CONNECTICUT STEM CELL RESEARCH ADVISORY COMMITTEE MEETING

AUGUST 21, 2012

1:20 P.M.

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

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

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

DR. JAMES HUGHES: Um-hum.

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

DR. HUGHES: Jay.

MS. HORN: Jay. Jay Hughes. And he is a bioethicist at the University of -- Trinity College in
Hartford, and we are delighted to have him on board. He has experience with some stem cell research in his past, and oversees the IRB at Trinity.

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

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

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

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

A MALE VOICE: Move to accept.

MS. HORN: And second? Any discussion?

Okay. All in favor?

VOICES: Aye.

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

A MALE VOICE: So moved.
MS. HORN: And second?

A MALE VOICE: Second.

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

VOICES: Aye.

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

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

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

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

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

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

MS. SARA DONOFRIO: Yes. The first one is number 08SCBUCHC011, Zecevic. That one was reviewed and did not see anything unusual, as well as the second item
for Mr. LoTurco. That one, as well, there was nothing unusual on that one either. I believe these were just here for informational purposes.

DR. RICHARD DEES: This is Richard Dees.

The second one is asking us to put it off for six months for internal reasons, right?

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

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

DR. LANDRY: I’m sorry. Could you repeat the question, sir?

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

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

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

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

DR. GENEL: I’ll second Richard’s motion.

MS. DONOFRIO: Okay. It’s approved. And I
can go onto item number four, annual reports. These are
to be considered for approval.

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

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

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

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

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

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

DR. TREENA ARINZEH: Hi. This is Treena
Arinzeh.
MS. DONOFRIO: Hi, Treena. Thank you.

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

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

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

DR. GERRY FISHBONE: We have a summary.

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

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

MS. DONOFRIO: Absolutely.

DR. DEES: Yeah.

DR. WALLACK: And specify more clearly their goals.

DR. DEES: Yes.

DR. FISHBONE: It’s a major step forward.

MS. DONOFRIO: Okay. Any further
discussion on that item? We’ll move on to 09SCBYALE14, Huang. Any discussion on that item?

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

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

(Off the record)

MS. DONOFRIO: Okay. Any further discussion on that item? Okay. We’ll move onto 09SCBYALE21. Any discussion for that item?

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

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

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

I’d like to take a motion to pass these annual reports.
DR. FISHBONE: So moved.

MS. DONOFRIO: Second?

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

MS. DONOFRIO: Okay.

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

MS. DONOFRIO: Yes.

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

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

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

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

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

VOICES: Aye.

MS. DONOFRIO: Okay. Number five, final reports received, we received two. The first, 06SCB11, and the second is 09SCBWE26. These were added for informational purposes, and we did not see anything unusual in either of these final reports.

DR. WALLACK: So moved.

DR. FISHBONE: Second.

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

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

VOICES: Aye.

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

MS. DONOFRIO: In the past, it didn’t look like we had.

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

DR. DEES: I didn’t see a technical report from the second grant. All I got when I downloaded was the financial report.
COURT REPORTER: Excuse me. Who is speaking?

DR. DEES: This is Richard Dees.

MS. DONOFRIO: Is that for the Naegele?

DR. DEES: Yes.

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

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

MS. DONOFRIO: I’m sorry. Could you repeat that?

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

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

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

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

MS. CLAIRE LEONARDI: But we keep track of
whether we receive both of those pieces, correct?

   DR. LANDRY: Yeah.

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

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

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

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

   MS. DONOFRIO: Right.

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

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

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

   MS. DONOFRIO: Let me see. The note I have
year one and two request falls within the 10 to 20 percent range.

DR. FISHBONE: So it doesn’t need approval?

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

DR. FISHBONE: And that’s above the range?

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

DR. FISHBONE: So moved.

MS. DONOFRIO: Second?

DR. GENEL: I second it.

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

VOICES: Aye.

MS. HORN: Anyone opposed?

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

The first item is 12SCBUCHC09, Chamberlain.

The next item is 12SCDISYALE01, Redmond. The third is 12SCBUCON01, Goldhamer. We would recommend these three for approval. Is there any discussion on any of those items?
DR. FISHBONE: Chamberlain, which she had a reduction in funding from four years to three years, so she wanted to use --

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

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

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

DR. WALLACK: Second.

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

VOICES: Aye.

MS. HORN: Opposed?

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

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

MS. DONOFRIO: Okay. Agenda item eight, Carry-over Requests, there was one, 09SCDUCHC01. Any
discussion on that item?

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

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

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

MS. HORN: Would you like additional explanation?

