

This transcript is the uncertified transcript of the California DHS Human Stem Cell Research (HSCR) Advisory Committee meeting held on December 5, 2006. This transcript has not been reviewed for accuracy and has not been approved by the CDHS HSCR Advisory Committee.

**STATE OF CA**

**Moderator: Shabbir Ahmad  
December 05, 2006  
2:00 pm PST**

Coordinator: At this time, we'd like to thank all participants for holding and let you know you'll be in a listen-only mode until the question and answer session of today's program.

Also, the call is being recorded. If you have any objections, you may disconnect.

I'd like to turn the call over to Hank Greely.

Thank you, sir.

Henry Greely: Thank you.

I'd like to welcome everyone to this teleconference, and I appreciate everyone being willing to put up with telephone conferences.

I'm not a great fan of teleconferences myself, but last week when we made the decision to go to the teleconference, we had only one set of public comments, shortly thereafter we got several more. But at the time, it seemed to me that it was not a good use of people's time to make them travel to a public meeting.

I still think that we now have four sets of public comments and some other things to talk about as well that we should be able to accomplish our goals through a one-hour teleconference meeting.

I don't think most of the comments are likely to be controversial. I hope I'm not proven wrong. We'll see.

But that's the thinking behind doing this in a teleconference mode rather than face-to-face. I do always generally prefer face-to-face meetings as I'm sure most of you do. But under the circumstances, it seemed like a better use of people's time and a better use of the state's money.

So with that said, the rule - let me let you know what the rules of the road are on the teleconference which are little different, I'm afraid, than what we've had been able to do in a face-to-face meeting.

Right now, only the committee members and the staff are in the mode where they can both hear and speak and be heard, at least.

I will open the session to comments from the public at a couple of times. And at that point, public members can speak and will be put into a speak-mode as well as a hear-mode.

It's not as good as being able to see someone frantically waving their hand with a useful factual addition or factual correction, and that's one of the disadvantages of the teleconference mode.

But if those of you listening, who can't speak, come up with such useful corrections, et cetera, please say them and I'll have a couple of moments in the agenda items - in each agenda item for public comment.

In terms of all speakers, whether they're members of the committee, the staff or, when the time comes, members of the public, please identify yourself by name when you first start. And, you know, even you've said 17 things, on the 17th time, still say this is Hank, this is so and so because not all of our voices will be that easily recognizable to everyone listening.

I think that's it for the rules of the road.

I'd like to go to a roll call of the members to make sure we know which members of the committee are here and then proceed from that to find out who from the staff is online at this point.

So, roll call of members, Dr. Blackburn.

Elizabeth Blackburn: Yes. Here. Hello.

Henry Greely: Hello. Welcome.

Dr. Cheshier?

Samuel Cheshier: I'm here.

Henry Greely: Great.

Dr. Dorff?

Not here. Was not, I think, expected.

Dr. Gage?

Also not here. Also not expected.

Hank Greely is here. I can testify to that.

Dr. Lo?

We're hoping to hear from - we're hoping that Bernie will call in. We expect him, but he doesn't seem to be on the line yet.

Dr. Lubin?

Bertram Lubin: Here. Dr. Lubin.

Henry Greely: Dr. Magnus?

David Magnus: Here.

Henry Greely: And Dr. Martinez-Maza?

Otoniel Martinez-Maza: Here.

Henry Greely: Dr. McLean?

Also someone we weren't expecting. I'm afraid Margaret is not on.

Professor Rao?

Radhika Rao: Here.

Henry Greely: Dr. Stock?

I think we were expecting Greg Stock, and we're hoping that he'll be able to join us.

Dr. Weissman?

Also not expected.

So right now, we're expecting nine members of the 13-member committee. We have seven members present at the meeting.

It would be nice if we had more, but I think that's sufficient for us to proceed, both legally and as practical matter.

Who's here from the department staff?

Shabbir Ahmad: Shabbir Ahmad.

Cindy Chambers: Cindy Chambers.

(Amber Christiansen):(Amber Christiansen).

Patricia Rodriguez: Pat Rodriguez.

Henry Greely: Okay.

Anyone else on this call, on speaker-mode who I should know about, who hasn't identified themselves already?

Shabbir Ahmad: We have another state staff...

Henry Greely: I'm sorry.

Shabbir Ahmad: Jackie Wilson. She will be - she's calling Dr. Lo and Dr. Weissman...

Henry Greely: (Unintelligible), probably. Okay.

Woman: Dr. Stock. Yeah.

Henry Greely: Dr. Stock, sorry.

Okay. Good.

One other procedural matter before I turn to the first agenda item and that is the approval of the minutes. You all received both electronically and by hard mail - by regular mail in hard copy the minutes of our last meeting.

Are there any corrections, additions, deletions, et cetera to those minutes?

David Magnus: Thought they were nicely done.

Bertram Lubin: Yes, so did I.

Henry Greely: Whoever you two were, who just said that?

Bertram Lubin: Bert Lubin.

Henry Greely: The staff appreciates it.

David Magnus: David Magnus.

Henry Greely: David and Bert. Okay.

So, is there a motion to approve the minutes of our meeting of September 20, 2006?

Woman: Move.

Henry Greely: Second? Is there a second?

Man: Second.

Henry Greely: All in favor say aye.

Man: Aye.

Woman: Aye.

Woman: Aye.

Henry Greely: All opposed?

Any abstentions?

The chair can't actually say that he sees no disagreement, but here's no disagreement at least.

