

VERBATIM PROCEEDINGS

CONNECTICUT STEM CELL RESEARCH ADVISORY  
COMMITTEE MEETING

AUGUST 21, 2012

1:20 P.M.

CONNECTICUT INNOVATIONS  
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RE: CONN. STEM CELL RESEARCH ADVISORY COMMITTEE MEETING  
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1 . . .Verbatim proceedings of the  
2 Connecticut Stem Cell Research Advisory Committee meeting,  
3 held at Connecticut Innovations, 865 Brook Street, Rocky  
4 Hill, Connecticut, on August 21, 2012 at 1:20 p.m. . . .

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6

7

8 MS. MARIANNE HORN: Well, then, we can go  
9 on the record. We're here at the Stem Cell Research  
10 Advisory Committee, August 21, 2012. My name is Marianne  
11 Horn, and I am standing in as the designee of the  
12 Commissioner of Public Health, who is on her way from the  
13 airport, and we expect her momentarily.

14 Nonetheless, we do have a quorum. I would  
15 like to -- this is our first meeting back since we did the  
16 grant reviews in June, so welcome back.

17 I would like to introduce our newest member  
18 of the Stem Cell Research Advisory Committee, Dr. is it  
19 James Hughes?

20 DR. JAMES HUGHES: Um-hum.

21 MS. HORN: And do you go by James or?

22 DR. HUGHES: Jay.

23 MS. HORN: Jay. Jay Hughes. And he is a  
24 bioethicist at the University of -- Trinity College in

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1 Hartford, and we are delighted to have him on board. He  
2 has experience with some stem cell research in his past,  
3 and oversees the IRB at Trinity.

4 If there's anything else that I'm leaving  
5 out from that very brief overview, please feel free.

6 DR. HUGHES: Well I used to work for the  
7 Center for Clinical Medical Ethics at the University of  
8 Chicago. I ran the research there, so that was my  
9 principal exposure to the very early stages of all of  
10 this.

11 MS. HORN: Okay. It's wonderful to have  
12 you on board, and we're going to start you right into work  
13 today.

14 Are there any other opening remarks? Okay.  
15 We have the approval of the April 17, 2012 minutes and  
16 June 11, 2012. Let's take the April 17, 2012 minutes. Do  
17 I have a motion to approve?

18 A MALE VOICE: Move to accept.

19 MS. HORN: And second? Any discussion?  
20 Okay. All in favor?

21 VOICES: Aye.

22 MS. HORN: And do I have a motion to accept  
23 the June 11, 2012 minutes?

24 A MALE VOICE: So moved.

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1 MS. HORN: And second?

2 A MALE VOICE: Second.

3 MS. HORN: And any discussion? All in  
4 favor?

5 VOICES: Aye.

6 MS. HORN: Okay, the minutes pass. Item  
7 three is the receipt of six-month fiscal reports.

8 DR. MYRON GENEL: How many vacancies are  
9 still on the Advisory Committee?

10 MS. HORN: I don't know that I have that  
11 off the top of my head, but I think there are at least  
12 three and potentially more.

13 DR. GENEL: Does that count the resignation  
14 of Dr. (indiscernible)?

15 MS. HORN: That, I'm not sure whether that  
16 would make it four, and then, with the additional of Dr.  
17 Hughes. I'm sorry. I just don't have my up-to-date list  
18 with me today, but we do still have some vacancies, so,  
19 no, you cannot resign.

20 Okay. Receipt of six-month fiscal reports.  
21 And, CI, are you going to take us through this, Sara?

22 MS. SARA DONOFRIO: Yes. The first one is  
23 number 08SCBUCHC011, Zecevic. That one was reviewed and  
24 did not see anything unusual, as well as the second item

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1 for Mr. LoTurco. That one, as well, there was nothing  
2 unusual on that one either. I believe these were just  
3 here for informational purposes.

4 DR. RICHARD DEES: This is Richard Dees.  
5 The second one is asking us to put it off for six months  
6 for internal reasons, right?

7 DR. JOSEPH LANDRY: Yeah, they had computer  
8 issues, and they'd like to delay that to December.

9 DR. DEES: But it seems like we probably  
10 need to have a vote to say that that's acceptable, don't  
11 we?

12 DR. LANDRY: I'm sorry. Could you repeat  
13 the question, sir?

14 DR. DEES: Don't we need to have a vote in  
15 order to accept that their proposal puts this off for  
16 another six months?

17 MS. DONOFRIO: Yeah, I think that would be  
18 fine.

19 DR. DEES: I'll move that, if that's what  
20 we need to do.

21 MS. DONOFRIO: Okay. Would we like to take  
22 a motion on item number two, LoTurco?

23 DR. GENEL: I'll second Richard's motion.

24 MS. DONOFRIO: Okay. It's approved. And I

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1 can go onto item number four, annual reports. These are  
2 to be considered for approval.

3 The first item, 09SCBYALE06, Kocsis, that  
4 one has been reviewed and would recommend that one for  
5 approval, as well as item two, which is 09SCBYALE13,  
6 Sutton.

7 DR. LANDRY: And, if approved, all of these  
8 have additional funding that would qualify them if they're  
9 accepted. I have the amounts.

10 MS. DONOFRIO: We would recommend these for  
11 approval, as well. Do we need to individually vote on  
12 each item?

13 MS. HORN: I think, if there is no  
14 discussion on any of them, the Committee members should  
15 feel free to weigh in on each of these as we go through,  
16 and then we can vote to approve them.

17 MS. DONOFRIO: Okay, so, we'll go back to  
18 the first item, Mr. Kocsis. Would there be any discussion  
19 on that item?

20 Okay. The next item, 09SCBYALE13, Sutton,  
21 any discussion for that one? Hello, caller. Can you  
22 please identify yourself?

23 DR. TREENA ARINZEH: Hi. This is Treena  
24 Arinzeh.

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1 MS. DONOFRIO: Hi, Treena. Thank you.

2 Okay, so, any discussion on the Sutton annual report?

3 DR. DEES: I have just one remark. The lay  
4 summary on the Sutton grant is not clear what the point of  
5 the research is in the lay summary, so if we could clarify  
6 that, that would be helpful.

7 MS. DONOFRIO: Okay, so, we can get back to  
8 Mr. Sutton on the lay summary for that. The next item, 09  
9 --

10 DR. GERRY FISHBONE: We have a summary.

11 DR. DEES: It just wasn't clear what the  
12 point of the research was to me, as a layperson reading  
13 these things. I could figure it out for the more  
14 technical stuff, but just reading the lay summary alone it  
15 wasn't clear.

16 DR. MILTON WALLACK: So can we just ask  
17 them to re-do the lay summary?

18 MS. DONOFRIO: Absolutely.

19 DR. DEES: Yeah.

20 DR. WALLACK: And specify more clearly  
21 their goals.

22 DR. DEES: Yes.

23 DR. FISHBONE: It's a major step forward.

24 MS. DONOFRIO: Okay. Any further

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1 discussion on that item? We'll move on to 09SCBYALE14,  
2 Huang. Any discussion on that item?

3 DR. DEES: This is Richard again. I was  
4 reading the lay summary very carefully. This one they  
5 talk about the sector that they're using, but in the lay  
6 summary, again, it's not clear what the Lin 28(phonetic)  
7 is. They just start talking about it, and for someone,  
8 who doesn't know anything about it, it doesn't make sense.

9 MS. DONOFRIO: Okay. We can request that  
10 he --

11 (Off the record)

12 MS. DONOFRIO: Okay. Any further  
13 discussion on that item? Okay. We'll move onto  
14 09SCBYALE21. Any discussion for that item?

15 Okay. Next item, 09SCBYALE27. Any  
16 discussion for that? The next item is 09SCBUCHC01. Any  
17 discussion there? The next item is 09SCBUCHC09, Shapiro.  
18 Any discussion?

19 The next one is 09SCBWESL26. No  
20 discussion? The next one is 09SCBUCHC01. Any discussion?

21 And the last item for annual reports is 09SCBUCHC20.

22 Okay.

23 I'd like to take a motion to pass these  
24 annual reports.

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1 DR. FISHBONE: So moved.

2 MS. DONOFRIO: Second?

3 DR. WALLACK: With the clarification on the  
4 two that we requested.

5 MS. DONOFRIO: Okay.

6 MS. HORN: Those will be brought to the  
7 next meeting?

8 MS. DONOFRIO: Yes.

9 DR. GENEL: If I may, you went so fast  
10 through that. The Shapiro summary for the lay public I  
11 think is an excellent model of what a lay public summary  
12 should be.

13 DR. DEES: I would agree with that. This  
14 is Richard Dees.

15 MS. HORN: Would you think that would be  
16 appropriate to send out to the other members, who are  
17 having more difficulty with their lay summary?

18 DR. GENEL: It's not a bad idea, and it  
19 might be -- a kudo to Dr. Shapiro might also be in order.

20 MS. DONOFRIO: Okay. Any other further  
21 discussion on the annual reports? All in favor?

22 VOICES: Aye.

23 MS. HORN: Opposed? Recused? Motion  
24 passes.

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1 MS. DONOFRIO: Okay. Number five, final  
2 reports received, we received two. The first, 06SCB11,  
3 and the second is 09SCBWESL26. These were added for  
4 informational purposes, and we did not see anything  
5 unusual in either of these final reports.

6 DR. WALLACK: So moved.

7 DR. FISHBONE: Second.

8 MS. DONOFRIO: Okay. The next item, number  
9 six --

10 MS. HORN: We need to vote. All in favor?

11 VOICES: Aye.

12 MS. HORN: I was just hesitating, about  
13 whether we actually approved the final reports.

14 MS. DONOFRIO: In the past, it didn't look  
15 like we had.

16 MS. HORN: We had, right. Right. It never  
17 hurts to over-vote. The final reports are received. Are  
18 these final reports, in your view, adequate to let you  
19 know how the research progressed, and whether progress was  
20 being made, and whether they met their milestones and so  
21 on?

22 DR. DEES: I didn't see a technical report  
23 from the second grant. All I got when I downloaded was  
24 the financial report.

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1 COURT REPORTER: Excuse me. Who is  
2 speaking?

3 DR. DEES: This is Richard Dees.

4 MS. DONOFRIO: Is that for the Naegele?

5 DR. DEES: Yes.

6 MS. DONOFRIO: I believe that was all that  
7 I had received on that one.

8 DR. DEES: So that would mean we haven't  
9 actually gotten the final report, right?

10 MS. DONOFRIO: I'm sorry. Could you repeat  
11 that?

12 DR. DEES: Does that mean we haven't really  
13 gotten the final report?

14 DR. LANDRY: The final technical report,  
15 no. Just the final fiscal report on July 3rd.

16 MS. HORN: Okay, so, we would still be  
17 expecting the final technical report.

18 DR. LANDRY: For example, I just got a  
19 small check from the Health Center for a different one,  
20 and they haven't had the final internal sign offs on the  
21 technical report. I think they figured they had closed  
22 the financial part of it out, so that will be coming up in  
23 the next agenda, so probably this is a similar case.

24 MS. CLAIRE LEONARDI: But we keep track of

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1 whether we receive both of those pieces, correct?

2 DR. LANDRY: Yeah.

3 MS. LEONARDI: So that we can let the  
4 Committee know --

5 MS. DONOFRIO: Any further discussion on  
6 the final reports? We'll move on to agenda number six,  
7 the Rebudgeting Requests. These are for approval.

8 The first item, 11SCDIS02. For this  
9 particular request, we are requesting approval on year  
10 three of year three. Prior to Emily's departure, she had  
11 approved years one and two. Year three was above the 20  
12 percent, so that one needs to be approved, as well as  
13 11SCAYALE33.

14 DR. FISHBONE: Boelsterli is moving money  
15 from each of three years, right?

16 MS. DONOFRIO: Right.

17 DR. FISHBONE: And these are the new. I  
18 was moving money from year one.

19 MS. DONOFRIO: Only year three of three was  
20 over 20 percent.

21 DR. FISHBONE: I thought you said they'd  
22 like to transfer 35,000 from year one, 35,000 year two,  
23 36,000 from year three. Am I wrong on that?

24 MS. DONOFRIO: Let me see. The note I have

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1 year one and two request falls within the 10 to 20 percent  
2 range.

3 DR. FISHBONE: So it doesn't need approval?

4 MS. DONOFRIO: Right. Year three, that  
5 request was for 36,889.

6 DR. FISHBONE: And that's above the range?

7 MS. DONOFRIO: Correct. I'd like to take a  
8 motion on both of those items.

9 DR. FISHBONE: So moved.

10 MS. DONOFRIO: Second?

11 DR. GENEL: I second it.

12 MS. HORN: Any further discussion? All in  
13 favor?

14 VOICES: Aye.

15 MS. HORN: Anyone opposed?

16 MS. DONOFRIO: Okay. Item number seven,  
17 Rebudgeting Request for 2012. These are the three items  
18 that requested rebudgeting, due to the grant review  
19 meeting.

20 The first item is 12SCBUCHC09, Chamberlain.

21 The next item is 12SCDISYALE01, Redmond. The third is  
22 12SCBUCON01, Goldhamer. We would recommend these three  
23 for approval. Is there any discussion on any of those  
24 items?

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1 DR. FISHBONE: Chamberlain, which she had a  
2 reduction in funding from four years to three years, so  
3 she wanted to use --

4 MS. HORN: Jean Redmond was the grant,  
5 where we disallowed some expenses for research that would  
6 have been conducted out of state.

7 DR. FISHBONE: Yeah. We wrote an  
8 application to reduce funding, yes. I would propose that  
9 we --

10 MS. DONOFRIO: Okay. A motion for those  
11 items. And a second?

12 DR. WALLACK: Second.

13 MS. HORN: Any further discussion? All in  
14 favor?

15 VOICES: Aye.

16 MS. HORN: Opposed?

17 DR. FISHBONE: These were both grants that  
18 we gave them less than asked for, so they had to  
19 reshuffle.

20 MS. HORN: Correct. So you just need to  
21 determine whether you still feel that the budget is  
22 adequate to do the research that they proposed.