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

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

DR. FISHBONE: Did we fund them again? This is from ’09, right? Did we fund them again this year?

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

DR. LANDRY: They’re still due 605.
MS. HORN: Their new award. They just got a core.

DR. LANDRY: I’m sorry. I was talking about year nine.

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

MS. HORN: Um-hum.

DR. GENEL: I won’t comment any further.

DR. FISHBONE: Can you explain your comment?

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

DR. FISHBONE: You’re merely suggesting they didn’t use --

DR. GENEL: No. It’s just an observation.

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

DR. FISHBONE: I’m sure they can use it, because we really didn’t give them very much for this
coming year.

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

If the Committee is comfortable with this explanation, that’s the Committee’s call.

DR. GENEL: I think it’s reasonable.

MS. HORN: You think it’s reasonable?

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

MS. HORN: Oh, it’s reasonable to have more information.

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

MS. HORN: Is that a motion?

DR. FISHBONE: Sure.

MS. HORN: We have a motion that we, the
Committee, be provided with additional information about the remaining funds, the circumstances under which they came to be remaining, and how they’re anticipating using the funds.

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

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

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

DR. GENEL: I’ll second it.

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

VOICES: Aye.

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

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

The next item is 10SCA47. Any discussion
for that?

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

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

MS. DONOFRIE: Okay.

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

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

DR. WALLACK: I’ll move that.

MS. HORN: Okay. Is there a second?

DR. FISHBONE: I’ll second that.

MS. HORN: Okay. Is there any further discussion? So the motion is not to grant it?
DR. WALLACK: Not to grant it.

MS. HORN: Pending further information.

DR. WALLACK: Right.

MS. HORN: Okay.

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

MS. HORN: Yes. All in favor?

VOICES: Aye.

MS. HORN: Opposed?

MS. DONOFRIO: The next item is 10SCA23.

Any discussion on that item?

DR. LANDRY: I mean I can mention that I did try to look in that file, and I haven’t seen a report ever submitted on that particular grant, and this is now two years, at least I couldn’t find one in our records. Drazinic I did find one that she submitted a year ago, but she’s probably late, as you gentlemen mentioned, but, on this next one here, I couldn’t find anything from that party, which may not mean she didn’t do it, but we didn’t receive it here, or file it correctly, so maybe we could ask her to, or them. I’m not sure.

DR. FISHBONE: He wants to extend it by a full year. It’s supposed to end September 30, 2012, and he wants to extend it through September 30, 2013.
MS. HORN: You’re saying we don’t have any technical or fiscal reports?

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

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

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

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

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

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

DR. WALLACK: Request the reports?

MS. HORN: Request the reports.

DR. WALLACK: I’ll move that.

MS. HORN: Okay. Is there a second?

Anybody seconding that motion?

DR. FISHBONE: Yeah, I’ll second.

MS. HORN: Okay. All in favor?
VOICES: Aye.

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

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

VOICES: Aye.

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

CHAIRPERSON JEWEL MULLEN: Thank you very much.

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

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

MS. DONOFRIO: Let’s see.

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

MS. DONOFRIO: Hi. Can the latest caller please identify yourself?
DR. PAUL PESCATELLO: Yeah. It’s Paul Pescatello. I just switched phones.

MS. DONOFRIO: Okay.

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

MS. DONOFRIO: I think so, yeah.

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

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

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

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

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

MS. HORN: That was all paid.

DR. LANDRY: So there’s nothing being held.

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

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

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

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

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

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

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

    MS. HORN: Okay, so, somebody make a motion to that effect?
DR. WALLACK: Yeah. I’ll move that we have him be more specific, come back to us with more specific clarity on his reporting about where he is, the status of his research.

MS. HORN: Okay, second?

DR. FISHBONE: I’ll second.

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

VOICES: Aye.

MS. HORN: Opposed? Motion passes.

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

DR. FISHBONE: Rodenheffer?

MS. DONOFRIO: Um-hum.

DR. FISHBONE: You’re moving them around a little.

MS. HORN: Keep us on our toes here.

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

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

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

DR. LANDRY: Only if they’re approving. I
think they want to vote separate.

MS. DONOFRIO: Okay. And we also would

need to go back and vote on Rasmussen, the first item.

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

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

MS. DONOFRIO: That one is 10SCA22,

Rodenheffer.

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

MS. DONOFRIO: Take a motion to pass.

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

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

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

A MALE VOICE: It sounded reasonable.
MS. DONOFRIO: Okay, so, the items that we’ll take a motion on are Rasmussen. That one is 09SCBUCON18. Also, Antic, 10SCD01. Rodenheffer would be the next one, and then, also, 10SCA05, as well as 10SCA13. I’d like to take a motion.