So the minutes will be considered approved.

Now, before I turn over to the report from the department, let me just ask to make sure. Do any of the members of the committee have anything else they want to add as preliminary matter or is this the agenda and the way of proceeding agreeable to everyone?

Margaret McLean: Hank, this is Margaret McLean. I want to let you know I'm here.

Henry Greely: Great. Wonderful.

Man: Great.

Henry Greely: Excellent. Wherever here is, you're in it.

Margaret McLean: Yes. Wherever it is.

Henry Greely: Any other comments?

Margaret McLean: Bernie just sent an email saying he's on the call. Yeah. This happened to me too. He can hear us but we can't hear him.

Bernie, dial star-0 and you'll get the conference coordinator and she'll open your speaking line. I had the same problem.

Woman: (Unintelligible).

Henry Greely: Okay. Well Bernie - when he comes in, I hope he'll say hello and check in.

Other comments?

All right. Well, let's turn it over then to Dr. Ahmad for a report from the department.

Shabbir Ahmad: Thank you, Hank.

On behalf of the California Department of Health Services, I welcome all of you to the California Human Stem Cell Research Advisory Committee Fourth Meeting.

This committee was created pursuant to (BC 22)...

Bernard Lo: Hi. This is Bernie.

Henry Greely: Hi Bernie. Welcome.

Bernard Lo: Hi. Good to hear you all.

Henry Greely: Good to hear you. You've been hearing us?

Bernard Lo: I've been hearing you. Yes.

Henry Greely: Okay.

Go ahead, Dr. Ahmad. Sorry for the interruption.

Shabbir Ahmad: No problem.

Codified in Chapter 506 Section 125118.5 to provide advice and recommendation to the California Department of Health Services in its development of guidelines for research involving the derivation and use of human embryonic stem cells.

In September 2006, Senate Bill 1260 authored by Ortiz and Runner, was signed by the governor and became law.

It continued the requirement of Senate Bill 322 codified at Section 125118 of the Health and Safety Code that California Department of Health Services create such guidelines.

Senate Bill 1260 added substantial statutory requirements confirming the use of Stem Cell Research Oversight Committee and the process of oocyte donation.

However, SB 1260 did not include any provisions for continuation of the Human Stem Cell Research Advisory Committee beyond December 31, 2006.

Stem cell science has changed and will continue to change rapidly. And according to Hank here, the MCH OFP branch needs update and add to the guidelines for the non-CIRM funded human stem cell research in California.

The program believes that the Advisory Committee has the kind of expertise needed to recommend guidelines for human stem cell research in response to changed scientific and other circumstances.

I am pleased to announce that the human stem cell research program of California Department of Health Services has decided to continue the Advisory Committee for another two years for providing advice and

recommendations to the human stem cell research unit of the MCH OFP branch.

We will receive a formal letter of appointment for the next two years from the program to that effect.

The committee members should have received copies of the following documents electronically of oversight - or overnight courier service. This includes the original comments that we received from Senator Ortiz' office, Center for Genetics and Society, and Pro-Choice Alliance for Responsible Research, and UC Office of the President.

So these are the four public comments, and we have included in your package, or either you received them electronically.

We also included in the package or electronically a matrix of summarized comments from the public and applicable changes to some regulation. This is a matrix, the table in Word format.

We also provided Human Stem Cell Research Advisory Committee proposed guidelines. Also included in your package, CIRM adopted regulations with proposed changes to recordkeeping and material sharing sections, Human Stem Cell Research Advisory Committee teleconference agenda, and Advisory Committee unapproved minutes -- which you already approved.

Also included, either in your email which you received yesterday or in your package which you received this week or last week, is the copy of Senate Bill 1260 and 322.

Members of the public can download these documents from California Department of Health Services, Maternal Child and Adolescent Health, Office of Family Planning Branch Web page, and the address is [www.mch.dhs.ca.gov](http://www.mch.dhs.ca.gov), M like mom, C like cat, H like ham, [mch.dhs.ca.gov](http://mch.dhs.ca.gov).

Henry Greely: But let me advise those of you listening as members of the public that particularly the matrix -- the document posted that lists the various proposals, comments from the public and CIRM regulation changes and ties them to our draft proposed recommendations -- is I think a very useful document. I intend to use it as the guide for our discussion of the public comments.

And if you can, I'd highly - if you don't have it already, I highly recommend you go to the Web site that Dr. Ahmad mentioned and get access to it.

Dr. Ahmad, perhaps you could give that URL one more time.

Shabbir Ahmad: [www.mch.dhs.ca.gov](http://www.mch.dhs.ca.gov).

Henry Greely: Okay.

Shabbir Ahmad: The members - at this moment, the public members they cannot have access to the original comments that came from Senator Ortiz' office or Center or Pro-Choice organization and the UC Office of President. That is because of some resource issues. We could not put them on our Web site today, but they would be available either tomorrow or this week definitely.

We would be posting the original comments on our Web site and the same Web site, [www.mch.dhs.ca.gov](http://www.mch.dhs.ca.gov).

Henry Greely: And if this meeting goes the way I hope it will, each of the comments from each of those four public commenter will be mentioned and discussed in today's meeting. So members of the public listening will be able to hear at least the gist of what those comments are even though we don't have the documents available on the Web site.

Shabbir Ahmad: Yeah. But we try to summarize the major points, most of the points in our matrix which is posted on the Web site.

Henry Greely: Right.

