed here today
18 for funding.
19 CHAIRMAN WASHINGTON: It's been moved and
20 seconded. All in favor?
21 [Chorus of Ayes.]
22 CHAIRMAN WASHINGTON: Okay, all opposed?

1 [No response.]

2 CHAIRMAN WASHINGTON: Okay, it was

3 everyone in terms of the record, actually.

4 Any abstentions?

5 [No response.]

6 CHAIRMAN WASHINGTON: The motion carries

7 and the slate is approved, and, again, thanks to

8 everyone involved.

9 Now, on to institute policies.

10 MR. BARNETT: I know it's very late and I

11 think we can move through this really very, very

12 quickly. It frankly does not have the sort of

13 substantive or rather strategic girth of what we've

14 been talking about for these many hours.

15 DR. KRUMHOLZ: I just want to go on record

16 with that. The strategic girth --

17 MR. BARNETT: Strategic girth is a good

18 thing. You want to have lots of it.

19 And I want to start by welcome Regina, who

20 is trying to find the clicker here, for her

21 willingness to really jump right in. We're really

22 delighted to have her onboard and thanks for being

1 here and then being willing to carry this agenda
2 item, albeit very, very quickly.
3 I just want to provide about a minute, two
4 minutes of context here in starting with the notion
5 that Anne and her team over the past several months
6 has really been working hard to sort of take the
7 organization to the next level.
8 If you remember, we sort of began by
9 creating the basic structures and controls to get
10 the organization up and running and then we've been
11 going through this process of sort of going back
12 and perfecting and refining and expanding those
13 processes as needed in order to move towards a more
14 sophisticated, more disciplined organizational
15 alignment.
16 So, what we have here is the culmination
17 of an effort to formalize some of our procedures
18 and I guess I want to stress that we don't want to
19 become too bureaucratic. That's certainly not the
20 intent here. We do want to maintain certain
21 elements of flexibility along the way, but it's
22 clear that having clear, written policies in place

1 is important from an organizational discipline
2 standpoint, but also frankly from an audit
3 standpoint because the nature of the audits that we
4 go through, the auditors come in and they want to
5 know specifically what our board-approved policies
6 and procedures are and then they want to see if
7 we're following them. So, it is important to note
8 the phrase "Board-approved policies and
9 procedures," which frankly is why we're here asking
10 for board action.
11 I do want to stress on last thing, and
12 that's that if you've gone through these policies
13 and procedures, you're going to scratch your head a
14 little bit and say it just doesn't seem like it's
15 all that new and different and the answer is that
16 it's not. This is really a codification of what
17 we've been doing and what we have in place today,
18 but it's important to put it in that kind of more
19 formal, written format so that we can satisfy
20 auditors and whomever.
21 So, that's my context. I'm going to turn
22 it over to Regina, who's going to walk us through

1 this very quickly.

2 MS. YAN: Okay, thank you. Okay, Kerry
3 just gave you a quick overview of what we are
4 trying to do and we have several things that we
5 have updated that we need your approval and before
6 we go to the policies, we have updated our
7 decision-making matrix. What we have done is that
8 previously Anne held the title of both the deputy
9 executive director and also COO. So, right now,
10 with the decision matrix, we need to update it to
11 separate out the two. So, this is what we have
12 done, and since you have approved this decision
13 matrix before and as we have updated it, we also
14 want to seek your approval for this one. So, I'd
15 like to take care of this one first.

16 UNIDENTIFIED BOARD MEMBER: So moved.

17 CHAIRMAN WASHINGTON: Okay. There's a
18 motion, it's been moved.

19 UNIDENTIFIED BOARD MEMBER: Second.

20 CHAIRMAN WASHINGTON: And second. All in
21 favor?

22 [Chorus of Ayes.]

1 CHAIRMAN WASHINGTON: All opposed?
2 [No response.]
3 CHAIRMAN WASHINGTON: Any abstentions?
4 [No response.]
5 CHAIRMAN WASHINGTON: Okay, the motion
6 carries.
7 MS. YAN: Thank you. Going back, we have
8 right now to put out policies into two buckets.
9 One would be the bucket that would require the
10 Board's approval. These we consider it as into two
11 policies. They include policies regarding
12 governance, risk management, and finance and
13 control. And finance and contracts and the other
14 we consider as administrative and operational
15 policies that will be taken care of by management,
16 so, we won't bother you with those.
17 The policies have been developed and the
18 FAAC, they have reviewed them and we have legal
19 counsel also reviewed them. That review was done
20 last week and we have sent the draft policies to
21 all of you and I thank you for taking the time to
22 review them carefully and I also thank many of you