DR. WALLACK: Move those latter four. I think there’s four.

MS. DONOFRIO: Second?

DR. FISHBONE: Seconded.

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

VOICES: Aye.

MS. DONOFRIO: Opposed? So that means Drazinich, Chhabra and Antic to request further information. Item number 10, Change in Personnel Request. There was one of those requests, and that is 10SCA06.

Any discussion on that item?

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

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

DR. FISHBONE: So moved.

CHAIRPERSON MULLEN: Okay, second?
DR. WALLACK: Second.

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

VOICES: Aye.

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

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

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

DR. GENEL: Well they didn’t stop working, did they?

DR. LANDRY: Let’s hope not.

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

MS. LEONARDI: With a substitution.
CHAIRPERSON MULLEN: Or was that sort of suspended effort, it almost looks like.

DR. FISHBONE: Yeah.

CHAIRPERSON MULLEN: Next summer.

DR. FISHBONE: Next summer.

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

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

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

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

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

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

DR. LANDRY: Maybe we should request like
at least like a fiscal report, too, so that, then, we can approach it to the next agenda as a topic for next month. You can get their financial information in the meantime.

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

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

   MS. DONOFRIO: Yes.

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

   MS. DONOFRIO: Right.

   DR. DEES: It seems like it’s coming in a funny form.

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

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

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

   DR. FISHBONE: I’ll move that.

   MS. DONOFRIO: Okay. Second?
CHAIRPERSON MULLEN: Second.

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

VOICES: Aye.

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

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

MS. HORN: Do we have a motion?

DR. WALLACK: I move.

DR. FISHBONE: You move, I’ll second.

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

VOICES: Aye.

MS. HORN: Opposed?

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

DR. FISHBONE: Can you explain what that
mean?  

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

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

DR. FISHBONE: Have they not received -- they haven’t received the money from the grants that we approved?

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

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

DR. LANDRY: I believe we still have some verification certification forms to be signed. The
assistance agreements are partially prepared, though we haven’t filled in the dollar amounts, as far as how they will be spread out over the years, so we have that work to do.

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

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

DR. LANDRY: I think that’s probably a reasonable goal, yeah.

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

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

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

DR. FISHBONE: Does everybody have to wait for the four that need the ESCRO approval? Is that what
you’re stating? They all start at the same time?

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

DR. FISHBONE: And is October 1st
acceptable?

MS. WILSON: Oh, it’s quite acceptable.

That would be wonderful.

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

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

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

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

I mean I guess we don’t know, Sara and I,
are some of these three-year or four-year terms, the ones that are not the 200,000? Is there a way to --

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

DR. LANDRY: Were they?

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

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

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

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

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

MS. HORN: No, we’re all set.

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

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

CHAIRPERSON MULLEN: See, what I would recommend is that, while you know you have every effort to
do this as quickly as possible, that you will allow for
all the people, who rely on you to get the money out, to
also get you the information that’s necessary, so you
would be able to do it.

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

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

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

MS. LEONARDI: I think what the
Commissioner is saying is that we’re driven by getting the
information, for example, from you, and we want to make
sure that if we get the information from you the end of
September, we’ve committed to the October 1st date, so maybe it’s 30 days after you provide us the information we’ll provide the funding.

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

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

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

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

CHAIRPERSON MULLEN: Yes.

COURT REPORTER: One moment, please.

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

MS. LEONARDI: So when do you think that
you would get all of the materials to us?

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

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

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

MS. WILSON: Well it’s different. It’s different for each institution.

MS. LEONARDI: Just speak for yourself,
like for Yale.

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

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

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

MS. WILSON: That would be fine, as long as

--

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

DR. WALLACK: Would it be appropriate to
say that our goal, our aim would be to get them the information by October 15th, depending upon the receipt of the information that we need within a two-week period from today, or whatever date you want to set?

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

DR. WALLACK: Right. I understand.

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

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

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

So you’ve stated that’s the goal, and, given that, I would say, given that you want everybody to start at the same time, if we had a clear, a November 1st date, but everything was signed off on before October 1st,
then, before November 1st, there’s nothing wrong with that either.

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

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

MS. HORN: Through this other process we’ve just gone through today.

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

MS. LEONARDI: I don’t know. I don’t really know.