Shabbir Ahmad: The other - I want to take this opportunity also to specifically thank the chair and the vice chair of the committee and also Dr. David Magnus, being the chair of the working group, for their excellent voluntary services to the department. We are very happy to have developed these guidelines, at least at this stage the draft guidelines within a year or less.

Also, one administrative announcement, if you have any travel reimbursement pending, please let me know. You have my email address. Just send me an email.

There are only two pending as far as we know, and we are working on those. One is for Dr. Otoniel Maza and the other one is for Dr. Elliot Dorff. Those are being taken care of.

The other - the last thing - you may be wondering what are the next steps. We will be receiving the final recommended guidelines from the committee through Professor Greely, and then we will be posting those on our Web site, not for comments but only for public access.

They would be - we will be preparing a package for our internal review both by legal as well as by the administration of the department, and we will submit the package of our final approval of these guidelines. And once we have that approval, these would be considered as final guidelines for California Human Stem Cell Research which is not funded by CIRM.

That's all I have, and thank you very much for your time today.

Henry Greely: Okay. Thank you, Dr. Ahmad, and thank you for the kind words to the committee, and thanks the department for deciding to continue our work.

I think -- I'd like to think -- I hope we've been effective and helpful and I hope we can continue to be so, and I hope that all the members of the committee will sign up for another two years.

Let me also, at this moment, read a letter I received - copy of the letter. The letter was actually sent to Secretary Kim Belshé of the California Health and Human Services Agency written by Dr. Robert C. Dynes, the President of the University of California.

He said, "I am writing to express the University of California's appreciation for the work of the California Department of Health Services Human Stem Cell Research Advisory Committee.

"As you will recall, this committee was convened pursuant to Senate Bill 322 to develop guidelines for the ethical and legal conduct of human embryonic stem cell research in California. Its work has been of great value.

“I anticipate that the guidelines it is expected to issue later this year will contribute to the promotion of ethical and effective human embryonic stem cell research in California.

“The group has examined both clinical and non-clinical research involving human embryonic stem cells and has sought to ensure that recommended guidelines are consistent with guidelines already issued or under consideration by the state and national groups.

“Given the complexity of the regulatory structure that surrounds stem cell research, such efforts to ensure consistency are appreciated and help to reduce the regulatory burden on research institutions like UC.

“The leadership shown by the group in its thoughtful examination of the many issues arising from human embryonic stem cell research has been welcomed and is appreciated.

“Please extend my gratitude both to the group’s members and to Professor Henry Greely and Dr. Shabbir Ahmad for ably chairing and staffing the committee.

“I’m sure you are aware, legislative authority for the Advisory Committee extends only until January 1, 2007 at which time Section 125118.5 of the Health and Safety Code, which established the committee, will be repealed.

“I believe that extending the committee’s work beyond January 2007 merits consideration. And I encourage you to examine whether it can continue its work as a standing advisory group to your department.

“As the field of stem cell research continues to develop rapidly, along with the legal and regulatory environment surrounding such research, I believe it could be of significant value for the department to be able to continue to draw upon the insight and advice of the assembled experts on this committee.

“I look forward to what I hope will be the continued contributions of this important committee. Sincerely, Robert C. Dynes.”

So committee, we should all feel patted on the back when the president of the world’s greatest public university is congratulating us for our work and hoping we’ll continue it.

That said, is there any other committee response to the report from the department?

No? Okay.

I don’t really think there’s anything in the report from the department that the public - that public comment would be particularly relevant to. And I’d like to move - we’re already half hour into this meeting, to the guts of the meeting and our discussion of the public comments.

I’m going to do that now. If public - if a member of the public does have something they want to say about that first agenda item, please save it for the next piece. But I think in the interest of efficiency, it’s best for us to move forward to Agenda Item 2: Discussion of draft recommendations in light to public comments and CIRM regulation changes.

My goal today is to get substantive decisions from the committee about how we should respond to these comments. I don’t think it’s sufficient for us to try

to craft language in committee. So my expectation is we'll decide on all of these comments -- whether to adopt them, accept them, whether to reject them, whether to try to deal with them. I think the vast majority of them will probably accept fairly quickly on ones that need new language or new wording.

I and other members of the committee, who I manage to (tragoon) into the act, will do the revisions and then send it on to - if it looks like there's anything controversial, send it back out to the entire committee. If not, just send it directly on to Dr. Ahmad as our recommendations.

Any comments on that process?

I do think trying to draft language in a conference call is even harder than trying to draft language in person -- which is harder than pulling teeth.

Woman: I agree.

Bertram Lubin: I agree. Dr. Lubin.

Henry Greely: Okay.

So, looking at the comments, we've got comments from four public entities, as well as changes from the CIRM and changes that are probably required, that are required, I think, as a result of the adoption and signing by the governor of SB 1260.

You'll remember at our last meeting when we came up with these, SB 1260 had not been signed. It had been passed, but the governor had not signed it. It wasn't, I think, clear to us whether he would or not.

So, some of these changes, I think, will be pretty - many of these changes, I think, will be pretty much pro forma. It does point out some of the difficulties of a moving target -- new legislation can change what the guidelines should be like, changes in the CIRM guideline may - CIRM regulations may change these guidelines.

I think it points out that in the long run, it probably makes sense to have one set of regulations and/or guidelines for the whole state. But we can't do that right now because of the structure of Prop 71.

Maybe it's not useful in the long run, but right now certainly we have to live with two separate sets of guidelines which means that the department - our committee and the department will have to be alert for changes in the CIRM regulations which we'll then have to decide whether we think our guidelines should align with them as the presumption will certainly favor.