1 who have sent me responses. And based on your
2 comments, we have made several updates. At least
3 the comments I have received so far have not been
4 significant, but we have incorporated those
5 comments anyway.
6 So, these set of materials were sent to
7 you electronically and these are the draft policies
8 that you have given me comments on. And this
9 morning, we have given you a set, the only 3
10 policies among the batch of 12 that we sent you
11 that we have gotten comments on and I want to very
12 quickly let you know what modifications we have
13 made. One slight modification we made was on the
14 employee acceptance of gifts and payments. In the
15 definition of what is a widely-attended event, we
16 had both the number, 25 people, and also the nature
17 of events, and the comment was the number may not
18 be most helpful, is probably more important to
19 really look at the nature of event. So, we have
20 removed the number of 25.
21 Secondly is about board meetings and
22 hearings. In the executive session of board

1 meeting, there was only slight clarifications. We
2 said that the Board can call a closed meeting for
3 matters concerning personnel and also privileged or
4 confidential advice of counsel. And with that, we
5 have simply added one word there, "that means
6 concerning matters requiring privileged
7 communication or confidential advice of counsel."
8 It's a very slight change, but I think that it is
9 much clearer and much easier for us to carry out.
10 And the very last one is in the pre-award
11 policy, that is under the approval of funding
12 slate. The current practice is that we have one
13 sentence there that says "the Board of Governors'
14 approval of the funding slate. In doing so, the
15 panel will reveal only general information and will
16 not be aware of the names of PIs or institutes
17 being considered." That is our current practice.
18 We can choose to continue that. That is fine, but
19 the comment is that we don't really need to have
20 that in there and we can decide whether to continue
21 the current practice or change. So, we have just
22 removed that one sentence.

1 And, of course, the Board approval will
2 continue to be made in the public setting. So,
3 those are the several minor modifications made to
4 the policies.
5 CHAIRMAN WASHINGTON: Okay. We all
6 received --
7 MS. YAN: I just want to add one thing.
8 That is that all our policies will be reviewed
9 periodically and will be updated and revised as
10 necessary. And we'll be presenting them to you as
11 a batch. So, we have another about 16 policies to
12 be developed and present to you in the future
13 meetings.
14 CHAIRMAN WASHINGTON: Okay, I see Zwolak
15 and I have a clarifying question and then Zwolak
16 and we'll go this way. Okay.
17 DR. EPSTEIN: Arnie Epstein. I'm not sure
18 I understood. Right now, we're reviewing the
19 policies, blind institution investigator, and are
20 you proposing to strike that?
21 MS. YAN: There was a comment that coming
22 in saying that that is our current practice and

1 that practice can continue as we choose, but that
2 may not need to be in the policy as --
3 DR. EPSTEIN: So, you're proposing to
4 strike it?
5 MS. YAN: Strike just that one sentence
6 from the current policy.
7 CHAIRMAN WASHINGTON: Okay, Zwolak.
8 DR. ZWOLAK: Bob Zwolak, Board.
9 In reviewing these one last time and in
10 consideration of the discussion about the
11 importance of the Methodology Committee and the
12 Methodology Report, there is in the post-approval
13 section a comment that says "An investigator may
14 unilaterally deviate from the adopted PCORI
15 methodologic standards by only informing the
16 staff," and I think given the importance we lay on
17 the methodologic standards that we should strike
18 that clause where an investigator can deviate from
19 our standards just by telling us that he or she is
20 doing so.
21 CHAIRMAN WASHINGTON: Okay.
22 MS. YAN: The Board can approve with that

1 amendment if that's what the Board wants.
2 CHAIRMAN WASHINGTON: Okay, I know it's
3 late in the day. We received this ahead of time.
4 So, I'm assuming we've read them and are
5 comfortable because we don't have to, as Kerry is
6 reminding me, approve these today, but most of it,
7 99 percent of it is the way we've been operating
8 since we developed policies.
9 So, other than that amendment, is there
10 another amendment?
11 [No response.]
12 CHAIRMAN WASHINGTON: Okay, Harlan and
13 then Allen, and Rick, is your card up?
14 DR. WEISMAN: So, when I look at the
15 slides originally, the ones that were sent to us in
16 advance, and it was actually on your slide that
17 introduced getting to this point, which is -- I'm
18 not sure where it is. But, anyway, you relegated
19 the Board and through the FAAC, recalling institute
20 policies and then to the executive director
21 policies related to human resources and --
22 MS. YAN: Administration and operation.