23 MS. DONOFRIO: Okay. Agenda item eight,  
24 Carry-over Requests, there was one, 09SCDUCHC01. Any

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1 discussion on that item?

2 DR. FISHBONE: That was a pretty big carry-  
3 over, wasn't it, \$235,000? Am I correct? This is Xu and  
4 Grabel. Does that mean they have that much money left  
5 over at the end of the year that they wanted to transfer?

6 DR. LANDRY: Yeah. The first three years  
7 were certainly a lot less than the year four budget is.  
8 It does seem to be a little bit heavy towards the end of  
9 the project, but I don't believe we know the technical  
10 reasons for that.

11 DR. FISHBONE: This was a core, I guess.

12 MS. HORN: Would you like additional  
13 explanation?

14 DR. DEES: This is Richard Dees. I mean  
15 there is some explanation there on the last page.

16 MS. HORN: Um-hum. Remaining funds and  
17 supplies, travel and other expenses are remaining, due to  
18 personnel changes.

19 DR. FISHBONE: Did we fund them again?  
20 This is from '09, right? Did we fund them again this  
21 year?

22 MS. HORN: The UConn core (multiple  
23 conversations) \$500,000.

24 DR. LANDRY: They're still due 605.

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1 MS. HORN: Their new award. They just got  
2 a core.

3 DR. LANDRY: I'm sorry. I was talking  
4 about year nine.

5 DR. FISHBONE: So the carryover is 68  
6 percent or so of what we awarded this year?

7 MS. HORN: Um-hum.

8 DR. GENEL: I won't comment any further.

9 DR. FISHBONE: Can you explain your  
10 comment?

11 DR. GENEL: Well, no. I mean since we  
12 limited the amount of money that we gave to the cores to  
13 10 percent of the available funding, just making an  
14 observation that the carryover is --

15 DR. FISHBONE: You're merely suggesting  
16 they didn't use --

17 DR. GENEL: No. It's just an observation.

18 MS. LEONARDI: I think, if the Committee is  
19 uncomfortable, we can certainly go back and ask for more  
20 information to justify. It is a large amount. I mean I  
21 don't have all the history that all you have, but it is a  
22 large amount of dollars.

23 DR. FISHBONE: I'm sure they can use it,  
24 because we really didn't give them very much for this

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1 coming year.

2 MS. HORN: It says we are anticipating the  
3 funds will be used to explore new cutting edge technology,  
4 and I think the Committee, if they wanted more information  
5 about what the personnel changes were that freed up the  
6 money and what the new cutting edge technologies are that  
7 they're going to be using it for, I think they would be  
8 well within their rights to explore that.

9 If the Committee is comfortable with this  
10 explanation, that's the Committee's call.

11 DR. GENEL: I think it's reasonable.

12 MS. HORN: You think it's reasonable?

13 DR. GENEL: Yeah. I think we ought to have  
14 more information.

15 MS. HORN: Oh, it's reasonable to have more  
16 information.

17 DR. FISHBONE: It just seems strange, you  
18 know, when they applied for a new grant and had so much  
19 money left over from the previous. I'm sure they can use  
20 the money, but it would be nice to know what they plan to  
21 use it for.

22 MS. HORN: Is that a motion?

23 DR. FISHBONE: Sure.

24 MS. HORN: We have a motion that we, the

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1 Committee, be provided with additional information about  
2 the remaining funds, the circumstances under which they  
3 came to be remaining, and how they're anticipating using  
4 the funds.

5 Would you like that in a written report, or  
6 would you like one of the PIs to come to a meeting and  
7 explain?

8 DR. FISHBONE: I think we ought to ask for  
9 a report first, and, then, if we would like more  
10 elaboration. You know, I'm sure there's no hanky-panky or  
11 anything. It would just be nice to know, you know, why  
12 there's so much.

13 MS. HORN: Okay, so, we have a motion. Do  
14 we have a second?

15 DR. GENEL: I'll second it.

16 MS. HORN: Any further discussion? All in  
17 favor?

18 VOICES: Aye.

19 MS. HORN: Anybody opposed? Okay. We will  
20 ask them for additional information, then.

21 MS. DONOFRIO: The next item, No cost  
22 extension. We received four requests for that. The first  
23 one is 09SCBUCON18. Any discussion on that item?

24 The next item is 10SCA47. Any discussion

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1 for that?

2 DR. WALLACK: Yeah. We've reviewed her  
3 applications, her progress, multiple times, and we've  
4 asked for more frequent updates. Have we received any of  
5 that? I think that we need more information about that,  
6 number one.

7 Number two, I could be wrong, but I also  
8 understand that she has either left the country, or is  
9 contemplating, or is in the process of leaving the  
10 country, so that I have no idea at all at this point, and,  
11 frankly, I've had issues with this particular grant for  
12 quite a while.

13 MS. DONOFRIO: Okay.

14 DR. WALLACK: And I certainly would want  
15 to, before we do anything at all about any further  
16 extensions, which we've been more than liberal with, I  
17 feel, find out, number one, is she going to be able to  
18 continue on the grant and where she is on the grant.

19 MS. HORN: Are you making a motion, Milt?

20 DR. WALLACK: I'll move that.

21 MS. HORN: Okay. Is there a second?

22 DR. FISHBONE: I'll second that.

23 MS. HORN: Okay. Is there any further  
24 discussion? So the motion is not to grant it?

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1 DR. WALLACK: Not to grant it.

2 MS. HORN: Pending further information.

3 DR. WALLACK: Right.

4 MS. HORN: Okay.

5 DR. FISHBONE: Did we skip over all the  
6 others in that category? Want to vote on that?

7 MS. HORN: Yes. All in favor?

8 VOICES: Aye.

9 MS. HORN: Opposed?

10 MS. DONOFRIO: The next item is 10SCA23.  
11 Any discussion on that item?

12 DR. LANDRY: I mean I can mention that I  
13 did try to look in that file, and I haven't seen a report  
14 ever submitted on that particular grant, and this is now  
15 two years, at least I couldn't find one in our records.

16 Drazinic I did find one that she submitted  
17 a year ago, but she's probably late, as you gentlemen  
18 mentioned, but, on this next one here, I couldn't find  
19 anything from that party, which may not mean she didn't do  
20 it, but we didn't receive it here, or file it correctly,  
21 so maybe we could ask her to, or them. I'm not sure.

22 DR. FISHBONE: He wants to extend it by a  
23 full year. It's supposed to end September 30, 2012, and  
24 he wants to extend it through September 30, 2013.

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1 MS. HORN: You're saying we don't have any  
2 technical or fiscal reports?

3 DR. LANDRY: Not that I could see even from  
4 like a year ago, so, I mean, I don't know if his funding  
5 happened way later, so this would be his first year to  
6 report. You'd think a '10 grant would have had like at  
7 least one or two reporting cycles by now.

8 MS. HORN: You're right, and, without  
9 those, he wouldn't have received additional funding.

10 DR. LANDRY: You wouldn't have thought,  
11 right, but it looks like that he has received his 200.  
12 I'm not sure that one is --

13 MS. HORN: Oh, okay. He got that on the  
14 signing of the contract?

15 DR. LANDRY: I would have to look back to  
16 see was it a 200 or was a 100/100, so I'll look into that.

17 MS. HORN: So is there a motion to --

18 DR. WALLACK: Request the reports?

19 MS. HORN: Request the reports.

20 DR. WALLACK: I'll move that.

21 MS. HORN: Okay. Is there a second?

22 Anybody seconding that motion?

23 DR. FISHBONE: Yeah, I'll second.

24 MS. HORN: Okay. All in favor?

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1 VOICES: Aye.

2 DR. FISHBONE: He does give a report of  
3 what he's doing here, but he needs another year to do some  
4 more.

5 MS. HORN: Right, and we just need to be  
6 sure that the requisite reports from prior to that have  
7 already been submitted. Put that on the agenda for next  
8 month, as well. All in favor?

9 VOICES: Aye.

10 MS. HORN: Opposed? Let the record reflect  
11 that Commissioner Mullen has arrived. Welcome.

12 CHAIRPERSON JEWEL MULLEN: Thank you very  
13 much.

14 MS. DONOFRIO: Okay, so, there's one other  
15 no cost extension, 10SCD01. Is there any discussion on  
16 that item?

17 DR. FISHBONE: What was the reason, Sara,  
18 for that request?

19 MS. DONOFRIO: Let's see.

20 DR. FISHBONE: This is another one for a  
21 full-year extension. Detailed annual report will be  
22 forthcoming.

23 MS. DONOFRIO: Hi. Can the latest caller  
24 please identify yourself?

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1 DR. PAUL PESCATELLO: Yeah. It's Paul  
2 Pescatello. I just switched phones.

3 MS. DONOFRIO: Okay.

4 DR. WALLACK: Would it be appropriate to  
5 have additional information on this?

6 MS. DONOFRIO: I think so, yeah.

7 DR. FISHBONE: Is it a problem if they  
8 don't want additional funds? It's surprising that they  
9 can use the same funds for another year, without need for  
10 more.

11 MS. HORN: Is this going into its final  
12 year?

13 DR. LANDRY: This looks like it was a one-  
14 shot deal to me. I think it was 500 in the first year.

15 MS. DONOFRIO: Looks like they were  
16 requesting the no cost extension period to continue  
17 service to service the CT laboratories, working on the  
18 HESC derived tissues.

19 DR. LANDRY: Again, that was a \$500,000  
20 grant, and all was paid.

21 MS. HORN: That was all paid.

22 DR. LANDRY: So there's nothing being held.

23 DR. FISHBONE: So he has the money, and he  
24 wants another year to finish the budget. Is that a

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1 problem, if he has the money?

2 DR. LANDRY: Unless she wants some type of  
3 interim report. It doesn't have to be his final, but he  
4 should probably provide something.

5 DR. WALLACK: Yeah, I would think that  
6 (multiple conversations). I don't think it would be  
7 inappropriate to get more clarity on where he is.

8 MS. LEONARDI: Because if they don't use  
9 the money, they owe it back to the fund, so even though  
10 they already have the money, if it's after the grant  
11 period, we could expect to get it back if we don't grant  
12 the extension.

13 DR. FISHBONE: It says detailed annual  
14 report will be forthcoming, in accordance with the  
15 assistance agreement, which I don't quite understand,  
16 because we should have had it.

17 DR. LANDRY: Maybe he considers this letter  
18 request like his report, his internal report. It's just  
19 not quite as full or comprehensive as some of the others.  
20 Maybe he's new.

21 DR. WALLACK: He's not new. There's not  
22 enough clarity here, I don't think.

23 MS. HORN: Okay, so, somebody make a motion  
24 to that effect?

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1 DR. WALLACK: Yeah. I'll move that we have  
2 him be more specific, come back to us with more specific  
3 clarity on his reporting about where he is, the status of  
4 his research.

5 MS. HORN: Okay, second?

6 DR. FISHBONE: I'll second.

7 MS. HORN: Any further discussion? All in  
8 favor?

9 VOICES: Aye.

10 MS. HORN: Opposed? Motion passes.

11 MS. DONOFRIO: The next item for No cost  
12 extension is 10SCA22. Any discussion on that item?

13 DR. FISHBONE: Rodenheffer?

14 MS. DONOFRIO: Um-hum.

15 DR. FISHBONE: You're moving them around a  
16 little.

17 MS. HORN: Keep us on our toes here.

18 MS. DONOFRIO: The next item, 10SCA05, any  
19 discussion for that item?

20 DR. FISHBONE: Did we finish Rodenheffer?  
21 Do we need a vote on that?

22 MS. DONOFRIO: Do we want to vote on them  
23 all separate?

24 DR. LANDRY: Only if they're approving. I

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1 think they want to vote separate.

2 MS. DONOFRIO: Okay. And we also would  
3 need to go back and vote on Rasmussen, the first item.

4 MS. HORN: Suppose you go through all the  
5 rest, and then we'll go back to the ones we haven't voted  
6 on.

7 MS. LEONARDI: Except for the negative  
8 ones, but everything else should be voted on. Why don't  
9 you repeat the one that you were just on?

10 MS. DONOFRIO: That one is 10SCA22,  
11 Rodenheffer.

12 DR. FISHBONE: And he's just asking for  
13 three months of effort and health coverage for the post-  
14 doc, and the other he's asking for 20,000 to be carried on  
15 for the three months. Sounds reasonable.

16 MS. DONOFRIO: Take a motion to pass.

17 MS. LEONARDI: The ones that are  
18 affirmative, you're going to do all together.

19 MS. DONOFRIO: Okay, so, then the next one  
20 is 10SCA05. Any discussion for that item? And the last  
21 item is 10SCA13. Any discussion for that one?

22 CHAIRPERSON MULLEN: So there's clearly no  
23 discussion on 05? I didn't hear any response.

24 A MALE VOICE: It sounded reasonable.

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1 MS. DONOFRIO: Okay, so, the items that  
2 we'll take a motion on are Rasmussen. That one is  
3 09SCBUCON18. Also, Antic, 10SCD01. Rodenheffer would be  
4 the next one, and then, also, 10SCA05, as well as 10SCA13.  
5 I'd like to take a motion.

6 DR. WALLACK: Move those latter four. I  
7 think there's four.

8 MS. DONOFRIO: Second?

9 DR. FISHBONE: Seconded.

10 MS. DONOFRIO: Any further discussion? All  
11 in favor?

12 VOICES: Aye.

13 MS. DONOFRIO: Opposed? So that means  
14 Drazinic, Chhabra and Antic to request further  
15 information. Item number 10, Change in Personnel Request.  
16 There was one of those requests, and that is 10SCA06.  
17 Any discussion on that item?

18 DR. FISHBONE: Let me just check it for a  
19 moment. He just wants to create the salary line of his  
20 graduate assistant?