We have four sets of public comments, the Pro-Choice Alliance for Responsible Research, the Center for Genetics and Society, State Senator Deborah Ortiz, and the UC Office of the President.

The first three sets are fairly similar, I think, it's fair to say, in both their - in their substance and their concerns.

The four sets in the UC Office of the President raises some additional issues.

The majority, I think, of things we have to talk about, are just caused by changes in the CIRM guidelines, most of which seem to be more in the way of wording than in the way of deep substantive changes.

My proposal is that you all look at the matrix produced by the DHS staff, I think by (Amber). And as we go through that, and we go through that item by item, I'll state each one and we'll see what members want to do with them.

Is that - anybody object to that way of proceeding?

Woman: No. That's good.

Henry Greely: I sure like it better when I can see all your faces.

So Comment 1, General Comment: The guideline should be in (unintelligible) from Senator Ortiz. The guideline should be entirely consistent with SB 1260 rather than with conflicting or different policy CIRM has adopted.

Certainly SB 1260 as a statute controls in a way that the CIRM guideline - the CIRM regulations don't. And that comment's absolutely right. They have to be consistent.

There may be some respects in which some aspects of 1260 may go beyond what our guidelines say, but I appreciate and accept the comment that we need to make sure that the guidelines are consistent with the valid reigning state law, SB 1260.

The alliance had a similar comment asking that we emphasize the importance of the consistency of guidelines with SB 1260 in addition to the CIRM regs and I accept that as well.

So what I propose is we note in the preface, the current status of 1260 that was signed and is law and that is relevant and will come to the specific issues throughout the regulations. As relevant, in the body of the guidelines, we

make comments; we make changes to make it clear what the requirements of 1260 are.

Objections to that?

Bertram Lubin: That sounds fine to me. Lubin.

Henry Greely: Okay.

Item 2, you know, I'm just going to state these and ask for objections. And if you don't say anything, I'll assume you're agreeing, so don't hesitate to speak up.

Include the data collection language from Section 125342 of SB 1260.

David Magnus: Hank, I think - this is David Magnus. I think that sounds great. The only thing to be careful about in the way in which its framed in terms of the language is that there's been a lot of discussion and some of the feedback about guidelines versus regulations and it's important that when we're putting something into the guidelines that are actually statutorily required that we not use the weaker language of guidelines for things that are required by statutes.

Henry Greely: Right. We wouldn't want people to get the impression, because we're citing 1260, that those aspects of 1260 are voluntary in the way guidelines are. I think that's a good point.

I also think the issue with the reporting, the reporting, as I recall from SB 1260, deals with oocyte retrieval procedures which overlap, to some extent, with stem cell research but not perfectly. So when we put these in, we need to make it clear that it only applies to oocyte retrieval that I think we can put that

in Section 8 -- right -- Section 8 of our guidelines that deals with oocyte retrieval.

But we also need to make it clear that it will also apply outside the scope of these guidelines to other oocyte retrievals for research purposes that don't fall within these guidelines.

And really just babbling on in support of your point, David that we need to make it clear that the statute has scope and power beyond the scope and power of the guidelines themselves. But we certainly don't want the guidelines to be inconsistent with the statute or to lead anyone to believe that they can do something less than what the statute requires.

Comments?

Radhika Rao: Hank, this is Radhika Rao.

So, my question here is, in terms of the data collection, it seems that some of the - what Senator Ortiz was asking that our guidelines include listing work - data that were not related to oocyte retrieval.

Henry Greely: From 125342?

Radhika Rao: Yeah. Let's see. She says, "Summaries of proposed research activities that went before that SCRO and the IRB and whether they were approved."

Is that...

((Crosstalk))

Radhika Rao: All the way to SB 1260? I guess so.

Policies and procedures adopted by the SCRO...

Henry Greely: You know, I may be - I was working off the matrix rather than...

Radhika Rao: The actual comments?

Henry Greely: The actual comments. The matrix refers them back to 125342...

Radhika Rao: 125342. Let me look.

Henry Greely: Which deals with research program or project that involves assisted oocyte procurement.

David Magnus: She actually - and so did the - sorry, this is David Magnus.

In her comment and also to the other comment, they recommended that in addition to the oocyte procurement process requirements of SB 1260 that also clinical trial adverse reactions should also be disclosed.

Radhika Rao: Yes. That's what I was thinking. I thought that they were asking about this...

((Crosstalk))

Henry Greely: Okay. So, it actually goes beyond 125342.

Radhika Rao: Yeah. In which case, if we're going to have, you know, mandatory versus kind of, you know, should versus must language, we have to have - do we separate out the different data collection elements?

Henry Greely: To the extent this goes - well, let's start with this question: To the extent it goes beyond the requirements of SB 1260 and 125342, do we think it's a good idea?

So Senator Ortiz, you know, I'm going to hope that the similar comments from the other commenters...

Radhika Rao: I think all three of them, the CGS, the Pro-Choice...

Henry Greely: They used the same...

Radhika Rao: Basically...

Henry Greely: Nine bullet points...

Radhika Rao: They used the same.

David Magnus: Yeah. They all say significant adverse reactions in clinical trial should be reported.

Radhika Rao: Yes.

David Magnus: Now, it's of course obligatory under federal law that they be reported to their IRB and to the FDA.

Radhika Rao: But they also wanted public reporting. This is Radhika Rao.

Henry Greely: Right. And that's an interesting step. Most, you know, that's information that, in general, most of the private entities that generally fund clinical trials consider to be proprietary data.