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

We try to anticipate what we can, but every once in a while somebody says, well, I would like to have this four percent changed to a one percent, and that holds us up for a couple of weeks. That’s what happened last year.
DR. LANDRY: Last year, we funded about two and a half million November 1st time period, but most of those were prior year awardees. They weren’t the new year awardees.

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

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

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

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

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

DR. WALLACK: Since there’s all the bases in here, can we communicate all of this to her, as well,
for UConn?

DR. LANDRY: Sure.

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

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

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

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

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

The first was with our Peer Review Committee, so just to review, we have 15 members of the Peer Review Committee, and we have, let’s see, 11 members
responded, the Chair, three of the four co-Chairs, and seven peer reviewers.

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

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

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

So the first set of recommendations went over that, dealt with the purpose of the stem cell research program expectations for the peer review process, review of the types of grants to be funded and the funding priorities, review of the two-level review process, roles
of the co-Chairs, the Chair and the reviewers, review timeline, and a review of the scoring process, based on NIH criteria of the supporting projects.

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

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

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

Then, in the critique and scoring process, you know, this was our first year doing it, and it may be similar every year. I’m not sure, but there appears to be
a bunching of scores in the middle or in the certain area, and that may be driven, in part, by the NIH one to nine scoring scale, so, you know, one and a half or two and a half.

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

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

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

We thought that we should do two primary
reviews or two reviews, rather than a primary and a secondary review.

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

So they’re all looking at it, two reviews, and they’re equally balanced and rated.

MS. HORN: And they get paid the same.

MR. STRAUSS: And they get paid the same.

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

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

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

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

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

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

   So then we come into a situation, where for
the proposals where the reviewers are unable to reconcile a proposal, what we did last year was to have the co-Chair assigned a proposal, essentially do the reconciliation by providing the next score that would, then, go to the study section.

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

And that would a lot be driven by the co-Chair or the Chairs that would be assigned that, because they’re going to try to figure out what the issues were. As well, that if the reviewers cannot reconcile the proposal, then they would provide a
statement, indicating why they could not reconcile the proposal. It would help drive the questioning.

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

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

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

Okay, so, improve the study section review of proposals for final scoring strength and instructions in the peer reviewer process to emphasize the role of the Chair and co-Chairs, including the expectation that the Chairs and co-Chairs would review and develop questions for all proposals they are assigned and lead the discussion of such proposals during the study section to determine the final proposal scores.
And, then, finally, move to -- from the NIH initial scoring methodology of one to nine to 10 to 90. Now what NIH does, actually, once the proposals are scored -- well, let’s see.

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

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

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

It would maybe help you in at least having more discrimination in the scoring, so that you can separate the quality of the proposals.
DR. GENEL: So you’re really just amplifying the score, aren’t you? I mean it’s really not -- it’s nothing different.

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

DR. GENEL: Like a loudspeaker.

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

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

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

The problem is that they’re trying to hedge too much, and what we want them to do is be more discriminating. I’m not sure that just saying, okay, scored on a 80-point scale is going to really help that any, because it just doesn’t make that much difference.
What we need to do is get them to really be making consistent distinction, so we still have the problem that the reviewers have sort of different scales in their head, and whether they’re using a 9-point scale or an 80-point scale doesn’t really make any difference in that respect, so we need to have them be consistent, and then we’re not going to have the problem that we were having.

CHAIRPERSON MULLEN: Can I ask a question? I’m asking a question. I understand that something is not working for us. Should we feel any better if there’s consistency between the reviewer scores and should we? I’m not asking anybody, except for maybe CASE. You know, you can do a statistical analysis and see whether or not the variation that we’re observing and the reviews that we’re getting is really beyond what we would expect.

I understand it makes it difficult for us, and I’m not trying to make this a harder discussion, but, on the other hand, I would be concerned if there was too much similarity between the reviews that we get from each person, so I just want to put that out there, so that we’re sure about everything that’s making us uncomfortable about this. Yes?
DR. HUGHES: Well, generally, we want to see intercoder reliability in sciences, because that would indicate that you’re actually measuring what you think you’re measuring, but I think the point that you’re raising is that because there’s so much variability in the grounds of which we might be judging the merits of these proposals that you wouldn’t necessarily expect that kind of intercoder reliability.

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

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

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

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

MS. LEONARDI: I just want to jump in. I
agree with you, but one of the things, and I don’t know if you said it when I was out, that struck me when I read some of the comments, was that some of the problems with the differentials in the scoring was that the peer reviewer didn’t explain.

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

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

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

MR. STRAUSS: No, no. That’s all in the records for the Committee to review and for the Peer
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Review Team to look at.

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

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

DR. GENEL: Yeah.