21 MS. DONOFRIO: That's correct. I'll take a  
22 -- I'm sorry? I'll take a motion on that item.

23 DR. FISHBONE: So moved.

24 CHAIRPERSON MULLEN: Okay, second?

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1 DR. WALLACK: Second.

2 MS. DONOFRIO: Any further discussion? All  
3 in favor?

4 VOICES: Aye.

5 MS. DONOFRIO: Anyone opposed? Next item,  
6 Extension of Time Served as PI. One request there. That  
7 one is 10SCA29. Any discussion on that item?

8 DR. LANDRY: I would just note for the  
9 reviewers that because so much time has transpired, it's  
10 going to be difficult for them to do the amount of work  
11 within now just one month or five or six weeks that's  
12 left.

13 They were originally hoping to accomplish  
14 it within the three-month time span, if it had been  
15 reviewed back in July. Just clarify, if we accept it, how  
16 they'll still be able to do it.

17 DR. GENEL: Well they didn't stop working,  
18 did they?

19 DR. LANDRY: Let's hope not.

20 DR. FISHBONE: He's accepted the new  
21 position, and it's full-time. He still has budget left.  
22 He would serve as a PI on the grant until October. Is  
23 this like a no cost extension?

24 MS. LEONARDI: With a substitution.

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1 CHAIRPERSON MULLEN: Or was that sort of  
2 suspended effort, it almost looks like.

3 DR. FISHBONE: Yeah.

4 CHAIRPERSON MULLEN: Next summer.

5 DR. FISHBONE: Next summer.

6 CHAIRPERSON MULLEN: Other than that, a  
7 student will be doing some of the work in between.

8 DR. FISHBONE: So he wants to finish it in  
9 the summer, and, meantime, use the money to pay for the  
10 student.

11 CHAIRPERSON MULLEN: Right, but then says  
12 he's still going to mentor the student during the year,  
13 but that the work is just going to maybe be done by the  
14 student, who we normally wouldn't fund.

15 DR. FISHBONE: He's a Ph.D. student. Do we  
16 know what he's talking about? I don't think there was any  
17 financial that came with it.

18 DR. LANDRY: I guess he'll be doing the  
19 additional work with no request for additional funds.  
20 It's just the 199 that was supplied so far to date. We  
21 don't have a report from them either.

22 DR. FISHBONE: Do we need some more  
23 information to understand what money?

24 DR. LANDRY: Maybe we should request like

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1 at least like a fiscal report, too, so that, then, we can  
2 approach it to the next agenda as a topic for next month.  
3 You can get their financial information in the meantime.

4 MS. HORN: He does indicate here that he's  
5 starting his new post tomorrow.

6 DR. DEES: This is Richard Dees. I mean  
7 we've already granted a no cost extension, right?

8 MS. DONOFRIO: Yes.

9 DR. DEES: So what he's really asking is --  
10 it should be a financial request, because it looks like  
11 he's reallocating the funds to pay for money, to pay for  
12 the student to do the work. Is that right?

13 MS. DONOFRIO: Right.

14 DR. DEES: It seems like it's coming in a  
15 funny form.

16 DR. FISHBONE: Could we ask for a little  
17 more clarification? It doesn't sound like it's a big  
18 amount of money.

19 DR. LANDRY: Maybe we can ask our UConn  
20 contact to help provide information on it.

21 MS. DONOFRIO: So we'll take a motion on  
22 requesting some additional information on 10SCA29.

23 DR. FISHBONE: I'll move that.

24 MS. DONOFRIO: Okay. Second?

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1 CHAIRPERSON MULLEN: Second.

2 MS. DONOFRIO: Okay. Any further  
3 discussion? All in favor?

4 VOICES: Aye.

5 MS. DONOFRIO: Any opposed? Next item,  
6 Addition of a Co-PI Request, and that one is for  
7 09SCDUCHC01. The addition would be for a Dr. Mark  
8 LaLande. Any discussion on that item?

9 DR. FISHBONE: Well it sounds like there  
10 were issues raised by the peer review that we submitted  
11 this year. There were some things raised by the peer  
12 review, which said they were not functioning as well as  
13 they might have, so I guess they're trying to improve  
14 that, by having Dr. LaLande as the sole principal.

15 MS. HORN: Do we have a motion?

16 DR. WALLACK: I move.

17 DR. FISHBONE: You move, I'll second.

18 MS. HORN: Any further discussion? All in  
19 favor?

20 VOICES: Aye.

21 MS. HORN: Opposed?

22 MS. DONOFRIO: The next item, number 13,  
23 Update on Funding of 2012 Assistance Agreements.

24 DR. FISHBONE: Can you explain what that

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1 means?

2 MS. HORN: Can you come up to the mike,  
3 please, and introduce yourself?

4 MS. PAULA WILSON: Hi. I'm Paula Wilson  
5 from Yale. I asked that this be put on the agenda,  
6 because the investigators are planning to start their new  
7 grants, and we wondered if we should plan on an October 1  
8 start date, or November 1 start date, and if it's at all  
9 possible, maybe the Committee could give us this in  
10 writing, so that we can start the grant process with the  
11 institutions, with setting up the account numbers, and  
12 getting things lined up, so we don't start out behind the  
13 eight ball when the grant kicks off.

14 DR. FISHBONE: Have they not received --  
15 they haven't received the money from the grants that we  
16 approved?

17 MS. WILSON: The notice of award said that  
18 it might be sometime in October. The institution will not  
19 accept that as a hard date to start the processing of the  
20 grant numbers.

21 DR. WALLACK: So, Joe, what date can we  
22 give them?

23 DR. LANDRY: I believe we still have some  
24 verification certification forms to be signed. The

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1 assistance agreements are partially prepared, though we  
2 haven't filled in the dollar amounts, as far as how they  
3 will be spread out over the years, so we have that work to  
4 do.

5 But if we're ready to proceed with these  
6 19, we could get that done within the month, and request  
7 the monies, and then get that probably accomplished I  
8 would imagine within September time frame without too much  
9 trouble, if everyone signs their agreements back.

10 DR. WALLACK: So would it be appropriate to  
11 say October 1st?

12 DR. LANDRY: I think that's probably a  
13 reasonable goal, yeah.

14 MS. HORN: Do you know, Paula, where the  
15 institutions stand, in terms of their ESCRO approvals and  
16 submission of verification forms?

17 MS. WILSON: Well I can speak for Yale.  
18 Yale is having the Committee -- the ESCRO is having their  
19 Committee meeting this week, so we have four more that  
20 need to be approved.

21 DR. WALLACK: So I'll move that we get the  
22 date out, as of -- that the date should be October 1st.

23 DR. FISHBONE: Does everybody have to wait  
24 for the four that need the ESCRO approval? Is that what

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1 you're stating? They all start at the same time?

2 MS. WILSON: Yes. We prefer that they all  
3 start at the same time.

4 DR. FISHBONE: And is October 1st  
5 acceptable?

6 MS. WILSON: Oh, it's quite acceptable.  
7 That would be wonderful.

8 MS. HORN: And can I just ask, in terms of  
9 the assistance agreements, have those gone out to the  
10 institutions for any review?

11 MS. DONOFRIO: No. We were still waiting  
12 for the verification and certification forms.

13 MS. HORN: I think the only change was that  
14 the reporting went back to an earlier version of the  
15 timing of the reports, which was more comfortable to the  
16 institutions and didn't matter to the Committee one way or  
17 another.

18 DR. LANDRY: Okay. I think we'd like to  
19 clarify on some of the installment payments. So we know  
20 like the \$200,000 grants are pretty straightforward, 100  
21 each of the first years for two years, but, on the other  
22 ones, do we typically, like, say, on the 750s, will we  
23 just be dividing those by three, 250 three years in a row?

24 I mean I guess we don't know, Sara and I,

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1 are some of these three-year or four-year terms, the ones  
2 that are not the 200,000? Is there a way to --

3 DR. WALLACK: They were all  
4 simulated(phonetic), I believe.

5 DR. LANDRY: Were they?

6 MS. HORN: Yeah. They should either be on  
7 the grants, applications, and check with the vote at the  
8 meeting, because, on a couple of them --

9 DR. WALLACK: It should be in the minutes  
10 of the June 11th meeting.

11 MS. HORN: For example, Chamberlain was cut  
12 back to a three-year grant from four.

13 MS. LEONARDI: And they have their new  
14 budgets that you approved, so that would drive the annual.

15 DR. LANDRY: Are we still waiting for the  
16 certification forms?

17 MS. HORN: No, we're all set.

18 DR. LANDRY: That's representing Yale, and  
19 need UConns, too, if you want to try to do as many of them  
20 together as possible.

21 DR. WALLACK: And that will work for you  
22 guys?

23 CHAIRPERSON MULLEN: See, what I would  
24 recommend is that, while you know you have every effort to

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1 do this as quickly as possible, that you will allow for  
2 all the people, who rely on you to get the money out, to  
3 also get you the information that's necessary, so you  
4 would be able to do it.

5 That's what makes a month give you the kind  
6 of leeway that might be necessary, rather than an October  
7 1st date, because for as much as can say, yes, we'll do  
8 it, we have to make sure that everything that comes back  
9 is actually acceptable.

10 That being said, I hear you, but I also  
11 understand that your to-do list just got longer along the  
12 way, and, in that regard, I also want to give you and us  
13 the flexibility to accommodate everyone, and then the back  
14 and forth, or the feeling of some delays that might  
15 actually be (papers on microphone).

16 DR. LANDRY: I wouldn't necessarily suspect  
17 that all 19 would get funded initially anyways. I think  
18 there will be some delays, and some assistance agreements  
19 won't be signed for whatever reasons, and parties might  
20 not be available.

21 MS. LEONARDI: I think what the  
22 Commissioner is saying is that we're driven by getting the  
23 information, for example, from you, and we want to make  
24 sure that if we get the information from you the end of

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1 September, we've committed to the October 1st date, so  
2 maybe it's 30 days after you provide us the information  
3 we'll provide the funding.

4 CHAIRPERSON MULLEN: And the request was  
5 that they prefer to have them all at once, so you might  
6 have 18 and still, on October 2nd, be saying to them it's  
7 not my fault, even though it's going to feel like it.

8 MS. LEONARDI: We can prepare a lot of the  
9 things ahead of time in anticipation of getting all of the  
10 different certifications.

11 CHAIRPERSON MULLEN: I mean I want to make  
12 this comfortable, because to say within a month, today is  
13 the 21st, and I'm thinking it's the 22nd, and then we have  
14 Labor Day. We have some holidays next month after Labor  
15 Day.

16 DR. FISHBONE: It sounds like we've done  
17 all we need to do, and we're waiting for the institutions  
18 to get back to us with the things that are needed, is that  
19 correct?

20 CHAIRPERSON MULLEN: Yes.

21 COURT REPORTER: One moment, please.

22 CHAIRPERSON MULLEN: Okay, so, I want to  
23 just be satisfied it's a comfortable time frame for you.

24 MS. LEONARDI: So when do you think that

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1 you would get all of the materials to us?

2 MS. WILSON: The only thing we want to  
3 avoid, and I'm sure UConn, well, I can probably speak for  
4 UConn, is that what happens is we say that we get the term  
5 starting on like October 1st, but we don't actually get  
6 the contracts delivered and through the institutions  
7 until, say, the middle of October, which means we're  
8 already starting two weeks out of the gate behind.

9 So if you feel November is a more  
10 comfortable date, I'm totally fine with that. It's just  
11 we're trying to avoid getting contracts that say they  
12 start on October 1 when we really don't have them signed  
13 off and in hand on October 1. That's all. I'm not  
14 pushing in any way. I'm just trying to get a feel for  
15 what date we should tell the PIs they should start  
16 working.

17 MS. LEONARDI: So the process is that we,  
18 once you give us the material, we complete the contracts,  
19 we send it to you, then you put it through your own  
20 process before your PIs start working, and that's  
21 typically a two-week?

22 MS. WILSON: Well it's different. It's  
23 different for each institution.

24 MS. LEONARDI: Just speak for yourself,

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1 like for Yale.

2 MS. WILSON: So, for Yale, we get the  
3 contracts, we have to get them signed by our institution,  
4 and we get them back to CI. CI has to sign them, and then  
5 I guess there's a period that they need to get the money  
6 to be able to send to the institution, so that varies and  
7 has in the past.

8 DR. LANDRY: I would say at least allow two  
9 weeks for each step, so maybe we are looking more like  
10 middle October or November 1st, if you want to be even  
11 safer for your internal information of what this is.

12 So your goal is to send it to us by the end  
13 of August, we'll do our assistance agreements and  
14 everything within September. By October, hopefully  
15 everything is in place. We can request the monies, and  
16 then maybe start the funding back by the end of October,  
17 which would satisfy November 1st for sure.

18 MS. WILSON: That would be fine, as long as  
19 --

20 DR. LANDRY: -- the scientists can start  
21 working on it. That's what you want. You want a start  
22 date for them, when they can start ordering supplies and  
23 things.

24 DR. WALLACK: Would it be appropriate to

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1 say that our goal, our aim would be to get them the  
2 information by October 15th, depending upon the receipt of  
3 the information that we need within a two-week period from  
4 today, or whatever date you want to set?

5 CHAIRPERSON MULLEN: I think it's fine to  
6 state a goal, but we also have to understand that the  
7 action steps aren't all in our control.

8 DR. WALLACK: Right. I understand.

9 CHAIRPERSON MULLEN: And stating a goal  
10 doesn't give them a firm start date, which is what they  
11 mostly need, so we can say we have a goal, but that's  
12 almost like saying your delivery is going to come between  
13 noon and 5:00.

14 DR. WALLACK: But the important trigger  
15 here is that we need to get the information from the  
16 institutions in order to implement our self.

17 CHAIRPERSON MULLEN: Yes, and I'm also  
18 appreciating that we have a team that's comprised of some  
19 new members that I also want to have everybody feel  
20 comfortable about all the steps along the way.