1 DR. WEISMAN: Administration, and I was
2 worried about that delegation until I went through
3 the appendix, and in the appendix it’s clarified
4 that in terms of human resource policies, if you
5 put compensation into that, that executive and
6 director compensation should be taken out of the
7 institute, which it is. I think there's a creation
8 of what's called an Executive Compensation
9 Committee. I wasn’t really clear on its structure,
10 but that would be very typical that a committee of
11 the Board asks on matters of executive and director
12 comp, but it isn't clear in the presentation.
13 MR. BARNETT: Yes, you’re right. It’s not
14 clear from that one slide, but, in fact, if you
15 look at the --
16 DR. WEISMAN: It’s in the appendix.
17 MR. BARNETT: If you look at the
18 authority, the full authority matrix, the authority
19 for executive compensation is delegated to the
20 Executive Compensation Committee, which is -- who
21 is it again, Steve? It’s --
22 VICE CHAIRMAN LIPSTEIN: [Off microphone.]

1 DR. SELBY: Yes, NFAC.
2 MR. BARNETT: So, your point is very well
3 taken, and, in fact --
4 DR. WEISMAN: I just want to make sure we
5 weren't abrogating --
6 MR. BARNETT: -- that that is not fully in
7 the hands of staff.
8 DR. WEISMAN: Right, right.
9 CHAIRMAN WASHINGTON: Any other amendments
10 or any other comment?
11 DR. DOUMA: A comment.
12 CHAIRMAN WASHINGTON: Please go.
13 DR. DOUMA: Yes, that's right.
14 Unfortunately, I didn't get this until I was
15 basically getting on a plane to come here.
16 CHAIRMAN WASHINGTON: That means you had
17 about five hours on the plane, Allen.
18 [Laughter.]
19 DR. DOUMA: And I had three other books to
20 read.
21 CHAIRMAN WASHINGTON: Oh, okay.
22 DR. DOUMA: Plus, actually, I didn't even

1 have a martini. It's also I assume we have some
2 change for a discussion, which it sounds like we're
3 not going to, plus we got stuff handed out this
4 morning, which I haven't looked at. Didn't know we
5 were going to be voting on those. But and I do
6 have some items that I would like to talk about,
7 but given the sense of the committee and where we
8 are and when we are, I don't want to be *persona non*
9 *grada* for bringing up issues.
10 MR. BARNETT: Well, let me make a
11 suggestion, if I could, and Allen, I want to make
12 sure you're comfortable with this. What I'm going
13 to suggest, and maybe this is self-serving, is that
14 we go ahead and have the vote, approve it.
15 Remember that these are our policies and which
16 means that we shape them, we change them when we
17 decide to change them, and maybe this can be done
18 right away, but certainly between now and the next
19 board meeting, we'll have a detailed conversation
20 between Regina and you and I'm happy to participate
21 and make that any questions that you have are
22 answered and if there are some proposed amendments

1 that come out of that, then we can consider those
2 at the next board meeting. But that's the request
3 that I would make. If you're comfortable with it.
4 DR. DOUMA: I am, but let me have one
5 minute just to sort of skip around and say why I'm
6 concerned.
7 One is it talks about the duty of
8 obedience for a Board member and it talks about the
9 duty and obedience to the organization's values.
10 And we're supposed to be faithful to the
11 organization's values. I don't even know how to be
12 faithful to the values.
13 [Laughter.]
14 DR. DOUMA: So, it also talks, and this
15 one is more significant in a way, under committees,
16 it says "Unless otherwise provided in a resolution
17 of the Board designating any committee, a majority
18 of the whole committee shall constitute a quorum
19 and the act of a majority of the members presents
20 at a meeting in which a quorum is present shall be
21 an act of the committee."
22 That sounds to me a lot like deliberation

1 and voting. Okay, which makes it a meeting. And
2 so, just for me, there's a conflict between this
3 language and the language that came before with
4 regard to how we define a meeting. And I'm okay to
5 let that ride, but that's the level of discussion
6 I'd like to have some time.
7 MR. BARNETT: And Allen, I appreciate the
8 questions. I think we've got really direct,
9 straightforward responses to both of those
10 questions, which is why I think that offline
11 conversation would be useful.
12 DR. DOUMA: And that would be good. Last
13 one.
14 MR. BARNETT: Okay.
15 DR. DOUMA: Because this might come up
16 sooner rather than later. It says in here "The
17 Board must not commit acts that are outside the
18 scope of the institute's powers and must abide by
19 federal and state laws."
20 Two questions. If I get a speeding
21 ticket, what's going to happen to me because I
22 broke a state law? What is the remedy for this