MR. STRAUSS: So they’re both on an equal footing.

DR. GENEL: Yeah.

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

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

One of the things that jumped out at me was that there seemed to be a cry for greater conversation...
between the reviewers, and I can understand that, because I think it came through to us, if there’s an area of improvement, that we needed to have more narrative about where each of the reviewers were coming from.

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

MR. STRAUSS: Right.

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

Having said that, one of the other things that I think jumped out at me was that there was an issue having to do with the reconciliation process, itself, and I’m wondering if we had three, and this was somewhat touched upon in your presentation, if we had three reviewers, each of whom would be primary reviewers, and when they had the study session, they would be able to work through, at that particular time, all the issues that, when we get it in June, or whenever we would get it in May ahead of the June meeting, so I would think that maybe we ought to discuss moving away from the reconciliation model, although you can put certain --
certain aspects of it you can hold in abeyance for now and try to see if we can, if we have three reviewers on each grant, and have them as primaries, like I said, and have them each go through a study session on them, greater conversation, if you will.

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

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

MR. STRAUSS: We didn’t get to that yet.

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

I don’t think they have to walk out of the room, but I think that I would rather they be silent on that particular grant if they were not allowed to vote on the grant.
MS. HORN: They should not be participating in the discussion of that grant at all.

DR. WALLACK: Right.

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

DR. WALLACK: It makes it more certain.

You’re absolutely right, Marianne.

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

DR. WALLACK: I agree with that. Right.

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

Secondly, there’s two or more types of communication. One is the verbal type, and the other is
the non-verbal type and signaling that some people on the Committee may see, and then they may be impacted in their decision making.

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

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

DR. WALLACK: Or three.

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

Now we want to do a better job in having the co-Chairs and the Chair engaged in this review process, and the idea of focusing the co-Chairs on specific grant types, as compared to having them spread out with both seed and established, so then you would have -- and, you know, a lot would depend upon the number of grants that came in in each category, as to how many co-Chairs were actually assigned to that category, and you’d
use the Chair as part of that co-Chair/Chair team.

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

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

As a result of that, there is a shifting, you know, based upon the discussion in that study section meeting of the final rankings, and the idea is, if we didn’t have any changes in the last process, which, you know, happened, in my view, it would have been better if there were some re-rankings there, because that would have shown, you know, the level of deliberations that the scoring wasn’t exact, and there were some differences that were resolved at that level, so that’s what we’re really shooting for, but if there are any changes at that level, then there’s also a statement, as to why that score was adjusted, so, again, you would see that whole thing.
So I’d say, you know, let’s see how it works going to the two reviewers, full reviewers, instead of reviewer and secondary. That may solve a lot of the problem, and then focusing our, you know, our second level review team on, again, you know, trying to get them working on the different categories more closely than just having their work randomly spread out among the categories, so that will, I think, drive us to maybe where you want to go and take a look at how that works.

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

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

I think that we may be back here a year from now, hopefully not, looking at the idea of maybe we
should readjust it, but that’s a year away.

MR. STRAUSS: Well this your all decision.

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

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

MR. STRAUSS: Well, you know, I don’t know whether you’re going to be able to solve that problem, but the idea of the two-level review and the co-Chairs asking questions, and having a couple of people that are familiar with the whole sub-set, or that category I think helps to build at least the opportunity for perhaps more consistency in the scoring.
In the bio-med process, up until this year, and I think it’s changing this year, the peer reviewers have served on a pro bono basis, so we were limited in the number of reviews that we could ask them to do, so we had like 20 for, you know, something like 17 or 18 proposals or whatever.

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

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

MS. LEONARDI: Fifteen.

DR. FISHBONE: Fifteen by legislation?

MS. LEONARDI: Correct.

DR. FISHBONE: That would not preclude reaching out to somebody on an ad hoc basis, would it?
MS. HORN: Well we’ve looked at that when we’ve had very specific grants. I’m not sure that’s ever happened officially, that the peer reviewers have used ad hoc.

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

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

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

MR. STRAUSS: What’s interesting is that all of the peer reviewers have expertise in the field of stem cell research, and, if you think about it, and I’m making this up, I don’t know whether it’s true or not, but let’s say in this sub-field you had 10 proposals, and you’ve got these two great stem cell researchers that are in that area and have great expertise in that area and say those are the people we’re going to assign to those 10 proposals.
Well, you know, that’s their field, and that’s their area of expertise, and they may rank those proposals pretty high, whereas that may be inconsistent with having a cross-section of people reviewing.

DR. GENEL: It’s not a perfect science.