21 So you've stated that's the goal, and,  
22 given that, I would say, given that you want everybody to  
23 start at the same time, if we had a clear, a November 1st  
24 date, but everything was signed off on before October 1st,

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1 then, before November 1st, there's nothing wrong with that  
2 either.

3 I don't think people would sit and just  
4 wait until the last week of the month. And then we can  
5 have a performance measure to get it for next year.

6 DR. FISHBONE: And this is just for the new  
7 grants, right? People, who are in the second or three  
8 years, will get their money --

9 MS. HORN: Through this other process we've  
10 just gone through today.

11 CHAIRPERSON MULLEN: And if you think I'm  
12 being too cautious on everybody's behalf, just say so.

13 MS. LEONARDI: I don't know. I don't  
14 really know.

15 MS. HORN: There always does seem to be  
16 some kind of a snag along the way, but I think the  
17 institutions are pretty good at keeping in touch with CI,  
18 and that communication is fine to just see where things  
19 are, so you can update your folks.

20 We try to anticipate what we can, but every  
21 once in a while somebody says, well, I would like to have  
22 this four percent changed to a one percent, and that holds  
23 us up for a couple of weeks. That's what happened last  
24 year.

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1 DR. LANDRY: Last year, we funded about two  
2 and a half million November 1st time period, but most of  
3 those were prior year awardees. They weren't the new year  
4 awardees.

5 Most of the new year awardees got done in  
6 the batch of the four million that was done end of  
7 December and January 1st, actually, of 2012, so it  
8 actually took quite a while for the new awardees to  
9 finally get their first monies. That's the reality of  
10 what we do.

11 And then other two or three million was  
12 spent later on into the spring as certain time periods  
13 came up.

14 CHAIRPERSON MULLEN: So, based on that, are  
15 you comfortable with November 1st?

16 DR. LANDRY: November 1st beats last year,  
17 so that would be a good thing to do, right, trying to get  
18 better?

19 CHAIRPERSON MULLEN: And we'll work on a  
20 way to make sure that -- I mean if there are some glitches  
21 in the process, that we can sort of suggest some  
22 different, you know, different interactions.

23 DR. WALLACK: Since there's all the bases  
24 in here, can we communicate all of this to her, as well,

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1 for UConn?

2 DR. LANDRY: Sure.

3 MS. HORN: Anything further? Number 14 is  
4 the Grant Review Process Evaluation, and I think I'm going  
5 to ask Rick from CASE to kick this off with his peer  
6 review evaluation, and then we can move into the appeals  
7 that we got after the grant reviews.

8 MR. RICHARD STRAUSS: Okay. Rick Strauss,  
9 Connecticut Academy of Science and Engineering. So what  
10 is your pleasure, in terms of what you would like me to  
11 get into here?

12 This was distributed to the Committee. Do  
13 you just want to go over questions? Do you want me to do  
14 an overview of it for 32 pages?

15 MS. HORN: No. The Committee might want a  
16 little bit of detail, somewhere between a half a page and  
17 32 pages.

18 MR. STRAUSS: So, to start with, we did --  
19 there were three, actually, inputs into the review  
20 process. One was our staff, Attorney Clark and myself,  
21 and then we did two surveys.

22 The first was with our Peer Review  
23 Committee, so just to review, we have 15 members of the  
24 Peer Review Committee, and we have, let's see, 11 members

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1 responded, the Chair, three of the four co-Chairs, and  
2 seven peer reviewers.

3 Then we also surveyed the Stem Cell  
4 Research Advisory Committee to get their perspective, so  
5 out of the 11 members and member for survey, and that  
6 excluded Commissioner Mullen.

7 And from the Stem Cell Research Advisory  
8 Committee, seven members responded by the survey, with  
9 eight responding by e-mail, so we had a pretty good  
10 response, and the details of the responses to the survey  
11 are summarized with charts and all that information as  
12 backup.

13 So what we did was to come up with several  
14 areas of recommendations for next year. The first was  
15 peer reviewer orientation, and we thought we should  
16 strengthen the orientation that we provided to the peer  
17 reviewers either via a teleconference meeting, or  
18 additional backup information via, you know, written  
19 documentation.

20 So the first set of recommendations went  
21 over that, dealt with the purpose of the stem cell  
22 research program expectations for the peer review process,  
23 review of the types of grants to be funded and the funding  
24 priorities, review of the two-level review process, roles

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1 of the co-Chairs, the Chair and the reviewers, review  
2 timeline, and a review of the scoring process, based on  
3 NIH criteria of the supporting projects.

4 The next area dealt with peer reviewer  
5 proposal assignments, and we thought that it would be a  
6 good idea if we could focus the peer reviewer assignments  
7 into specific grant categories of the grant, so seed or  
8 established, instead of having a reviewer to both seed and  
9 established, so that might provide for more consistency in  
10 the scoring.

11 We thought it would be good for the peer  
12 reviewers to provide kind of like their areas of expertise  
13 in stem cell research, so the Chair, in making the  
14 assignments, might be able to better match up the  
15 reviewers with the proposals.

16 And, also, we thought that it would be a  
17 good idea if the RFP could require the principal  
18 investigators to identify the stem cell research area sub-  
19 field that's the focus of their proposal in a very brief  
20 statement, so that could be used by the Chair to, again,  
21 make better matching of assignments.

22 Then, in the critique and scoring process,  
23 you know, this was our first year doing it, and it may be  
24 similar every year. I'm not sure, but there appears to be

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1 a bunching of scores in the middle or in the certain area,  
2 and that may be driven, in part, by the NIH one to nine  
3 scoring scale, so, you know, one and a half or two and a  
4 half.

5 So what's happening is, you know, there  
6 were a bunch of proposals in those areas, so it made it  
7 difficult for the Advisory Committee to then make  
8 decisions about, well, which one had a higher scientific  
9 value or merit than another.

10 But what was interesting, in terms of  
11 comments from Advisory Committee members, at least once or  
12 twice, was while there may not be that much of a  
13 difference between a 1.5 and a two, because, you know,  
14 that's pretty close, but if you were to extrapolate that  
15 into a 90 or 100-point scale, you might be talking about,  
16 I'm making this up, because I don't have the exact number,  
17 but it might be like an 87 versus a 76. If you said 87  
18 versus 76, you might pick the 87.

19 So that was kind of like the background for  
20 what we thought we wanted to try to address. We thought  
21 that include in the screening process for new Peer Review  
22 Committee members (coughing) conducting reviews using the  
23 NIH criteria would be one idea.

24 We thought that we should do two primary

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1 reviews or two reviews, rather than a primary and a  
2 secondary review.

3 In effect, you're doing a primary and  
4 secondary review, but there's no waiting between the  
5 primary and secondary review, so that seems a little out  
6 of balance.

7 So they're all looking at it, two reviews,  
8 and they're equally balanced and rated.

9 MS. HORN: And they get paid the same.

10 MR. STRAUSS: And they get paid the same.

11 Okay and, then, insure that each reviewer provides  
12 information for all criterion requested in the review,  
13 including strengths and/or weaknesses or comments, as  
14 required. It's indicated on the scoring sheet.

15 So what we would do is to have the Chair  
16 and the co-Chairs assigned to each proposal, review each  
17 proposal for the scoring sheet to assure the reviews are  
18 complete with an acceptable summary of the justification  
19 of proposal score, at least in their meaning.

20 Now we didn't do that this year. What we  
21 did was to make, you know, if we got a no response on a  
22 sub-category, where nothing was provided, we would go back  
23 and say could you please provide a comment, or say you  
24 don't have any. At least fill in the blank. So I think

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1 that would help a bit.

2 And, then, in the reconciliation process,  
3 when reviewer scores or proposal have a difference of one  
4 point or greater, we would use the reconciliation process,  
5 so for proposals reconciled by the reviewers, the co-  
6 Chairs and the Chair assigned to the proposal would review  
7 the reconciliation provided by the two reviewers.

8 What they would do is to make sure that  
9 that statement provided adequate information, as to the  
10 reason for the reconciliation, and that's particularly  
11 important where the reconciliations, for reconciliation,  
12 where there was a difference of more than two points or  
13 more, because some of the comments were, you know, one  
14 reviewer had a two, and another reviewer rated it a nine,  
15 and they came together and divided the difference and  
16 whatever that average was.

17 It might have been difficult for the  
18 Advisory Committee to say, well, how did they get to that  
19 middle score, so the idea is that our co-Chairs and Chair,  
20 whoever is assigned to it, would make sure that they could  
21 understand it, and that final score was justified, based  
22 upon the statement that was provided. At least those are  
23 good goals to have.

24 So then we come into a situation, where for

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1 the proposals where the reviewers are unable to reconcile  
2 a proposal, what we did last year was to have the co-Chair  
3 assigned a proposal, essentially do the reconciliation by  
4 providing the next score that would, then, go to the study  
5 section.

6 What happened was we're looking at starting  
7 up the bio-med review process, and I was chatting with the  
8 Chair or our proposed Chair for that review team and  
9 mentioned the process that we used, and she made a really  
10 good point and said, well, I'm not sure that that's a good  
11 idea, because you just have another person giving their  
12 opinion on that, so what we did was to say, well, let's  
13 change that around, then, and let's have the co-Chairs and  
14 the Chair assigned to the proposal review those grant  
15 proposals, come up with questions, bring the questions to  
16 the study section, and the study section, the review team,  
17 the peer reviewers, would then, by consensus, come up with  
18 the score for the proposal, so it would receive a larger  
19 review to get that reconciled.

20 And that would a lot be driven by the co-  
21 Chair or the Chairs that would be assigned that, because  
22 they're going to try to figure out what the issues were.

23 As well, that if the reviewers cannot  
24 reconcile the proposal, then they would provide a

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1 statement, indicating why they could not reconcile the  
2 proposal. It would help drive the questioning.

3 So all of that would be helpful, I think,  
4 for the Advisory Committee to get an understanding about  
5 what the final score was.

6 DR. GENEL: Rick, are you saying that the  
7 meeting of the reviewers, the final, would only discuss  
8 those in which there was a difference, a wide difference  
9 of opinion?

10 MR. STRAUSS: No, no, no, but they would  
11 specifically be assigned to come up with a score for those  
12 proposals, where, in the other cases, they would be  
13 reviewing all the proposals, then could make adjustments  
14 in the final score of any proposal, but that seemed like a  
15 way to deal perhaps in a better way with those that could  
16 not be reconciled.

17 Okay, so, improve the study section review  
18 of proposals for final scoring strength and instructions  
19 in the peer reviewer process to emphasize the role of the  
20 Chair and co-Chairs, including the expectation that the  
21 Chairs and co-Chairs would review and develop questions  
22 for all proposals they are assigned and lead the  
23 discussion of such proposals during the study section to  
24 determine the final proposal scores.

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1                   And, then, finally, move to -- from the NIH  
2                   initial scoring methodology of one to nine to 10 to 90.  
3                   Now what NIH does, actually, once the proposals are scored  
4                   -- well, let's see.

5                   They move into a study section review, and  
6                   then each peer reviewer or person participating, whatever  
7                   they call that, in that review process scores the proposal  
8                   from one to nine.

9                   They, then, average it, and then they  
10                  multiply it by 10, so they get a score of 10 to 90. Now  
11                  we're doing it slightly different, but, in the final  
12                  review, or for, you know, we start with the one to nine,  
13                  but they would use 1.1, 1.2, and then we would multiply  
14                  it, and you would see scores 10 to 90, rather than one to  
15                  nine, so that's something to think about.

16                  It puts it in the 100-point scale that most  
17                  people are thinking about, instead of saying 1.5, then a  
18                  1.75, oh, they're pretty close, or a 1.5 and a two are  
19                  pretty close, so when the peer reviewers look at it and  
20                  they say 1.5/two, those are pretty close, so, you know,  
21                  they're both really good.

22                  It would maybe help you in at least having  
23                  more discrimination in the scoring, so that you can  
24                  separate the quality of the proposals.

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1 DR. GENEL: So you're really just  
2 amplifying the score, aren't you? I mean it's really not  
3 -- it's nothing different.

4 MR. STRAUSS: Well maybe, but, you know --

5 DR. GENEL: Like a loudspeaker.

6 MR. STRAUSS: Maybe, but the response was,  
7 you know, from the Committee comment, from this  
8 Committee's comments, there isn't really much difference  
9 between a 1.5 and a 2.

10 DR. DEES: This is Richard Dees. I  
11 actually think that's not going to help because that's not  
12 what the problem is, because (indiscernible) there isn't  
13 too much difference between a 1.5 and a 2 and saying it  
14 looks like more of a difference, because the difference  
15 between 15 and 20, no, it's not. They're still close.

16 The problem we're having with them is that  
17 the peer reviewers are coming through and saying, okay,  
18 look, you know, this really -- this grant has big flaws --  
19 we should just give it a six.

20 The problem is that they're trying to hedge  
21 too much, and what we want them to do is be more  
22 discriminating. I'm not sure that just saying, okay,  
23 scored on a 80-point scale is going to really help that  
24 any, because it just doesn't make that much difference.

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1                   What we need to do is get them to really be  
2 making consistent distinction, so we still have the  
3 problem that the reviewers have sort of different scales  
4 in their head, and whether they're using a 9-point scale  
5 or an 80-point scale doesn't really make any difference in  
6 that respect, so we need to have them be consistent, and  
7 then we're not going to have the problem that we were  
8 having.

9                   CHAIRPERSON MULLEN: Can I ask a question?  
10 I'm asking a question. I understand that something is not  
11 working for us. Should we feel any better if there's  
12 consistency between the reviewer scores and should we?

13                   I'm not asking anybody, except for maybe  
14 CASE. You know, you can do a statistical analysis and see  
15 whether or not the variation that we're observing and the  
16 reviews that we're getting is really beyond what we would  
17 expect.

18                   I understand it makes it difficult for us,  
19 and I'm not trying to make this a harder discussion, but,  
20 on the other hand, I would be concerned if there was too  
21 much similarity between the reviews that we get from each  
22 person, so I just want to put that out there, so that  
23 we're sure about everything that's making us uncomfortable  
24 about this. Yes?