And so, in general, those things are not adverse events in clinical trials, at least not until after Phase III approval. Those are generally not disclosed to the public. But there are pretty good arguments for why, in general, there's some value to making those kinds of adverse events available to the public.

Radhika Rao: I like that they were making that information available to the public.

Henry Greely: Yeah, me too.

Bertram Lubin: In a way it's like I don't know whether it's to public or whether it's to this committee, but it's like it's functioning like a DSMB, in a certain way, Disease Safety Monitoring Board, and then this committee could make it available to the public or to go directly to the public.

I'd be concerned about going directly to the public without a definition of what the adverse event is.

Shabbir Ahmad: This is Shabbir, Hank. I just want to remind that before a comment is made...

Henry Greely: Identify ourselves.

Shabbir Ahmad: Identify yourselves because it's being recorded.

Henry Greely: Thank you.

Bertram Lubin: So the last one was Bert Lubin.

David Magnus: Right. It was David Magnus before that.

Henry Greely: Well, you know, I'm looking now at the nine different - this is Hank Greely. I'm looking at the nine different points that all three of the sets of public comments are put forward, and I have to confess I'm looking at them substantively for the first time because looking at the language of the comment, I thought they were just incorporating 125342, and they're going quite far beyond that to things like requiring reporting of an overview of all human stem cell research being done at an institution, all the policies and procedures adopted by SCRO, a summary of results, both positive or negative of any non-CIRM funded research or clinical trial.

This strikes me as really quite substantive disclosure requirements and I'm not sure there's a good precedent for that much-mandated disclosure of research results. That doesn't necessarily mean it's a bad thing. But I think this is a fairly - some of those nine items are fairly substantial steps. The adverse reactions is just one of the nine things called for, and most of them are not governed by 125342.

David Magnus: Right. And again, the ways in which, especially both the adverse event reporting to the public and then second, disclosing that particular trials were sent to - or particular research was proposed as SCROs and whether it was approved or not, those are things that they may - and I'm not saying that this is a bad idea. And again, this is David Magnus.

I think some of these may be a very good idea, but we should be aware that many companies will be opposed to this because it can have a very large impact on them.

If, you know, if there's either a disclosure of an adverse event or people know that a trial that they wanted to put at an institution has been then turned down, that's public information, that can actually have a pretty big impact on things like stock prices and all that sort of stuff, and that's one of the reasons why in the past, they've opposed making any of this information public, right? They've generally sought to keep all those things proprietary as they are at the federal level.

Bernard Lo: Yeah. Hank, this is Bernie.

I think this is a tough issue because there's competing things we're trying to do. I think, you know, trying to keep the public informed is a good idea, you know, sort of not putting barriers in the way of researchers and sponsors is also good.

I think we need to think through a little bit more what kind of information the public should have. I mean it seems to me the difference between serious unexpected adverse events or events that cause early termination of a clinical trial, I mean, those kinds of things, I think one can make an argument that the public needs to know.

I think more broader reporting of all results -- positive and negative -- outside the peer review process; I think there are some problems with that.

Man: Yeah.

Bernard Lo: I think primarily we should be encouraging people to publish all results -- positive or negative -- in a peer-reviewed format.

I think putting clinical trials in an nih.gov database so that you know when someone starts a trial and you can sort of track it over time, I think that kind of information, we should go (unintelligible). We need to - and also, I think the real problem with when in the course of adverse events do you go public, you know, I think you currently don't want to supersede DSMB who really can judge whether an adverse event is severe or whether the trend is going to continue.

I think we shouldn't - we should all think, you know, information that's valid and is significant, we think is clear. And where there's a context to interpret it, there's a bad precedent for having all adverse events in all the clinical trials go to every site's IRB and they are overwhelmed with information that was uninterpretable.

Henry Greely: This is Hank again.

You know, I think we should revise the guidelines to incorporate the data collection requirements of SB 1260 125342. To go beyond that with these nine specific items, or at least those of the nine specific items that aren't included in the statute, requires some more substantive thought and discussion, then, I'm afraid, our teleconference format will give.

I'm not - so what I'd propose right now is to see if we agree that we should revise it to include the reporting requirements and the statute and continue for some later consideration whether to expand to all nine of the data collection requirements proposed in the comments. I say it that way because, as I recall, Bernie, didn't you have specific - do you have a specific data collection or reporting suggestion yourself or am I...

Bernard Lo: Right.

((Crosstalk))

Henry Greely: Registered clinical trial.

Bernard Lo: Registered clinical trial.

Henry Greely: So what I propose is we say yes, we'll incorporate 1260s but at this point, put off pending further thought, any further non-statutorily required disclosure requirements of those suggested by the three sets of public comments that recommend such change. We'd recommend, I think, all the same nine elements as well.

Woman: Yeah.

Elizabeth Blackburn: This is Elizabeth Blackburn.

It struck me there was in the third of the list of nine that Senator Ortiz' letter says an overview of all human stem cell research and it strikes me that there's an ambiguity there, for example, someone who was working with, you know, adult skin cells.

Henry Greely: Right.

Elizabeth Blackburn: No relationship at all to pluripotent cells that, you know, that I think really needs clarification. I don't know if there was something like that included in the section.

Henry Greely: There was not.

Elizabeth Blackburn: No, no that one. But even if it were a good idea, I think it has to be much more clarified than in the letter. And I think the same statement was made in two of other public comments. Yes. And one of them says an overview of all human stem cell research being done in the institution.