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

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

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

And one of the points that I don’t think we have covered of his was incorporating a triage system, where the bottom 50 percent are not discussed to insure adequate discussion of the competitive grants.
So I think he’s talking about for those grants that are scored six to the nine, and it’s consistent when both reviewers are saying this is a core grant, and it’s not likely to get funded.

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

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

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

Now, in practice, most likely that won’t happen, but there may be one of the 15 reviewers that says, you know, this got rated a nine, and you guys missed the point here, and this really -- would we really miss that this is so innovative it should be a one.
COURT REPORTER: One moment, please.

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

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

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

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

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

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

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

DR. GENEL: Okay.

DR. FISHBONE: I think most of the reviewers were relatively comparable, in terms of the two
reviewers. There were some that were markedly outstanding. The one that’s giving us all the heebie jeebies is when one guy gave a nine, and the other one gave a one, and it was reconciled to be a six.

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

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

MR. STRAUSS: Well, correct.

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

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

Their initial summary statements and, you know, score, justification of the score was provided for
each of those reviews, so this year what we want to do is
to have, if they’re unable to reconcile, they need to
provide a statement, saying why they were unable to
reconcile, so that will provide further guidance for the
co-Chair review, and then the discussion among the peer
reviewers at the study section for the ranking of the
proposal, so I think that would help address the scoring
disparity issue.

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

Did Diane have other things, or was that --

MS. HORN: I think we covered them. What

I’ll do is attach these. I’ll ask Sara to attach these to
the minutes, so that they’re part of the record, but I
think we’ve covered the comments that were made, and Ron
Hart had a comment on the appeal process, so we’ll get
into that.

DR. FISHBONE: David had several.

MS. HORN: Yes. I think we covered most of

them.

DR. GENEL: David’s major suggestion was
that you actually have a formal study section review process, rather than an individual reconciliation process.

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

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

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

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

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

That’s one of the goals for this year, is to really make sure that there’s a discussion on the proposals using as much, you know, persuasion as possible to say we’ve really got to review those.
And there will be some proposals that will not be reconciled, so there will have to be discussion during the study section.

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

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

DR. GENEL: Well, right. So, I mean, as I said, this is the first time we’ve actually had any kind of a discussion regarding how the peer review was managed. The second is that, you know, we have a limited amount of funds available, so there’s always going to be -- it’s always going to be tough at the margins to discriminate between those that are above and those that are below the line.

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

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

MR. STRAUSS: Well let me --

DR. FISHBONE: You touched on this before.
MR. STRAUSS: Well we do not assign the peer reviewers to the proposals. It’s the responsibility of the Chair, so the Chair uses a process to say this reviewer is going to review this proposal, and this reviewer will review this one, this one is a secondary, or a primary reviewer, so that’s how it works.

That’s what I know about how the Chair assigned the proposals.

DR. FISHBONE: Presumably, that’s based on the --

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

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

MR. STRAUSS: Right. We had some -- you know, sometimes, administratively, there may be reviewers or individuals you’re dealing with that are very difficult
to deal with, and they may be the best reviewers, so one
is on the administrative side, and then there’s the
quality of the reviews, and I think, you know, what we
want to do we have the 15 reviewers. I don’t think
there’s anyone that we have that we would say we wouldn’t
suggest be invited back, but I think we need to put these
steps in place to assure that the reviewers are producing
the type of quality in their reviews that we expect, and I
think, you know, some of the mechanisms that, if we do it,
that we’re suggesting will help to do that, assuming, you
know, the leaders, the co-Chairs and the Chair actually,
you know, play a significant role in making sure that the
statements provided, you know, are acceptable and do
reflect the proper justifications of the scores that are
being given.

MS. HORN: So what else do you need?

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

One was that if a proposer has another
grant under the Stem Cell Research Program, that that
should be identified in the proposal, and the other one
was that if a proposer has submitted more than one grant in the current process, then the Committee should be aware of that.

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

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

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

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

We thought that it would be good for all Stem Cell Research Advisory Committee members to have
access to all the proposals as soon as possible, as soon
as they become available online, and that, in some way,
the members should, then, be required to notify CI of any
conflict, so that before the assignments are made for
review, all those conflicts are taken care of, and they
don’t have to start reassigning proposals.

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

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

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

MR. STRAUSS: It was some work, but, you
know.
DR. FISHBONE: It’s the first time we’ve ever had anything like this, that, you know, you spoke to all of the reviewers, and got their feelings about what was happening, and I think it’s been extremely helpful.