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1 DR. HUGHES: Well, generally, we want to  
2 see intercoder reliability in sciences, because that would  
3 indicate that you're actually measuring what you think  
4 you're measuring, but I think the point that you're  
5 raising is that because there's so much variability in the  
6 grounds of which we might be judging the merits of these  
7 proposals that you wouldn't necessarily expect that kind  
8 of intercoder reliability.

9 CHAIRPERSON MULLEN: And I almost would  
10 want to have a subsequent discussion. That challenges us  
11 to see how consistent we can be in the way we discuss them  
12 after we get the scores, because I'm not sure that we are  
13 as consistent in the ways in which we look at the merits  
14 once we figure out the numerical exercise.

15 My role is to help challenge us to keep,  
16 you know, comprehensive excellent, more excellent process.

17 MR. STRAUSS: Well we brought up moving to  
18 the 10 to 90 scale, one, because of, you know, the  
19 observations, but, also, that the way in which NIH has  
20 their final scoring is on the 10 to 90 scale, not on the  
21 one to nine scale.

22 These are just some thoughts for you to  
23 think about, and there you go.

24 MS. LEONARDI: I just want to jump in. I

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1 agree with you, but one of the things, and I don't know if  
2 you said it when I was out, that struck me when I read  
3 some of the comments, was that some of the problems with  
4 the differentials in the scoring was that the peer  
5 reviewer didn't explain.

6 You come from a different place, and you  
7 could agree or disagree, but if you see just a  
8 differential in score, with no explanation, it's hard to  
9 reconcile it even in your head.

10 MR. STRAUSS: Right, and that's why what  
11 we're trying to do is to strengthen the process to make  
12 sure that there's a clear justification and a  
13 reconciliation that's reviewed by the co-Chair and Chair,  
14 specifically, keeping in mind that the question from the  
15 Stem Cell Research Advisory Committee is how did you come  
16 to the reconciliation? How did you come to agree on that  
17 score, and, for that matter, on all of the summary  
18 statements and the information, that it's clear and  
19 understandable and justifies the score that's been  
20 provided?

21 MS. LEONARDI: But I don't think you want  
22 to lose the original differential and opinion.

23 MR. STRAUSS: No, no. That's all in the  
24 records for the Committee to review and for the Peer

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1 Review Team to look at.

2 DR. GENEL: And part of it may also be, if  
3 somebody was a secondary reviewer, rather than a primary  
4 reviewer, they would not have necessarily gone into as  
5 much depth in their critique as the, quote, "primary  
6 reviewer."

7 MR. STRAUSS: Right, so, going to two  
8 reviews, as compared to what a primary and a secondary may  
9 help in itself.

10 DR. GENEL: Yeah.

11 MR. STRAUSS: So they're both on an equal  
12 footing.

13 DR. GENEL: Yeah.

14 DR. WALLACK: First of all, I think that it  
15 has to be noted that every year we have reassessed where  
16 we are, and we made improvements, and I think that we all  
17 agree that the end of the June session, thanks to, Rick,  
18 what you did and Terry did and CASE, that this was  
19 probably the best session that we've ever had.

20 However, having said that, as we've done in  
21 the past, we want to make it even better, so I had some  
22 other observations as I read through this.

23 One of the things that jumped out at me was  
24 that there seemed to be a cry for greater conversation

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1 between the reviewers, and I can understand that, because  
2 I think it came through to us, if there's an area of  
3 improvement, that we needed to have more narrative about  
4 where each of the reviewers were coming from.

5 And I think it was just said, specifically,  
6 because there was differential between reviewer one and  
7 reviewer two.

8 MR. STRAUSS: Right.

9 DR. WALLACK: And reviewer two often times  
10 would not give enough information, at least to make me  
11 feel very comfortable. I could have felt more comfortable  
12 with it.

13 Having said that, one of the other things  
14 that I think jumped out at me was that there was an issue  
15 having to do with the reconciliation process, itself, and  
16 I'm wondering if we had three, and this was somewhat  
17 touched upon in your presentation, if we had three  
18 reviewers, each of whom would be primary reviewers, and  
19 when they had the study session, they would be able to  
20 work through, at that particular time, all the issues  
21 that, when we get it in June, or whenever we would get it  
22 in May ahead of the June meeting, so I would think that  
23 maybe we ought to discuss moving away from the  
24 reconciliation model, although you can put certain --

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1 certain aspects of it you can hold in abeyance for now and  
2 try to see if we can, if we have three reviewers on each  
3 grant, and have them as primaries, like I said, and have  
4 them each go through a study session on them, greater  
5 conversation, if you will.

6 This, then, would require, and I think I  
7 sort of sensed this when one reviewer talked about having  
8 to look at 16 applications, perhaps we have to look at  
9 increasing the number of reviewers, in order to  
10 accommodate if we agree to go to three reviewers for each  
11 grant and improve narrative, so that would be something  
12 that I would like to put on the table for conversation.

13 One other thing. On the recusing of one's  
14 self, I think that came up.

15 MR. STRAUSS: We didn't get to that yet.

16 DR. WALLACK: Okay. Okay. I don't  
17 personally see any issue with the individuals being in the  
18 room, but I definitely feel that they should not, whether  
19 they vote or not vote, they should not be able to comment  
20 on the particular grant that we're talking about.

21 I don't think they have to walk out of the  
22 room, but I think that I would rather they be silent on  
23 that particular grant if they were not allowed to vote on  
24 the grant.

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1 MS. HORN: They should not be participating  
2 in the discussion of that grant at all.

3 DR. WALLACK: Right.

4 MS. HORN: And I think the issue is, having  
5 them at the table, sometimes the discussion moves away  
6 from the particular grant, gets into some generic issues,  
7 they start to talk on those, and then it comes back to the  
8 specific, and then they have to remember to not comment,  
9 so having them removed is just one way of making sure --

10 DR. WALLACK: It makes it more certain.  
11 You're absolutely right, Marianne.

12 MR. STRAUSS: I mean if you have a member  
13 of the Advisory Committee, whose grant is being discussed,  
14 they shouldn't be in the room.

15 DR. WALLACK: I agree with that. Right.

16 MR. STRAUSS: What we were saying is that  
17 if someone on the Committee is recusing themselves from  
18 the discussion, there's a need for them to get up and  
19 remove themselves from the table for a couple of purposes,  
20 one, there's an audience, and the audience isn't  
21 necessarily familiar with who is who around the table, so  
22 that's an important part.

23 Secondly, there's two or more types of  
24 communication. One is the verbal type, and the other is

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1 the non-verbal type and signaling that some people on the  
2 Committee may see, and then they may be impacted in their  
3 decision making.

4 DR. WALLACK: Rick, I wouldn't go to the  
5 mat on that last, on this last item, because I think you  
6 see the intent of what I'm striving at, but the first part  
7 of what I tried --

8 MR. STRAUSS: Let me -- we actually have --  
9 so if you got rid of the secondary and you went to two  
10 reviewers, that would be a big change.

11 DR. WALLACK: Or three.

12 MR. STRAUSS: Well let me address the three  
13 piece. So, one, your legislators were mandated by law a  
14 maximum number of reviewers, but what we do have is this  
15 co-Chair system with the Chair, so there are other people  
16 that are familiarizing themselves with the grant.

17 Now we want to do a better job in having  
18 the co-Chairs and the Chair engaged in this review  
19 process, and the idea of focusing the co-Chairs on  
20 specific grant types, as compared to having them spread  
21 out with both seed and established, so then you would have  
22 -- and, you know, a lot would depend upon the number of  
23 grants that came in in each category, as to how many co-  
24 Chairs were actually assigned to that category, and you'd

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1 use the Chair as part of that co-Chair/Chair team.

2           So like for the seed, you might have three  
3 of the five, and those three co-Chairs would familiarize  
4 themselves with all of the proposals and questions for the  
5 reviewers, and that would really play into the discussion  
6 and the final proposal ranking.

7           Now, in the bio-medical review process, you  
8 know, a lot depends on players and who the Chair is. We  
9 have a great Chairperson, and she really directs the  
10 discussion and knows the proposals, along with, you know,  
11 hopefully, the co-Chair or co-Chairs that we have in that  
12 process.

13           As a result of that, there is a shifting,  
14 you know, based upon the discussion in that study section  
15 meeting of the final rankings, and the idea is, if we  
16 didn't have any changes in the last process, which, you  
17 know, happened, in my view, it would have been better if  
18 there were some re-rankings there, because that would have  
19 shown, you know, the level of deliberations that the  
20 scoring wasn't exact, and there were some differences that  
21 were resolved at that level, so that's what we're really  
22 shooting for, but if there are any changes at that level,  
23 then there's also a statement, as to why that score was  
24 adjusted, so, again, you would see that whole thing.

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1                   So I'd say, you know, let's see how it  
2 works going to the two reviewers, full reviewers, instead  
3 of reviewer and secondary. That may solve a lot of the  
4 problem, and then focusing our, you know, our second level  
5 review team on, again, you know, trying to get them  
6 working on the different categories more closely than just  
7 having their work randomly spread out among the  
8 categories, so that will, I think, drive us to maybe where  
9 you want to go and take a look at how that works.

10                   There very well could be, you know, on the  
11 co-Chair thing, we would break up the, let's say, the  
12 seed. Let's say there's two, so they'd each have half,  
13 but those -- where they would be responsible for half of  
14 the proposals, but they would familiarize themselves with  
15 all of them.

16                   DR. WALLACK: I don't usually have a  
17 problem with incremental adjustments, so that, certainly,  
18 to have two primaries, each of whom understood that  
19 they're primaries and responded to us in a clearer, more  
20 descriptive idea of why they're doing what they're doing  
21 would certainly be, I think, a further improvement, and  
22 we've already made improvements.

23                   I think that we may be back here a year  
24 from now, hopefully not, looking at the idea of maybe we

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1 should readjust it, but that's a year away.

2 MR. STRAUSS: Well this your all decision.

3 DR. WALLACK: Right, so, certainly, the  
4 idea of primaries is essential. In the same regard, I  
5 think what, and you already said it in your first remark,  
6 orientation, and I'll just stress one part of orientation,  
7 and that is that there are certain reviewers, who feel  
8 that a ranking of two, or 2.5 is very good, others, who  
9 feel that only a ranking of, if it's very good, they may  
10 want to give it a 1.5, so that there's some  
11 inconsistencies that hopefully we can get, by better  
12 orientation, the reviewers to be more consistent, more  
13 consistent on how they're grading the various application.

14 I think that's an important thing, and I  
15 know you already mentioned orientation, and I hope that's  
16 what you meant, but I just wanted, if you did mean it,  
17 really stress that part of it very, very, very strongly.

18 MR. STRAUSS: Well, you know, I don't know  
19 whether you're going to be able to solve that problem, but  
20 the idea of the two-level review and the co-Chairs asking  
21 questions, and having a couple of people that are familiar  
22 with the whole sub-set, or that category I think helps to  
23 build at least the opportunity for perhaps more  
24 consistency in the scoring.

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1                   In the bio-med process, up until this year,  
2                   and I think it's changing this year, the peer reviewers  
3                   have served on a pro bono basis, so we were limited in the  
4                   number of reviews that we could ask them to do, so we had  
5                   like 20 for, you know, something like 17 or 18 proposals  
6                   or whatever.

7                   You really want to try to avoid that,  
8                   because now you have many more people, so it's almost  
9                   better to see how can you structure the thing with the  
10                  right number of reviewers to limit, and limit the number  
11                  of reviewers that are working in any one category, so that  
12                  you can try to at least have some consistency within the  
13                  category, and then use the two-level process with really  
14                  hopefully, and maybe this is too strong, address  
15                  familiarity by the co-Chairs and those at kind of like the  
16                  oversight level to help to drive towards, you know, the  
17                  final scoring. It's an imperfect science.

18                  DR. FISHBONE: Are we limited to 16 members  
19                  by legislation?

20                  MS. LEONARDI: Fifteen.

21                  DR. FISHBONE: Fifteen by legislation?

22                  MS. LEONARDI: Correct.

23                  DR. FISHBONE: That would not preclude  
24                  reaching out to somebody on an ad hoc basis, would it?

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1 MS. HORN: Well we've looked at that when  
2 we've had very specific grants. I'm not sure that's ever  
3 happened officially, that the peer reviewers have used ad  
4 hoc.

5 I think they've perhaps had people at their  
6 labs, where, if they needed a little expertise, they had  
7 them weigh in, but they were the official reviewer, so we  
8 haven't ever set up an ad hoc. I think it would be okay,  
9 but we haven't checked all of that out.

10 DR. GENEL: Well, I mean, one of the issues  
11 that comes up is whether or not the members of the Peer  
12 Review Committee have all of the expertise needed on all  
13 of the various proposals.

14 In a situation like that, I don't know any  
15 reason why you couldn't reach out for an ad hoc reviewer.

16 MR. STRAUSS: What's interesting is that  
17 all of the peer reviewers have expertise in the field of  
18 stem cell research, and, if you think about it, and I'm  
19 making this up, I don't know whether it's true or not, but  
20 let's say in this sub-field you had 10 proposals, and  
21 you've got these two great stem cell researchers that are  
22 in that area and have great expertise in that area and say  
23 those are the people we're going to assign to those 10  
24 proposals.

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1 Well, you know, that's their field, and  
2 that's their area of expertise, and they may rank those  
3 proposals pretty high, whereas that may be inconsistent  
4 with having a cross-section of people reviewing.

5 DR. GENEL: It's not a perfect science.

6 MR. STRAUSS: So the idea is to kind of do  
7 this triage. The real step is get rid of the secondary  
8 reviewer, have two reviewers, and then do a triage with  
9 the co-Chairs to make sure they're actively engaged in  
10 asking questions to assure that we have the most accurate  
11 score for that program and it's as consistent as possible  
12 with the other proposals in that category.

13 DR. WALLACK: I can see that happening  
14 fairly well, because it sort of does speak to my thought  
15 of three reviewers, because he's got the co-Chair there  
16 anyway, so I have no problem with that.