I don't think that that's their intent.

Henry Greely: Yeah. Okay.

Any objection to my proposal for how to deal with this comment at this point?

David Magnus: Can you clarify it a little—so for right now...

Henry Greely: That we revise the guidelines to say to add the data collection - to note that the data collection requirements of SB 1260 and to note that those will be mandatory to anybody doing research that falls within that but that we not, at this time, add any of the nine specific data collection and reporting requirements that the public commenters have suggested. Since the committee is continuing, that's something that we can consider later for possible amendments to the guidelines, and we may be able to have some discussion of it via email after today's meeting.

David, is that acceptable?

David Magnus: Yeah. And now that we've got another two years, I guess, it's especially - I guess there's not as much pressure to try and get everything done by today.

Radhika Rao: Radhika - this is Radhika, Hank.

Henry Greely: Yeah.

Radhika Rao: But I think then we should be probably, given that we have three - we had both - we had Senator Ortiz and a couple of groups asking about them that we then put these on the agenda for the next.

Henry Greely: I think that makes sense.

David Magnus: I agree.

Bertram Lubin: And I'd like to say, Hank...

((Crosstalk))

Bertram Lubin: When you opened up this meeting today, when we decided to do this by conference, we really only had one comment.

Henry Greely: Right.

Bertram Lubin: I think if we had seen what we have right now, we would have realized it would be better to do this in person.

Henry Greely: But at least that particular comment - I still think the rest of them are - the rest of the comments are relatively easy one way or the other. I have to confess, I looked at it and it said data requirements of 125342 and I didn't read further to see just how much boarder the proposed requirements were than in fact the data requirements of 125342.

So, I'll take some responsibility for not having carefully parsed the comments that we got, some of which - which are worded, to some extent, differently.

But this is much more substantive change than just making it comply with the statute. Okay?

Bertram Lubin: Okay.

Henry Greely: So, moving on.

Another fairly big issue coming both from UCOP and also from Dr. Lo is replacing regulations languages with guidelines - with language more appropriate for guidelines, questions about whether we should use should, must or shall. To some extent, we worked - we talked about this at our previous meeting and this went through the lawyers that the department consulted, and the imperative mood, or whatever it is we've got these in now, has been blessed by the department lawyers.

The way I think about it is you should do this; you shall do this in order to comply with the guidelines. The guidelines themselves are just guidelines that you don't have to comply with. If you want to comply with the guidelines, you shall do the things we say in the guidelines.

Personally, I prefer the current verbs. And apparently, the administrative lawyers for the state are happy with the existing verbs, but others may well disagree.

Bernie?

Bernard Lo: Well, yeah, this is Bernie.

Hank, I think it's a convention, right, it's a linguistic convention and I'm fine. I think it might be worth having a clear sort of - couple of scientists beginning

saying that these are regular - these are guidelines not regulations and we use the terms shall or should to indicate compliance with these guidelines, which, of course, are voluntary and exhortatory, not rigidly required and maybe that would address the UCOP comments Ellen already said.

David Magnus: This is David Magnus.

But again, in that preface, distinguishing between the guidelines that are voluntary and the portions that are - where SB 1260 had been incorporated in where compliance is mandatory.

Man: Yeah.

Bernard Lo: Right. And, you know, again if it's possible and we're drafting where we are actually saying you have to comply with the law or regulation or SB 1260 in particular, then we kind of indicate that and that - right where that text is in our guideline.

Henry Greely: That may be possible. That may be awfully clunky.

Bernard Lo: Yeah.

Henry Greely: To take a look. But it's certainly worth considering and I certainly - this is Hank, I certainly am open to the kind of prefatory language you suggest to undercut the binding nature of the guidelines to point out that the guidelines do not have binding nature.

I think we can - I think I can write that and square the circle.

Other comments on this issue?

Okay. That's it for the ones that say general or say preface.

Some of the specific ones, the comment from UCOP on Page 3, Lines 10 through 12 clarify that not all research involving derivation or use of hESCs will require approval by both SCRO and an IRB. Revise, do some research, yes, I think that's a very good pickup.

But I should say I thought in general all the comments were very useful. Right? All four public comments.

I suggest we accept this comment.

Okay. Hearing no objection, the next one is on Page 4 Lines 7 through 19. This comes from both the alliance and the council - the center, Center of Genetics and Society suggesting that we place a prohibition against the transfer to uterus of a genetically modified human embryo into our guidelines.

We discussed this at our last meeting and decided that since it was only very tangentially, if at all, related to human stem cell research that we didn't think it should go in to these human stem cell research guidelines. We've already considered and discussed it, but does anyone have - want to revisit this question?

David Magnus: David Magnus. I think we were right before.

Henry Greely: Okay.

Anybody else?

Radhika Rao: I think we were - this is Radhika Rao. I think we were right as well. Although if it causes a great deal of controversy, I mean at some level we decided not to include it, not for substantive reasons but simply because we thought it didn't make sense, it went beyond our mandate.

Henry Greely: Yeah. Well, my recommendation and if we can - if we reject this comment and continue to stay with our existing language, again, with the understanding that in doing it we, by no means, mean to endorse the idea of transfer to a uterus of a genetically modified human embryo but it's just to be on the scope of our guidelines. It's something we haven't considered and don't feel we need to consider because it's not closely related to our task.

Objections to that?

Next comment, from the alliance, the majority of SCRO members should not be research scientists and should include at least one community member. The "at least one community member" I think is already incorporated by - in our guidelines as it is in the CIRM requirement. We talked about - that's at Page 7, Page 8.