1 recreant Allen Douma for having gotten a speeding
2 ticket?
3 CHAIRMAN WASHINGTON: You're going to get
4 voted off the island, Allen.
5 DR. DOUMA: All right.
6 [Laughter.]
7 DR. DOUMA: I just want to know how I can
8 get off gracefully.
9 UNIDENTIFIED BOARD MEMBER: You have to go
10 back to the FAAC for a year.
11 DR. DOUMA: No, no, that's cruel and
12 unusual punishment.
13 VICE CHAIRMAN LIPSTEIN: So, Gene, I kind
14 of shared Allen -- I had some ideas, too. But I
15 think what we should do is I'd like to make --
16 DR. DOUMA: Well, it --
17 MR. LIPSTEIN: -- a motion to approve
18 these policies, that we approve these policies and
19 that --
20 CHAIRMAN WASHINGTON: With the amendment?
21 VICE CHAIRMAN LIPSTEIN: With the
22 amendment, and at some point in the future, we will

1 revisit with the FAAC updates to these policies
2 that would reflect Allen's input and some of the
3 ideas that I have, as well. But I would make a
4 motion --
5 DR. DOUMA: I second that motion.
6 MR. LIPSTEIN: -- that we go forward.
7 CHAIRMAN WASHINGTON: Okay, so moved and
8 second. The motion actually included the
9 amendment, so --
10 UNIDENTIFIED BOARD MEMBER: [Off
11 microphone] that document.
12 CHAIRMAN WASHINGTON: Bob's amendment.
13 All in favor?
14 [Chorus of Ayes.]
15 CHAIRMAN WASHINGTON: All opposed?
16 [No response.]
17 CHAIRMAN WASHINGTON: Any abstentions?
18 [No response.]
19 CHAIRMAN WASHINGTON: Okay, the motion
20 carries. Thank you.
21 MS. YAN: Thank you very much, and this is
22 not the last batch. There will be more to come.

1 If there are further comments, send them to me.
2 Thank you.
3 CHAIRMAN WASHINGTON: Yes, thank you.
4 Joe, a couple of comments before I wrap
5 up. It's been a long, productive day.
6 DR. SELBY: We always say this was an
7 action-packed day more than maybe any in memory. I
8 have a set of four or five slides of next steps,
9 but I really feel like I should spare you at this
10 point and if we get a moment, present them tomorrow
11 in closed session just so that you can see where
12 we're going, but a lot of --
13 CHAIRMAN WASHINGTON: I think for the
14 public, if you have them, you just --
15 DR. SELBY: Post them?
16 CHAIRMAN WASHINGTON: [Off microphone.]
17 Okay.
18 DR. SELBY: Okay, all right.
19 CHAIRMAN WASHINGTON: Because it'll take
20 less than five minutes. I know [off microphone].
21 We have to remember that there are others that are
22 participating.

1 DR. SELBY: So, in the area of the
2 Strategic Plan, it was very clear that our work
3 includes developing the metrics for our Strategic
4 Plan, continuing to develop them at the level of
5 both the outputs and the goals in close
6 consultation with --
7 MS. HOLE-CURRY: Sorry, Joe, can you use
8 the other mic, please? It's not clear that that
9 one's carrying. I just want to make sure our
10 public can hear it.
11 DR. SELBY: Thanks. Better? Oh, yes.
12 But now what did I do? Good.
13 So, in close consultation with the Board
14 of Governors, we'll develop those metrics. And
15 dashboards need to be developed, tailored to
16 individual audiences. For example, the Board,
17 other stakeholder groups, staff. We need to
18 develop charters for the clinical trials and
19 advisory panel and the Rare Diseases Advisory Panel
20 to have for the September meeting. Part of the
21 Strategic Plan also includes continuing work and
22 completing PCORI's evaluation plan, which is linked

1 to the Strategic Plan and builds actually on the
2 metrics that we're talking about. And to continue
3 developing PCORI's dissemination and implementation
4 blueprint.
5 We want to, this is Harlan Weisman's and
6 others' points, build into our Strategic Plan a
7 more refined, and I would say now we've categorized
8 it a more refined pre-award portfolio management
9 strategy. The numbers, sizes, length of award and
10 types of awards. And in developing the metrics for
11 outputs, we need to consider the interaction and
12 crossover between outputs. So, this really is a
13 call for more complex metrics which are actually
14 sometimes to put the influence of two or three
15 outputs together and to look for patterns among
16 those outputs as we build our metrics.
17 Okay, in the area of dissemination and
18 communication, and this actually came from
19 discussions. Part of it came from the discussions
20 yesterday, the Scientific Publications Committee,
21 develop a strategic publications plan, and so, that
22 means what audiences, what messages, what papers