MR. STRAUSS: There’s one other suggestion that’s not in here, but it’s based upon the discussion of the meeting, regarding the post-decision-making process. I think you ought to do the same thing for the award process in getting the people under contract. I think you need to set a goal much quicker than five months to get people under contract to get this work underway.

DR. FISHBONE: That’s a good point.

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

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

MS. HORN: Some of it, I think, is an ESCRO
MR. STRAUSS: Well whatever it is. I don’t know how long any of that stuff takes place. If you think that there’s a way to facilitate that in some way to shorten it from five months.

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

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

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

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

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

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

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

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

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

DR. GENEL: I don’t really think we -- it’s
our job to tell or it’s appropriate to tell peer reviewers what the goals of the program are. We’re asking them to judge the science. It’s our job to determine those priorities.

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

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

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

I appreciate so much what you’ve provided. I’m going to reiterate that, at the same time that we’ve gotten you to review for us the more I’ll say quantitative
elements of the review process, there’s probably still some other work this body can do around the qualitative part that we provide in our review in our meeting, and discussions, such as the purpose, is a part of that, because once we get this other piece, as perfect as it can be, until we criticize it again for the next year, I think we also have to continue to hold ourselves to a process that people can feel good about, so that they don’t keep coming back to us, saying I still have a problem with what happened.

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

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

MR. STRAUSS: Okay.
CHAIRPERSON MULLEN: But you’re welcome to stay there if you want.

MR. STRAUSS: Well I’m going to go back.

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

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

One of the reviewers, who commented, said, well, we really don’t make our decision. The Advisory Committee decision is based solely on the scientific merit, and I think that’s sometimes something that gets
lost for the people sitting, listening to the grants being reviewed, that there is a whole overlay that the Advisory Committee weighs in on, but I think that, looking at our Advisory Committee process, those are some things that we can look at and talk about more thoroughly.

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

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

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

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

We took it back to the peer review. They agreed -- they did not agree that there was no misconduct, if that’s not too many negatives. They felt that there was, because of another grant that had not been cited,
that was very similar to this proposal, that there was, indeed, an issue, so there we were, so I propose that it go to the Advisory Committee for two scientific members to have an independent review, and then I realized that was not anything that the Advisory Committee had signed off on.

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

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

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

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

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

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

The appeal goes to that process, and it doesn’t come to the Advisory Committee, so that would be,
you know, my thought.

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

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

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

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

MS. HORN: He’s back.

MR. STRAUSS: I’m back. Sorry. Rick
Strauss.

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

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

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

It’s only for the institution to determine what it might want to do as a result of what may or may not be an issue. It’s just somebody’s opinion that has
been cited that needs further review, and the institution
should be given an opportunity, if there’s reason for
concern, to be able to deal with the researcher and the
proposal as they see fit, and that might involve
withdrawing the proposal from the review process or not.

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

MS. HORN: So volunteers.

A MALE VOICE: I would volunteer.

MS. HORN: Rick, I’ve got you down?

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

MS. HORN: Thank you.

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

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

If it’s okay, I will share that. Marianne
and I have sometimes gone back to DPH and been concerned
that we did not necessarily put forward the kind of
objectivity that those, who are so dependent or hopeful to
receive these awards, would feel, especially in a small
community, where we don’t have to recuse ourselves, but
know some of these people.

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

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

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

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

DR. HUGHES: Thank you.

MS. HORN: For your consideration, it would
not involve a great deal of time.

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

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

DR. HUGHES: Okay.

MS. HORN: All right. I’ll be in touch.

Thank you very much. And then I think, unless there’s anything more we can leave out there on grant review process, recognizing that we would just circle back at some point, look more at the Advisory Committee process, we have a category here for Next Steps, and I think there were a few items that we were going to talk about here.

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

When you think about where we are in the stem cell program, we’re six years in, it’s late enough that we should start seeing some results. I know there are results.
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And it gives us also an opportunity to really go out there and talk to the community from a scientific standpoint about the importance of this program, because we’ve got four years left, and, you know, I know how important it is for the community just to sort of step back.

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

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

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

So what I would like to do, Marianne and I have been talking about, is conducting that scientific research. I know each of the institutions puts together
something every year that talks about what’s been done, and you can say, well, that’s great, that may be all relevant, but is it marketing, and I’d like to be able to say, from a scientific perspective, we’ve got, you know, we’ve done these things.

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

CHAIRPERSON MULLEN: Yes.

MS. LEONARDI: Okay. Any thoughts?