It must include at least one nonscientist member, the public who's not employed by, appointed to, or remunerated by the relevant research institution, not a family member. In addition, shall include at least one patient advocate.

The first part about a majority not be research scientists is I think new. It is not in our draft, it is not in the CIRM regulations; it's not in the NAS guidelines as far as I know.

Personally, I don't see any reason to impose that requirement, especially given the vast amount of expertise necessary for the proper working of a SCRO. So I would recommend rejecting that. But comments from the committee members?

Otoniel Martinez-Maza: Oto Martinez-Maza. I would agree with your recommendation. I think that there's - being on a SCRO now, there's a tremendous amount of scientific expertise needed to review proposals and I see this thing functionally appropriate.

Henry Greely: Yeah. And I guess I think - I'm not saying that a majority should be research scientists, but I think foreclosing that flexibility given the high scientific requirements would be a mistake.

Other comments from members?

Bertram Lubin: I don't think there should be a restriction.

Henry Greely: Okay.

Bertram Lubin: Lubin.

Henry Greely: The next long set of comments, I think, should all be relatively non-controversial. Most of them involve changes to the CIRM-proposed regulations, and the issue would just be whether we continue to be consistent with them. And as far as I can tell, none of these CIRM changes are sufficiently controversial that there should be any real question about whether - any good reason for us to break consistency for them. So that's Page 8, Lines 3 and 4.

Permissible expenses, Page 8 Lines 6 and 7. In addition, a SCRO committee shall have - actually, I better look at that again. Sorry.

The patient advocate, they've struck the patient advocate. I didn't realize that.

Bernie, can you say anything about that?

Bernard Lo: Okay. Help orient me to what you're asking now.

((Crosstalk))

Henry Greely: It's on the matrix needed the requirement of a patient advocate, is that correct?

Bernard Lo: No, that should not be correct. I mean on the SCRO. Let me...

((Crosstalk))

Henry Greely: Wait a second. It says it was deleted because it was - as it was already included.

Bernard Lo: There's one written here. I mean there's a lot of...

Henry Greely: Okay, that's fine.

Bernard Lo: Changes that have to do with kind of cleaning up the...

((Crosstalk))

Henry Greely: So it's not a substantive change?

We'll redouble our efforts to check that, but assuming that's right then there shouldn't be any problem.

David Magnus: It is correct. It's at Lines 3 and 4...

((Crosstalk))

Bernard Lo: Well, it's a double printing.

((Crosstalk))

Henry Greely: Okay. Good.

Bernard Lo: I'm sorry about that.

Henry Greely: The professional at Page 8 Line 9, professional and financial stake has been cut from the CIRM regulations which is consistent with the UCOP recommendation. Also, IRB was deleted from CIRM regulation. This is at Lines 9 and 10 of Page 8 for us.

Similarly at Page 9 Lines 16 and 18, I'm just going down the matrix here. For such SCRO sentence was deleted from the CIRM regulations.

Page 9 Line 17, UCOP recommends changing "the" to "a" to make sure we're not implying there can only be one expert in assisted reproduction, which strikes me as completely unobjectionable. It's a very good recommendation.

Then though - so, does anybody have any problems with those?

I think from my read, it does look like they should all be completely non-controversial.

Page 10 Line 23, there's a UCOP recommendation that I think is a little tricky. They recommend that we change "The assurance of the confidentiality of the donor is protected" to "Privacy of the donor is protected and the confidentiality of identifiable information is maintained."

That language doesn't bother me; it may even be better language. But I believe that the CIRM regulations continue to use the language that we use, which makes me reluctant to deviate from it.

Anybody have any reactions to that?

Probably a moment when - and it's unfortunate that the public members are cut out. I suspect Ellen Auriti is listening to this and has a good explanation. But I think adding people as speakers is too hard to do for one person at one time.

So Ellen, if you're listening and if you have a good explanation for it, I'll - we'll give you a chance to make it. But at this point, I don't understand why we should make that change.

Does anybody?

Radhika Rao: In her - this is Radhika Rao. In her letter, she says it's because it would more closely mirror federal regulations.

Henry Greely: Well, I can understand that, though I hate to have a deviation from the CIRM regulations, assuming the CIRM regulations aren't themselves incorrect - given incorrect set of rules given the federal regulation which I don't think...

Bernard Lo: Well, one thing we could do is make a recommendation to CIRM to amend the regulations which are now in effect, and this will be, I think, a relatively minor modification. But it will still have to go through the administrative law process.

Henry Greely: Yeah.

Bernard Lo: So that would - I mean we change those if we're to take some time to change.

Henry Greely: Right. I think for today we don't want to change this. But let's - I've started this, and when the public comment period comes up, if Ellen or someone else from UCOP can explain the thinking behind this persuasively. We might want to either change it in the current guidelines or recommend that CIRM change theirs, and when they change theirs we'll change ours.

David Magnus: Hank this is David.

Henry Greely: Yeah.

David Magnus: It does seem to me that the language that's been proposed here is better. It does more closely reflect the federal requirements. My guess is this is going to be one of those minor changes that CIRM will probably be implementing in the near future, and so it might make sense to get a head start for once.

Henry Greely: Okay. Yeah. We don't have to follow - there's no requirement that when changes are made we follow CIRM. But let's put a star by this and see what Ellen or someone else says at the public comments section.