17 MS. HORN: If I could, I had a couple of  
18 people send responses in. Diane Krauss was one, and I  
19 think most of her points have been already covered here,  
20 and David Goldhamer.

21 And one of the points that I don't think we  
22 have covered of his was incorporating a triage system,  
23 where the bottom 50 percent are not discussed to insure  
24 adequate discussion of the competitive grants.

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1                   So I think he's talking about for those  
2 grants that are scored six to the nine, and it's  
3 consistent when both reviewers are saying this is a core  
4 grant, and it's not likely to get funded.

5                   They've had their two reviews, and that  
6 they don't necessarily have to go anywhere else, that they  
7 have a six and a nine. You reconcile, but it's still not  
8 going to get funded, so maybe weighting those less and not  
9 spending a long time on those, similar the way that we do  
10 with the Advisory Committee, where we don't spend time on  
11 grants that are --

12                   MR. STRAUSS: That's probably a pretty good  
13 point, however, you know, we don't have 5,000 proposals.  
14 We have like 99 and 100, or 50, or 30 in a group.

15                   So, in the peer review process, I wouldn't  
16 put anything in place to restrict the Peer Review Team  
17 from discussing any project that they think should be --  
18 they should have the opportunity to discuss anything,  
19 regardless of the ranking, through the study section.

20                   Now, in practice, most likely that won't  
21 happen, but there may be one of the 15 reviewers that  
22 says, you know, this got rated a nine, and you guys missed  
23 the point here, and this really -- would we really miss  
24 that this is so innovative it should be a one.

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1 COURT REPORTER: One moment, please.

2 DR. GENEL: We've operated that way in the  
3 Advisory Committee, and I would expect the Peer Review  
4 Committee to. Have you discussed any of this with Stein?

5 MR. STRAUSS: I think, when we did our  
6 initial report, we sent it out to the Peer Review  
7 Committee for their review or information, so they're  
8 aware of all of this.

9 In the last week, based on -- we met with  
10 Claire and Marianne last week, so there were some  
11 modifications in this, so the final version has not gone  
12 out, and we actually have a couple of minor things.

13 DR. GENEL: My point was has the Chair  
14 given you any comments on any of this at all?

15 MR. STRAUSS: No, other than, you know, we  
16 did go out and ask the Committee members for their  
17 comments, and we got their comments from the survey.

18 DR. GENEL: But you have a number of  
19 recommendations.

20 MR. STRAUSS: Yeah. We didn't go over them  
21 in detail with anybody on the Peer Review Committee.

22 DR. GENEL: Okay.

23 DR. FISHBONE: I think most of the  
24 reviewers were relatively comparable, in terms of the two

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1 reviewers. There were some that were markedly  
2 outstanding. The one that's giving us all the heebie  
3 jeebies is when one guy gave a nine, and the other one  
4 gave a one, and it was reconciled to be a six.

5 MR. STRAUSS: Well I'm not exactly sure  
6 about that one, but I think that that was not reconciled,  
7 and the co-Chair provided the score that was then used and  
8 became the final score, so the co-Chair reviewed the  
9 reviews, and then made a decision about what the score  
10 would be.

11 DR. FISHBONE: Right, but the revision just  
12 put it in the non-fundable category.

13 MR. STRAUSS: Well, correct.

14 DR. FISHBONE: Most of the issues I think  
15 were relatively minor. Just dealing with something we  
16 have such a gross difference is very difficult in how you  
17 handle that.

18 MR. STRAUSS: Well that's why we wanted to  
19 put in place -- this year, if the proposals could not be  
20 reconciled, it went to the co-Chair. We didn't ask them  
21 to make a specific statement, as to identify the reasons  
22 why you were unable to reconcile.

23 Their initial summary statements and, you  
24 know, score, justification of the score was provided for

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1 each of those reviews, so this year what we want to do is  
2 to have, if they're unable to reconcile, they need to  
3 provide a statement, saying why they were unable to  
4 reconcile, so that will provide further guidance for the  
5 co-Chair review, and then the discussion among the peer  
6 reviewers at the study section for the ranking of the  
7 proposal, so I think that would help address the scoring  
8 disparity issue.

9 I mean I think there were some other issues  
10 with that proposal. There was a lot of discussion on it  
11 among the co-Chair with the reviewer, one of the reviewers  
12 in question, and then the Chair, so there was a lot of  
13 activity on that particular proposal.

14 Did Diane have other things, or was that --

15 MS. HORN: I think we covered them. What  
16 I'll do is attach these. I'll ask Sara to attach these to  
17 the minutes, so that they're part of the record, but I  
18 think we've covered the comments that were made, and Ron  
19 Hart had a comment on the appeal process, so we'll get  
20 into that.

21 DR. FISHBONE: David had several.

22 MS. HORN: Yes. I think we covered most of  
23 them.

24 DR. GENEL: David's major suggestion was

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1 that you actually have a formal study section review  
2 process, rather than an individual reconciliation process.

3 MR. STRAUSS: Well we do have a formal  
4 study section process, and there was an opportunity to  
5 revise the scores. The Committee just didn't use the  
6 opportunity to revise the scores this year.

7 DR. GENEL: One of the reviewers commented  
8 that he was prepared to spend five hours on the conference  
9 call and it lasted an hour.

10 MR. STRAUSS: Well let me put it this way.  
11 This one lasted an hour. It might be the longest one ever  
12 in the six or seven years that they've had (telephone  
13 interruption) sections.

14 DR. GENEL: That may very well be, yeah.

15 MR. STRAUSS: So there may have been -- and  
16 there are reviewers that had participated. In other  
17 words, we had some new people to the process this year,  
18 but there also were a number of carryover people, so they  
19 may have been used to the fact that there was a 10-minute  
20 session instead of a five-hour session, so whatever.

21 That's one of the goals for this year, is  
22 to really make sure that there's a discussion on the  
23 proposals using as much, you know, persuasion as possible  
24 to say we've really got to review those.

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1                   And there will be some proposals that will  
2 not be reconciled, so there will have to be discussion  
3 during the study section.

4                   DR. GENEL: If I may editorialize? I think  
5 this is, by all means, the most transparent process that  
6 we've had in seven years. This is the first time we've  
7 actually even sat here and discussed the peer review  
8 process, if I recall.

9                   DR. FISHBONE: But we never knew what the  
10 process was.

11                  DR. GENEL: Well, right. So, I mean, as I  
12 said, this is the first time we've actually had any kind  
13 of a discussion regarding how the peer review was managed.

14                  The second is that, you know, we have a  
15 limited amount of funds available, so there's always going  
16 to be -- it's always going to be tough at the margins to  
17 discriminate between those that are above and those that  
18 are below the line.

19                  And somebody once said that the peer review  
20 is an imperfect process, but it's the best one we have.

21                  DR. FISHBONE: Could I ask? You try to  
22 assign them according to the expertise of the reviewers?

23                  MR. STRAUSS: Well let me --

24                  DR. FISHBONE: You touched on this before.

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1 MR. STRAUSS: Well we do not assign the  
2 peer reviewers to the proposals. It's the responsibility  
3 of the Chair, so the Chair uses a process to say this  
4 reviewer is going to review this proposal, and this  
5 reviewer will review this one, this one is a secondary, or  
6 a primary reviewer, so that's how it works.

7 That's what I know about how the Chair  
8 assigned the proposals.

9 DR. FISHBONE: Presumably, that's based on  
10 the --

11 MR. STRAUSS: I have no presumptions on how  
12 he did it. I don't know. I mean he knows many of the  
13 peer reviewers, because that's his field, and some of the  
14 people were, you know, that he's familiar with at the  
15 different universities, so, you know, that probably helped  
16 in making the decisions, but I can't tell you how he went  
17 through that decision process.

18 MS. LEONARDI: Is there a review process on  
19 whether the peer reviewers have done a good job at the end  
20 of the cycle, to say, you know, some did a really good  
21 job, some didn't? Do we want to go back and --

22 MR. STRAUSS: Right. We had some -- you  
23 know, sometimes, administratively, there may be reviewers  
24 or individuals you're dealing with that are very difficult

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1 to deal with, and they may be the best reviewers, so one  
2 is on the administrative side, and then there's the  
3 quality of the reviews, and I think, you know, what we  
4 want to do we have the 15 reviewers. I don't think  
5 there's anyone that we have that we would say we wouldn't  
6 suggest be invited back, but I think we need to put these  
7 steps in place to assure that the reviewers are producing  
8 the type of quality in their reviews that we expect, and I  
9 think, you know, some of the mechanisms that, if we do it,  
10 that we're suggesting will help to do that, assuming, you  
11 know, the leaders, the co-Chairs and the Chair actually,  
12 you know, play a significant role in making sure that the  
13 statements provided, you know, are acceptable and do  
14 reflect the proper justifications of the scores that are  
15 being given.

16 MS. HORN: So what else do you need?

17 MR. STRAUSS: In the request for proposal  
18 category of the recommendations, two of the comments were  
19 based upon, or two of the suggestions were based upon  
20 comments at the Advisory Committee, Edie(phonetic), when  
21 you were reviewing the grants.

22 One was that if a proposer has another  
23 grant under the Stem Cell Research Program, that that  
24 should be identified in the proposal, and the other one

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1 was that if a proposer has submitted more than one grant  
2 in the current process, then the Committee should be aware  
3 of that.

4 I'm not sure that has any standing in the  
5 peer review process, but for the purpose of the Advisory  
6 Committee, you may want to know that. We just put it in,  
7 because those were comments that you made that we thought  
8 you at least would want to consider.

9 The last comment in that category is that  
10 if there's any proprietary information in her proposal,  
11 then that information is not publicly released.

12 The problem is that the proposers in some  
13 cases didn't clearly identify the information that was  
14 proprietary, so that all has to be redacted, so what we're  
15 saying is that if it's proprietary, it's got to be  
16 highlighted in yellow, and then we know what's proprietary  
17 and what's not proprietary, and then that's redacted from  
18 what is made publicly available through CI.

19 We went over the fifth item, the last item,  
20 at least I think it's the last item, on the  
21 recommendations that were the Stem Cell Research Advisory  
22 Committee process, so we dealt with the recusing piece.

23 We thought that it would be good for all  
24 Stem Cell Research Advisory Committee members to have

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1 access to all the proposals as soon as possible, as soon  
2 as they become available online, and that, in some way,  
3 the members should, then, be required to notify CI of any  
4 conflict, so that before the assignments are made for  
5 review, all those conflicts are taken care of, and they  
6 don't have to start reassigning proposals.

7 And, then, with whatever system we use for  
8 your accessing the peer review documents, that the members  
9 should immediately check to see whether their computer  
10 systems work, so that we can take remedial steps to get  
11 the information out in a timely manner, so that, you know,  
12 you have enough time to do the review, and we have enough  
13 time to get it to you in the format that you can use it.

14 This was the first time we tried the method  
15 that we tried, and, in many cases, it worked out okay,  
16 but, you know, we also learned that if you have a Mac, you  
17 can't view an embedded PDF, so that was an issue, so,  
18 anyway, it worked out, but that's it.

19 DR. FISHBONE: I just want to complement  
20 you on an excellent review and series of recommendations.  
21 It seems like it was a tremendous amount of work to put  
22 all this together.

23 MR. STRAUSS: It was some work, but, you  
24 know.

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1 DR. FISHBONE: It's the first time we've  
2 ever had anything like this, that, you know, you spoke to  
3 all of the reviewers, and got their feelings about what  
4 was happening, and I think it's been extremely helpful.

5 MR. STRAUSS: There's one other suggestion  
6 that's not in here, but it's based upon the discussion of  
7 the meeting, regarding the post-decision-making process.

8 I think you ought to do the same thing for  
9 the award process in getting the people under contract. I  
10 think you need to set a goal much quicker than five months  
11 to get people under contract to get this work underway.

12 DR. FISHBONE: That's a good point.

13 MR. STRAUSS: I mean I don't know really  
14 how long it takes, or what the deal is, but, you know, is  
15 two months enough time? Is there any way to get  
16 information out to the, you know, whatever has to be  
17 signed?

18 I mean if these researchers want the  
19 \$200,000, can't they be given a two-week period to get the  
20 documentation in? They all know when you're making the  
21 decision. They all know when the grant award information  
22 is going out, and the University should want the 10  
23 million dollars, so, you know, do it or lose it.

24 MS. HORN: Some of it, I think, is an ESCRO

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1 review.

2 MR. STRAUSS: Well whatever it is. I don't  
3 know how long any of that stuff takes place. If you think  
4 that there's a way to facilitate that in some way to  
5 shorten it from five months.

6 DR. WALLACK: So I know that you didn't  
7 speak to Dr. Stein about the funneling to certain  
8 expertise, or we didn't make that suggestion. I have a  
9 sense that he tried to do that, actually, but perhaps it  
10 wouldn't -- perhaps it would help if we specify our  
11 recommendation, that he try to do that even more so.

12 I don't know how you would want to handle  
13 that, if you would want to handle it at all.

14 MR. STRAUSS: Well we handled it, in part,  
15 by suggesting that the proposers identify their sub-field  
16 in stem cell research, and that our peer reviewers also do  
17 that with, you know, some form of a checklist for the  
18 Chair to use for that, and, secondly, by having the peer  
19 reviewers be focused on, you know, one of the grant  
20 categories, so we're not, to the extent possible,  
21 spreading them out.

22 DR. WALLACK: No, I heard that before. I  
23 would only add to that that if we can be even more  
24 specific with that checklist and so forth utilizing that

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1 checklist a little bit more so.

2 He may already be doing it, so I think this  
3 is a very, very general reminder kind of thing. Do we and  
4 is it important to review, as part of the orientation,  
5 what our evolving goals are as a Committee?

6 What I mean by that is that, when we  
7 started six years ago, we talked about funding best basic  
8 science, and we've seen two changes now, and one into the  
9 translational area, and then disease-directed, so,  
10 certainly, I would think that the idea of that we, as we  
11 represent the state's interests, are thinking more in  
12 terms of translational.