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

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

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

We had talked in April, I think, about having some of this work begun over the summer, utilizing
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interns or whatever. I don’t believe that’s ever happened, but, certainly going forward, I think it’s going to be essential, especially since this will, I believe, be the last year that we’ll be able to fund for a four-year grant.

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

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

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

And the problem is, when you start off on a totally new science, you know, it hasn’t existed before, and, also, when you make lots of promises to people and five, six years down the road, although a lot has been done, you really don’t have anything to show for it.
And I think one of the things that we’ve been trying to push is the translational aspect of what we’re doing, and I think there are a number of projects that are beginning to show that there’s something coming out of it, particularly in the Parkinson’s area, in the musculoskeletal area, but it’s a difficult thing to sell when you don’t have a cure.

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

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

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

DR. GENEL: They were pretty tense.

CHAIRPERSON MULLEN: Yes, so, that was the
first stab at having people break things down in ways that were understandable, but we still have a way to go there.

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

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

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

    MS. LEONARDI: Dollar leveraging is a really important piece of this, is that, you know, the state is putting up this, but we brought in dollars from other places. I think that’s an important component of what we should look at, too.
DR. WALLACK: That Yale put up a building that was not going to be used for what it’s being used. Stem cell doesn’t have the whole building. It’s got 30 percent of the Amistad building, 82 million dollars. I mean that’s an incredible commitment from Yale.

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

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

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

MS. LEONARDI: I agree with you. I think
that’s the outside stamp of approval or whatever is important, because, otherwise, it would start to look like a marketing document.

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

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

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

MS. LEONARDI: If I could ask, if we could get the questions together before the meeting, mainly because part of the -- one of the difficulties here is
that we really want to make sure we have this review done by the end of the year.

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

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

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

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

MS. LEONARDI: It would just be good to have sort of a straw man to look at it the next meeting, as opposed to throwing it just on the table.
COURT REPORTER: One moment, please.

MS. LEONARDI: I’m done.

CHAIRPERSON MULLEN: Any other Next Steps?

I said everything I needed to say.

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

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

DR. WALLACK: Right.

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

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

I think these are opportunities that
California is interested in, as we’re sending people virtually to these retreats to begin to make more connections with scientists here.

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

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

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

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

I think that you’re right. I mean I think there’s also the state’s general commitment to bio-science, and you’re part of those discussions. Do we want to re-think how stem cell and some of the personalized medicine things go together?
I mean there’s a whole, I think, overall state strategic discussion that has to happen, but one of the first pieces of this, obviously, is a review of what’s happened, I think, so far. I’m just speaking for myself.

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

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

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

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

MS. LEONARDI: Exactly.

DR. WALLACK: And the modification of the legislation, itself, for example, Rick identified, we’re
legislatively involved with having 15 reviewers. These
are small things that at the beginning we never thought
would be a factor, but things like that, Advisory
Committee make up.

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

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

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

Okay. Public comment? Hearing none,
motion to adjourn? Oh, I’m sorry.

MS. WILSON: Can I just make one
announcement? The Yale Stem Cell Center is having their
annual retreat on October 19th, on Friday, all day, and
the committee is certainly welcome, and I will send an
invitation to Sara, and, if it’s okay, maybe she can send
it out to all of you, because we’d like you to see what’s going on at Yale.

    DR. GENEL: West campus again?
    MS. WILSON: No. This year, it’s going to be in Harkness.

    DR. GENEL: Okay.
    MS. WILSON: We’re going to try doing it right on the medical school campus.

    MS. HORN: What was the date, again, Paula?
    MS. WILSON: October 19th.
    MS. HORN: Any other public comment? Do we have a motion to adjourn?

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

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

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

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

    DR. WALLACK: Yes. Yom Kippur.
    CHAIRPERSON MULLEN: See, I told you there were holidays coming up.
DR. WALLACK: Yeah, yeah, yeah, you did.

MS. HORN: So is the 25th awkward?

DR. WALLACK: The 25th?

MS. HORN: Yes.

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

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

DR. WALLACK: Right.

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

DR. WALLACK: The 11th.

DR. FISHBONE: I won’t be here.

DR. WALLACK: Can you call in here?

DR. FISHBONE: I have a meeting.

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

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

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

DR. DEES: Works for me.

MS. HORN: September 19th, okay. And what I’ll do is I’ll send out a copy of the current RFP, and we can take a look at what we need to dust off there, because
I think we ought to start thinking about getting that prepped.

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

DR. WALLACK: You’ll have your phone on?

DR. GENEL: I’ll have my phone on.

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

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

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

VOICES: Aye.

(Whereupon, the hearing adjourned at 3:45 p.m.)
# AGENDA

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