1 serve that message scientific and for the lay
2 press.
3 Today, we heard be certain that as we
4 commission these landscape reviews, we push for
5 publication of them and to think of communication
6 as a change management tool. So, think about
7 communicating change.
8 In the area of research prioritization,
9 the suggestion that as one way of generating
10 research topics, particularly big rock type of
11 research topics, consider carving out a piece of
12 future board meetings simply for brainstorming good
13 research ideas. These could be linked to a
14 consideration of proposed targeted PFAs, they could
15 be linked to review of what we've already funded.
16 But we need time for those good ideas to surface
17 and I saw a suggestion came up offline during the
18 meeting today that maybe even an offline process
19 among Board members might be a good way to get that
20 rolling.
21 Regarding the targeted PFAs and
22 prioritization of those, one approach that was

1 suggested was to enhance the landscape data
2 collection before the prioritization process so
3 that we've done more of the data collection and
4 maybe gotten to a smaller number of more specific
5 topics which get prioritized, although it was
6 recognized that you have to balance that against
7 respecting the basic process, and it looks like I
8 got cut off in midsentence, but not undercutting
9 the other parts of the process that we've set up.
10 So, both approaches. The broader solicitation and
11 prioritization and more topics and the more
12 detailed landscaping before we prioritize both have
13 attraction. And I think really the trick for us is
14 working with the advisory panels and the Board to
15 create a balanced mutually agreed upon approach
16 that allows for good topics to rise to the top
17 quickly, but also to have a systematic approach.
18 In launching the landscape reviews, we
19 really need to be sure to standardize the request
20 when we send out review for landscapes, make sure
21 that we ask the same questions in the various
22 landscapes so that we get findings that can be

1 compared and weighted against each other.
2 And in terms of active portfolio
3 management, the point was made that we need to, and
4 it's not easy, identify the boundary between useful
5 involvement of staff and being overbearing or
6 bureaucratic. So, that was a point well taken.
7 And from the methods discussion, we need
8 to develop metrics for monitoring the
9 implementation of the recommended actions. This is
10 at a national level. And this is critically
11 important and actually there are -- let's see, work
12 with the Methodology Committee to develop tools for
13 training and supporting the Merit Review Panelists
14 for this exercise.
15 So, this was a point that was made well.
16 We heard it and we will get on with one way or
17 another finding the staff support, working with the
18 Methodology Committee to develop these tools for
19 training and then supporting reviewers as they
20 determine with each application whether it adheres
21 to the appropriate methodologies standards.
22 Let's see. Oh, so, that's very

1 interesting. Somehow, these made it on and I
2 didn't know I got these on.
3 So, this is the same topic again, this
4 first one. I've just already said that.
5 The second one is consider strategies, and
6 this was Harlan Krumholz's point and others',
7 considering strategies for increasing pre-award
8 support, and perhaps especially for nontraditional
9 researchers, the idea of an hour or two of
10 consultation on methods, possibly some time on
11 patient engagement, we really hear the message that
12 we need to get the examples out, we need to get
13 more information out to the entire research
14 community on what we think we mean by good patient
15 engagement.
16 We also need to analyze those applications
17 that don't quite get funded, looking at the scores
18 and what drove the scores down. Were there some
19 that could be brought up maybe with enhanced
20 engagement? And then the last consideration,
21 and I apologize for the rapid and faulty note
22 taking here, consider setting aside a certain

1 amount of dollars or in some ways influencing the
2 way we score applications to give particular note
3 to applications that might be completed in less
4 than three years.
5 So, that was what I got and I'm sure I
6 missed some stuff. So --
7 CHAIRMAN WASHINGTON: No, we're not going
8 to open it for a discussion right now, Joe.
9 DR. SELBY: Oh, come on.
10 CHAIRMAN WASHINGTON: Okay, discussion is
11 closed. This was for the public and we will be
12 following up.
13 So, I want to conclude today by thanking
14 all of those who joined us in-person as well as via
15 Webcast or via the teleconference and to remind
16 everyone that all the materials presented today are
17 available at our Web site at www.pcori.org and also
18 the Webcast from today will be archived and
19 available later this week. And, finally, you're
20 always encouraged to provide us with feedback at
21 info@pcori.org or through our main Web site
22 pcori.org. And thanks again to the staff and to

1 the Board for your tremendous work on behalf of the
2 institute and I will see all the Board members
3 tonight at the reception and the dinner. We've had
4 a very productive, I believe invigorating day and
5 thanks, everyone.
6 [Whereupon, at 5:46 p.m., the PCORI Board
7 of Governors meeting was concluded.]
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