13 I don't know if that's important for them  
14 to know or not, but it's a thought that I wanted to put on  
15 the table.

16 MR. STRAUSS: Well we, in the first item of  
17 what we said for orientation, was the purpose of  
18 Connecticut Stem Cell Research Program, so that probably  
19 should come from whatever that statement is that should be  
20 used for the Peer Review Committee consideration should be  
21 provided by the Committee.

22 DR. WALLACK: And that can be the modified  
23 RFP, because we modified it on April 17th anyway.

24 DR. GENEL: I don't really think we -- it's

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1 our job to tell or it's appropriate to tell peer reviewers  
2 what the goals of the program are. We're asking them to  
3 judge the science. It's our job to determine those  
4 priorities.

5 MS. LEONARDI: But the question I have,  
6 just to push back on that, is if you have a specific focus  
7 that you want the fund to be after, you could have the  
8 greatest proposal that doesn't address the focus, and if  
9 the peer reviewer isn't looking at it in the context of  
10 this is what the program wants this year, it could be  
11 rated a one and be the greatest science and shouldn't be  
12 funded, just because it doesn't fit, so it's a matter of  
13 (multiple conversations).

14 DR. GENEL: Well, no, but I think that's  
15 the job of the Advisory Committee.

16 CHAIRPERSON MULLEN: Can I say that's the  
17 purpose of the secondary review. I just want to point out  
18 to people that we can go over this for a long time, and  
19 some of the recommendations that might be coming out now  
20 perhaps should be tabled for discussions about the future  
21 of the program.

22 I appreciate so much what you've provided.  
23 I'm going to reiterate that, at the same time that we've  
24 gotten you to review for us the more I'll say quantitative

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1 elements of the review process, there's probably still  
2 some other work this body can do around the qualitative  
3 part that we provide in our review in our meeting, and  
4 discussions, such as the purpose, is a part of that,  
5 because once we get this other piece, as perfect as it can  
6 be, until we criticize it again for the next year, I think  
7 we also have to continue to hold ourselves to a process  
8 that people can feel good about, so that they don't keep  
9 coming back to us, saying I still have a problem with what  
10 happened.

11                   There's a lot that I didn't say in that,  
12 but if we're going to keep striving for excellence and  
13 figure out the future and where this work goes, because  
14 we're also talking about perhaps ask for people that  
15 exceed the resources that we have for, you know, what we  
16 want to be doing, so there are probably some other  
17 thoughts we have to have along the way about the overall  
18 future, as we look at what's happening in these last few  
19 years.

20                   But I just wanted to say that, because I  
21 also know that we've had you sitting up here presenting  
22 for a while, and we could have a very ongoing conversation  
23 about all of this.

24                   MR. STRAUSS: Okay.

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1 CHAIRPERSON MULLEN: But you're welcome to  
2 stay there if you want.

3 MR. STRAUSS: Well I'm going to go back.

4 MS. HORN: The second part of this  
5 discussion was in follow-up to the meeting that we had in  
6 June. There were three comments, appeal requests, if I  
7 may categorize them that way, that came forward, so I  
8 wanted to have a brief discussion.

9 I think my goal would be to have an ad hoc  
10 group. We've had small committees before take a look at  
11 this kind of issue and come back to the Committee with a  
12 recommendation on the appeal process, on an appeal process  
13 in specific situations, and, if so, how, and not take up a  
14 lot of time with the Committee today, but certainly got a  
15 flavor for two of the complaints were about either things  
16 that were discussed at the Advisory Committee that were  
17 either wrong, or had relevance to the grant, that the  
18 grants, some of them, were more poorly scored than the  
19 ones that did not get funded, and there was some concern  
20 about that.

21 One of the reviewers, who commented, said,  
22 well, we really don't make our decision. The Advisory  
23 Committee decision is based solely on the scientific  
24 merit, and I think that's sometimes something that gets

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1 lost for the people sitting, listening to the grants being  
2 reviewed, that there is a whole overlay that the Advisory  
3 Committee weighs in on, but I think that, looking at our  
4 Advisory Committee process, those are some things that we  
5 can look at and talk about more thoroughly.

6           The other one -- so those were two of the  
7 reviews. We invited the reviewers to come today and be  
8 part of public comment, but I don't see them here.

9           Another one had really to do, and this is  
10 one you referred to earlier, Dr. Fishbone, was a review  
11 that appeared to be a research misconduct issue, and, so,  
12 we looked at the federal process and referred that over to  
13 the institution to deal with it.

14           It was scored very poorly by one peer  
15 reviewer, based on that research was going to end, scored  
16 quite highly by another one.

17           It was scored a third time independently by  
18 a peer reviewer and scored a six and did not get funded,  
19 so there was some back and forth, and the institution did  
20 not think that there was any research misconduct.

21           We took it back to the peer review. They  
22 agreed -- they did not agree that there was no misconduct,  
23 if that's not too many negatives. They felt that there  
24 was, because of another grant that had not been cited,

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1 that was very similar to this proposal, that there was,  
2 indeed, an issue, so there we were, so I propose that it  
3 go to the Advisory Committee for two scientific members to  
4 have an independent review, and then I realized that was  
5 not anything that the Advisory Committee had signed off  
6 on.

7 We really didn't have a process for this  
8 kind of an appeal, went back to the institution, said, I'm  
9 sorry, it has to go through the regular process, and  
10 probably got things all stirred up by proposing something  
11 and then having to bring it back, but it did highlight the  
12 fact that we really don't have any kind of an appeal  
13 process for something like that, where, you know, you've  
14 got two pieces disagreeing with one another, and probably  
15 a very good grant stuck in the middle of that and nowhere  
16 to go.

17 So, I think, if we could have a small ad  
18 hoc group of people, who have had research experience, who  
19 are interested in working on this, and CI and I can  
20 facilitate this, and maybe Rick or Terri might have a  
21 little time to help us out with it, and just have a  
22 meeting or two to look at what kind of a process would we  
23 want to have in place, if any.

24 Most of the comments that I got on the

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1 appeal process, per se, is basically come back next year  
2 and do your grant. There really is no appeal process, but  
3 do we want to have something for this rare occasion, where  
4 there truly is a problem with a peer review that we can't  
5 resolve with the peer review. I can't even think of other  
6 facts that might fit in. Is that acceptable to the  
7 Committee?

8 DR. WALLACK: Yeah. I just want to reflect  
9 on one or two things, and that is that it's clear that  
10 there cannot be a formal after-the-fact appeals process.  
11 I can't imagine how that could happen, because we have  
12 distributed the dollars, and I don't have to say any more  
13 about that.

14 As far as any kind of concern for going  
15 forward, certainly, there are exceptions upfront, I think,  
16 and, certainly, professional misconduct is that kind of an  
17 example.

18 My only thought about that is that where  
19 there's an issue of professional misconduct that it should  
20 be resolved in the peer review process, in the peer review  
21 process, and that whatever that outcome is, that's the  
22 appeal.

23 The appeal goes to that process, and it  
24 doesn't come to the Advisory Committee, so that would be,

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1 you know, my thought.

2                   Lastly, I have to say that I am really  
3 very, very proud, very proud to be part of a process that,  
4 and I think Mike said it, that is as open and transparent  
5 as it is, and we must have in the process already have  
6 reviewed 500 applications for grants.

7                   If we've had a handful of concern  
8 expressed, that's a lot, so I think that -- and I think  
9 David identified this, if there's no problem, don't -- to  
10 fix a problem, it's not a problem, and I would be in  
11 agreement with that.

12                   And I think we have to keep in mind the  
13 fact that we're doing a pretty darn good job. We always,  
14 as the Commissioner said, should be doing better. We  
15 intend to do better. That's why we have these  
16 conversations every year.

17                   But, certainly, if there's an issue of  
18 appeal, it should be in a restricted area. Professional  
19 misconduct is one. It gets taken care of early, not  
20 later.

21                   MS. HORN: He's back.

22                   MR. STRAUSS: I'm back. Sorry. Rick  
23 Strauss.

24                   MS. HORN: Thirty seconds.

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1 MR. STRAUSS: Yeah, 30 seconds. Well,  
2 first of all, it would be good to call this research  
3 integrity, as compared to professional misconduct, so  
4 think about it in those terms.

5 In that particular case, I'm not really  
6 sure that that's a peer review issue. It may be an issue  
7 that comes up as a result of the peer review process, but  
8 it can become an issue, because the peer review results  
9 become public.

10 And NIH has an Office of Research  
11 Integrity, and they have a whole system for dealing with  
12 an issue that may involve research integrity if it does  
13 come up, with a limited number of people being aware and  
14 informed about what the issue is, going to the Research  
15 Integrity Office at the University, or the institution, or  
16 the company, or wherever, so that it could be handled  
17 professionally and in the right way with decisions, then,  
18 being made, as to what action the institution wants to  
19 take, because it's not an issue for, as I understand it,  
20 for the Peer Review Team, for CI, or for the Department of  
21 Public Health.

22 It's only for the institution to determine  
23 what it might want to do as a result of what may or may  
24 not be an issue. It's just somebody's opinion that has

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1 been cited that needs further review, and the institution  
2 should be given an opportunity, if there's reason for  
3 concern, to be able to deal with the researcher and the  
4 proposal as they see fit, and that might involve  
5 withdrawing the proposal from the review process or not.

6 So I think you need a committee to talk  
7 about it and come up with some guidelines.

8 MS. HORN: So volunteers.

9 A MALE VOICE: I would volunteer.

10 MS. HORN: Rick, I've got you down?

11 MR. STRAUSS: If you would so like, I would  
12 do it.

13 MS. HORN: Thank you.

14 CHAIRPERSON MULLEN: One of the things that  
15 we can do and learn from is whether or not there's  
16 anything in our discussions that might make people more  
17 inclined to question a decision.

18 I've only read the transcripts of a few  
19 meetings. I have actually read some transcripts, but  
20 there might be some learning for us and reflecting back  
21 what our conversations have been and how they might be  
22 perceived in a transparent process.

23 If it's okay, I will share that. Marianne  
24 and I have sometimes gone back to DPH and been concerned

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1 that we did not necessarily put forward the kind of  
2 objectivity that those, who are so dependent or hopeful to  
3 receive these awards, would feel, especially in a small  
4 community, where we don't have to recuse ourselves, but  
5 know some of these people.

6 And we might, as the day goes by, sometimes  
7 say things that maybe we're not taking so seriously, but,  
8 obviously, taking more seriously along the way, and that's  
9 in the context of having a process with a lot of  
10 integrity, but it's a different process, and it's a very  
11 public and open process. It's just something else to be  
12 mindful of.

13 MS. HORN: I think that's very important,  
14 particularly if it gets along towards 5:00 in the  
15 afternoon with a long review day. It's always hard to be  
16 on your toes.

17 So I have a committee of two. I'm looking  
18 down the table. Have you met our newest member, who I'm  
19 about to put on the spot here? This is Dr. James Hughes  
20 from Trinity College, a bio-ethicist.

21 CHAIRPERSON MULLEN: I only know you by  
22 C.V. and letter. Welcome.

23 DR. HUGHES: Thank you.

24 MS. HORN: For your consideration, it would

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1 not involve a great deal of time.

2 DR. HUGHES: Okay. We can do this by  
3 phone?

4 MS. HORN: Yeah. Generally, we would do it  
5 by phone. I'd like to keep things moving and just kind of  
6 pick people's brains, and then come back, because this is  
7 probably something that should go into the RFP if we're  
8 going to --

9 DR. HUGHES: Okay.

10 MS. HORN: All right. I'll be in touch.  
11 Thank you very much. And then I think, unless there's  
12 anything more we can leave out there on grant review  
13 process, recognizing that we would just circle back at  
14 some point, look more at the Advisory Committee process,  
15 we have a category here for Next Steps, and I think there  
16 were a few items that we were going to talk about here.

17 MS. LEONARDI: When I took over CI and  
18 began to really orient myself, this was one of the things  
19 I looked at, and Mary and I, Marianne and I began  
20 discussions of have we done a scientific look back?

21 When you think about where we are in the  
22 stem cell program, we're six years in, it's late enough  
23 that we should start seeing some results. I know there  
24 are results.

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1                   And it gives us also an opportunity to  
2 really go out there and talk to the community from a  
3 scientific standpoint about the importance of this  
4 program, because we've got four years left, and, you know,  
5 I know how important it is for the community just to sort  
6 of step back.

7                   I was the Chair of the UConn Health Center  
8 when this started, and I know the state of research at  
9 that time, and I know, also, the state of collaboration,  
10 and there was very little collaboration among the  
11 institutions across the state, and that's a really  
12 important result.

13                   Now that, alone, I don't think justifies  
14 100 million dollars, but what I'm thinking of is, as we  
15 look forward in four years, is this a program that we all  
16 want to promote to continue?

17                   And I think, without evidence that there's  
18 been true scientific advancement, which I'm sure there has  
19 been, whether it's, you know, a basic science, whether  
20 it's translational, whether it's the clinic, that we will  
21 be at a loss to be able to really promote this.

22                   So what I would like to do, Marianne and I  
23 have been talking about, is conducting that scientific  
24 research. I know each of the institutions puts together

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1 something every year that talks about what's been done,  
2 and you can say, well, that's great, that may be all  
3 relevant, but is it marketing, and I'd like to be able to  
4 say, from a scientific perspective, we've got, you know,  
5 we've done these things.

6 So I'm looking for your support, comments.  
7 We would, obviously, involve the committee, and we've been  
8 starting to talk with CASE about potentially helping us  
9 with that review, so that we are organized in a way that  
10 really stands up in the public, public perspective. I  
11 think that I have your support.

12 CHAIRPERSON MULLEN: Yes.

13 MS. LEONARDI: Okay. Any thoughts?

14 DR. WALLACK: I think that it's absolutely  
15 essential, and every year we put together an annual  
16 report. Last year, we didn't need to, but we put one out  
17 anyway. Before that, we needed to.

18 Perhaps our goal could be that, for the one  
19 that comes out in 2013, that it includes the scientific  
20 progress from everything that we've invested.

21 I'm not even going to say the institutions,  
22 but everything we've invested in the State of Connecticut.

23 We had talked in April, I think, about  
24 having some of this work begun over the summer, utilizing

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1 interns or whatever. I don't believe that's ever  
2 happened, but, certainly going forward, I think it's going  
3 to be essential, especially since this will, I believe, be  
4 the last year that we'll be able to fund for a four-year  
5 grant.

6 If we don't begin to document the  
7 importance, and you said this, not just the collaboration,  
8 but all the outcomes that have occurred, we're going to  
9 have a hard time going forward, and I think it's essential  
10 that we look to that, to the new funding, so I totally  
11 agree with where you're coming from.

12 MS. LEONARDI: I think it has to be a story  
13 that a lay person will understand, and that's part of the  
14 translation of what's happening in the lab, for something  
15 that we can really tell the story and promote it.

16 DR. FISHBONE: This has been a real  
17 problem. I think (indiscernible) is facing the same  
18 problem to people in California, who are starting to say,  
19 you know, what do we have to show for all this money?

20 And the problem is, when you start off on a  
21 totally new science, you know, it hasn't existed before,  
22 and, also, when you make lots of promises to people and  
23 five, six years down the road, although a lot has been  
24 done, you really don't have anything to show for it.

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1                   And I think one of the things that we've  
2                   been trying to push is the translational aspect of what  
3                   we're doing, and I think there are a number of projects  
4                   that are beginning to show that there's something coming  
5                   out of it, particularly in the Parkinson's area, in the  
6                   musculoskeletal area, but it's a difficult thing to sell  
7                   when you don't have a cure.

8                   MS. LEONARDI: Except I think, also, we  
9                   have to be able to describe in laymen's terms the  
10                  scientific building blocks that perhaps were part of the  
11                  basic science, a piece of this.

12                  And while it's easier to understand when  
13                  you have a disease or something that's in the body of the  
14                  clinic, I do think we can't ignore some of the scientific  
15                  building blocks that may have come out of this program,  
16                  and how to capture that is obviously the trick and  
17                  describe it.

18                  CHAIRPERSON MULLEN: That was one of the  
19                  reasons that we actually decided to ask for some other  
20                  report last year, which was that the annual reports in the  
21                  preceding years weren't in real laymen's English, and we  
22                  were trying to --

23                  DR. GENEL: They were pretty tense.

24                  CHAIRPERSON MULLEN: Yes, so, that was the

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1 first stab at having people break things down in ways that  
2 were understandable, but we still have a way to go there.

3 MS. LEONARDI: I also think, too, it sounds  
4 like the program, as it has evolved, it becomes something  
5 different. When you think about building capacity early  
6 on, you know, there were no core facilities. There was no  
7 infrastructure, and that is an accomplishment, itself.

8 On a one-year basis, it's hard to get sort  
9 of a full picture of what the trajectory of the program  
10 has been over time, so it should be something that, you  
11 know, sort of leads the reader or the storyteller from  
12 where we started to where we are now in a way that's easy  
13 to understand.

14 DR. WALLACK: I don't think there's even an  
15 awareness. Besides the scientific progress part of it,  
16 which is crucial and picks up on Parkinson's Disease, but  
17 what it's brought to the state already, in terms of jobs,  
18 already, in terms of 55 or so million dollars in federal  
19 grants that could not have been accessed otherwise.

20 MS. LEONARDI: Dollar leveraging is a  
21 really important piece of this, is that, you know, the  
22 state is putting up this, but we brought in dollars from  
23 other places. I think that's an important component of  
24 what we should look at, too.

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1 DR. WALLACK: That Yale put up a building  
2 that was not going to be used for what it's being used.  
3 Stem cell doesn't have the whole building. It's got 30  
4 percent of the Amistad building, 82 million dollars. I  
5 mean that's an incredible commitment from Yale.

6 These are stories in lay language that need  
7 to be shared. I'm not sure if we made any promises. We  
8 said that, down the line someplace, some clinical  
9 applications will occur, whether it be in direct  
10 therapies, or drug therapies, totally different kind of  
11 understanding, and that can be clearly shown, so I think  
12 it's absolutely crucial, and you're absolutely right.

13 I think the format could be the next annual  
14 report, unless you feel differently, and have a tone to it  
15 that accomplishes what you want to do.

16 DR. GENEL: Well that's one way of doing  
17 it. Obviously, I have a vested interest in this coming  
18 out under the (background noise) imprimatur, because the  
19 academy has done exactly that sort of thing on a number of  
20 topics. It does have I think at least the aura of some  
21 independence, so that a report coming from an independent  
22 academy I think might have more credibility than coming  
23 from a State agency.

24 MS. LEONARDI: I agree with you. I think

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1 that's the outside stamp of approval or whatever is  
2 important, because, otherwise, it would start to look like  
3 a marketing document.

4 If we're going to try to use it as a  
5 document to prove that this has been important, there's  
6 got to be. That's one of the reasons we started talking  
7 to CASE. There has to be somebody that's doing this,  
8 besides me.

9 MS. HORN: So what we've been thinking, and  
10 Rick is madly developing plans as we speak and as we spoke  
11 last week, so that's certainly one of the things that we  
12 had been talking about, but we also want the Committee to  
13 start thinking about what are the questions that we should  
14 be asking, so, for next month, if people could think about  
15 that again.

16 We'll probably have another ad hoc  
17 committee, once the group is finished, to just set a  
18 framework for this report, and one of the things we're  
19 really going to evaluate how we're going to know that we  
20 have gotten where we started out and not forgetting any of  
21 these milestones and how we can demonstrate progress.

22 MS. LEONARDI: If I could ask, if we could  
23 get the questions together before the meeting, mainly  
24 because part of the -- one of the difficulties here is

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1 that we really want to make sure we have this review done  
2 by the end of the year.

3 And I know that, from a scientific review  
4 standpoint within academia, that's very hard, but if we  
5 don't have it ready for the next legislative session and  
6 we start getting, you know, we're starting to socialize  
7 these kind of things, I think that we will be behind the  
8 eight ball.

9 So if we could get the questions either to  
10 me, or I don't know how you want to do it, we can at least  
11 assemble them, you know, without a lot of the same  
12 suggestions. I can tie in with Rick and see if we can get  
13 sort of a group of questions and say, okay, here are the  
14 five things that we think are key to know or whatever.

15 MS. HORN: I can touch base with California  
16 and Jeff Lomax. They had a review done by the Institute  
17 of Medicine that really was very broad, but he might have  
18 some ideas of sort of what they -- how they ask the  
19 questions. It might save us some time.

20 If I get that, I can send that out to you  
21 all.

22 MS. LEONARDI: It would just be good to  
23 have sort of a straw man to look at it the next meeting,  
24 as opposed to throwing it just on the table.

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1 COURT REPORTER: One moment, please.

2 MS. LEONARDI: I'm done.

3 CHAIRPERSON MULLEN: Any other Next Steps?  
4 I said everything I needed to say.

5 DR. WALLACK: Do we need to reiterate the  
6 collaboration part?

7 MS. HORN: That California has, again,  
8 reached out?

9 DR. WALLACK: Right.

10 MS. HORN: Yes, I did get an e-mail from  
11 them, following up on our legislative proposal last year,  
12 to try to give us the authority to enter into a  
13 collaborative agreement with any other state or country  
14 that's doing research, and I told them the sad story of  
15 how it just kind of got left on the line there, but that  
16 we would be resubmitting it, and that we would be  
17 interested in other collaborative efforts that we could do  
18 without that MOU in place before the legislation, which  
19 may not go through until next June.

20 I've asked Paul Pescatello. I've been  
21 copying him on all those things. I'm not sure how much  
22 time he has to do anything for these research retreats and  
23 so on.

24 I think these are opportunities that

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1 California is interested in, as we're sending people  
2 virtually to these retreats to begin to make more  
3 connections with scientists here.

4 Milt has some connections with Maryland,  
5 but I think these things can happen much more informally  
6 and without much money, but the legislation will go  
7 through it.

8 DR. WALLACK: So do we also need to begin  
9 as Next Steps seriously thinking about, and this ties in  
10 to what you're talking about, Claire, when we're going to  
11 develop those funding proposals for the next 10 years?

12 I think that, by 2013, by the end of 2013,  
13 we should be ready to go into the legislature, by 2014 at  
14 the latest.

15 MS. LEONARDI: Well the thing is, if you  
16 typically, and I don't know if this is typical, if you  
17 typically award four-year grants, knowing whether the  
18 program is going to continue or not continue will drive  
19 some of your decision-making.

20 I think that you're right. I mean I think  
21 there's also the state's general commitment to bio-  
22 science, and you're part of those discussions. Do we want  
23 to re-think how stem cell and some of the personalized  
24 medicine things go together?

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1 I mean there's a whole, I think, overall  
2 state strategic discussion that has to happen, but one of  
3 the first pieces of this, obviously, is a review of what's  
4 happened, I think, so far. I'm just speaking for myself.

5 I do think that it should be part of -- the  
6 committee needs to have that strategic discussion, and,  
7 once you have that data in hand, you'll begin to be able  
8 to think about what's next, and we have to, obviously,  
9 understand all the political side of it, but it's very  
10 clear the administration is very committed to bio-  
11 sciences.

12 CHAIRPERSON MULLEN: I think the discussion  
13 is, in that regard, bigger than this committee.

14 MS. LEONARDI: That's exactly right, but I  
15 think this committee could have a voice, because you've  
16 committed so much time, and part of this the whole time it  
17 is absolutely bigger than its committee, but we should  
18 also make sure that this committee knows what it would  
19 like to see happen. I don't control it.

20 DR. WALLACK: Well the committee has  
21 credibility, so we bring that to the process.

22 MS. LEONARDI: Exactly.

23 DR. WALLACK: And the modification of the  
24 legislation, itself, for example, Rick identified, we're

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1 legislatively involved with having 15 reviewers. These  
2 are small things that at the beginning we never thought  
3 would be a factor, but things like that, Advisory  
4 Committee make up.

5 We have to think in terms of whether or not  
6 we had people from universities any longer on board. It's  
7 become a problem in the past, so there are these tweaks to  
8 a very, very, very good body of legislation. As you know,  
9 it's probably the best legislation in the country, if not,  
10 the best one or the top two or three.

11 It's sensational, but we see needs to tweak  
12 that, too, so these are all things, as Next Steps, we have  
13 to be looking at.

14 MS. HORN: And I think this report is just  
15 going to give us a lot of ammunition for knowing what  
16 we're talking about, where we've come, and what we've  
17 brought to the state already.

18 Okay. Public comment? Hearing none,  
19 motion to adjourn? Oh, I'm sorry.

20 MS. WILSON: Can I just make one  
21 announcement? The Yale Stem Cell Center is having their  
22 annual retreat on October 19th, on Friday, all day, and  
23 the committee is certainly welcome, and I will send an  
24 invitation to Sara, and, if it's okay, maybe she can send

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1 it out to all of you, because we'd like you to see what's  
2 going on at Yale.

3 DR. GENEL: West campus again?

4 MS. WILSON: No. This year, it's going to  
5 be in Harkness.

6 DR. GENEL: Okay.

7 MS. WILSON: We're going to try doing it  
8 right on the medical school campus.

9 MS. HORN: What was the date, again, Paula?

10 MS. WILSON: October 19th.

11 MS. HORN: Any other public comment? Do we  
12 have a motion to adjourn?

13 DR. WALLACK: Before you do, your next  
14 meeting. September 18th happens to be the second day of  
15 Rosh Hashanah.

16 MS. HORN: Oh, dear. Okay. We do that  
17 every year, I think. So we could go the next week.

18 DR. WALLACK: Before you do that, one  
19 second.

20 MS. HORN: I think the 26th is Yom Kippur,  
21 right?

22 DR. WALLACK: Yes. Yom Kippur.

23 CHAIRPERSON MULLEN: See, I told you there  
24 were holidays coming up.

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1 DR. WALLACK: Yeah, yeah, yeah, you did.

2 MS. HORN: So is the 25th awkward?

3 DR. WALLACK: The 25th?

4 MS. HORN: Yes.

5 DR. WALLACK: Well it starts at sundown,  
6 and I know some people travel before sundown.

7 MS. HORN: We could do the week before. I'm  
8 just trying to keep it to a Tuesday.

9 DR. WALLACK: Right.

10 DR. GENEL: We're talking about the 12th?

11 DR. WALLACK: The 11th.

12 DR. FISHBONE: I won't be here.

13 DR. WALLACK: Can you call in here?

14 DR. FISHBONE: I have a meeting.

15 MS. HORN: It doesn't have to be a Tuesday.  
16 It just seems that people have some Tuesdays.

17 DR. WALLACK: So would you consider having,  
18 instead of the 18th, the 19th, the following day?

19 MS. HORN: That's fine with me. Does that  
20 work for other people?

21 DR. DEES: Works for me.

22 MS. HORN: September 19th, okay. And what  
23 I'll do is I'll send out a copy of the current RFP, and we  
24 can take a look at what we need to dust off there, because

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1 I think we ought to start thinking about getting that  
2 prepped.

3 DR. GENEL: I teach a class until close to  
4 1:00. I'll be here.

5 DR. WALLACK: You'll have your phone on?

6 DR. GENEL: I'll have my phone on.

7 MS. HORN: Okay, so, Wednesday, September  
8 19th, here at 1:00.

9 DR. DEES: This is Richard Dees again. I  
10 took a look at my calendar. I can be there from 1:00 to  
11 about 2:15.

12 MS. HORN: We don't typically go this late.  
13 We just had a lot to work on today. Thank you. I think  
14 we had a second. All in favor?

15 VOICES: Aye.

16 (Whereupon, the hearing adjourned at 3:45  
17 p.m.)

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