Radhika Rao: And Hank, I agree with David. I do think this language was a little bit better than the CIRM language. This is Radhika Rao.

Henry Greely: I think that's right. I mean not really. Donors don't have confidentiality.

Radhika Rao: Okay.

Henry Greely: Information is confidential.

Radhika Rao: And it seems as if this would be a slightly broader protection because the information would then be protected -- the identifiable information and not just the donor, you know, for example, if the donor is dead or...

Henry Greely: Okay. You guys have convinced me. Presumption pending the public comment, public open session to actually change it, at least if Ellen comes up with a good reason why we should, or that CIRM is - assures us that we won't cause some deep conflict with CIRM's regulations by this.

Next item, Page 12 Lines 2 to 5. These sentences were cut from the CIRM regulations.

Next item, Page 14 Section 7, comment from Senator Ortiz in the center. The language should be directly from SB 1260. This is at Page 14 Section 7 of our draft guidelines.

David Magnus: It's really not just Section 7; I think it's also Section 6.

Henry Greely: Okay.

David Magnus: What I think is tricky is that the way in which the CIRM regulates - this is - sorry, this is David.

Henry Greely: Yeah. Go ahead.

David Magnus: The way in which the CIRM regulations are written and which are - follow - flows in a certain way that's not identical to the way SB 1260 flows. So I would recommend if we're going to bring in the language from SB 1260 and those sections explicitly, it would be worth going through very carefully to see whether there are things that are also included over and above the language from SB 1260 that are in the CIRM regulations that we want to have preserved in our guidelines.

Henry Greely: So basically, we should adopt the thrust of this to make sure that our guidelines are fully consistent with those sections of 12 - of SB 1260.

David Magnus: Right.

Henry Greely: Given the structure of our guidelines and the CIRM regulations, it's probably more than just inserting in exact language, the words from the statutory section will require some thought and some drafting work.

David Magnus: Right?

Henry Greely: I think that makes sense.

Any comments on that? Suggestion for going forward?

So basically, we adopt the thrust of this to make sure that the guidelines are consistent and include the requirements of those sections on SB 1260 but we do it by adapting the language to the structure of our guidelines rather than completely replacing our guideline structure with the statutory structure which won't fit the rest the guidelines very well.

Radhika Rao: That sounds good. This is Radhika.

Henry Greely: Okay.

Hearing no other comments, the next is a UCOP comment. Consider reordering Sections 7 and 8 so it is clear which provisions apply to all covered stem cell research versus research only involving derivation of the human stem cell lines.

I'm not sure that it's unclear, but it's certainly can't hurt to consider reordering them to make sure it's clear. And if we're redoing 7 and 8 in light of SB 1260 anyway, I think this is a good thing for us to bear in mind while trying to make sure we've got SB 1260 covered.

Bernard Lo: Hank, this is Bernie.

I'll agree strongly with that one. We were doing the CIRM regulations. Things that we thought were pretty clear turned out to be very unclear to institution. They were having a lot of trouble understanding it. So I think anything we can do to make clear what applies to whom would be useful.

Henry Greely: Okay. It's that - okay. I'm not sure I see why 7 and 8 are unclear, but it can't hurt to take another look at them and try to make sure they're crystal clear.

UCOP at Page 14 includes the word “knowingly.” To include the word “knowingly” at Page 14 Line 11 as the CIRM regulations do, that’s in “The research shall not compromise the optimal reproductive success of the woman in infertility treatment” so to make that say “shall not compromise” -- “shall not knowingly compromise.”

I think being consistent with the CIRM regs makes sense there as well. And I’ll just - talking slowly because I’m trying to find the precise part of the CIRM regulation that deals with this.

But anyway, I think making sure that these are consistent, certainly a good idea. And if the CIRM regs says “knowingly,” our regs should say “knowingly.”

Radhika Rao: Hank, this is Radhika.

Henry Greely: Yeah.

Radhika Rao: Just to make sure that that is also consistent with SB 1260?

Henry Greely: Yes, of course.

Radhika Rao: Because I can’t remember...

Henry Greely: To the extent it isn’t, then it has to be - then our regs - our guidelines will have to be consistent with 1260 rather than CIRM.

Radhika Rao: Exactly.

Henry Greely: Because we're governed by 1260 and they're not.

Radhika Rao: Yes.

Henry Greely: At least. Yes.

Okay. So that's to be checked and double-checked.

The next one from UCOP. Rather interesting one. At Page 14 Lines 13 and 14, this is the section about requiring - the funded institution has agreed to assume the cost of any medical care required as a direct and proximate result of oocyte donation for research.

There are actually two comments with that sentence. UCOP wants it deleted because it doesn't allow institutions to negotiate medical cost with the commercial sponsors and instead just keep Section 8C on Page 15 which says, "The institution that's performing the research shall develop procedures to ensure that an individual who donates oocytes for covered research has access to medical care at no cost to the donor that is required as the direct and proximate result of the donation."

I think that sounds reasonable. We certainly wouldn't want to foreclose a research institution from - getting a (commitment) from somebody else to do it.

Radhika Rao: Hank, this is Radhika.

Henry Greely: Yeah.

Radhika Rao: A suggestion: maybe we could use the language of SB 1260 and that might help with this problem.

SB1206 says that the IRB has got to make sure - let's see, that it ensure that the subject has access to and coverage for medically appropriate medical care that is required as the direct result of the procedure for research purposes, and the research program or project shall ensure the payment of coverage of resulting medical expenses be provided at no cost to the subject.

Henry Greely: Right, which is different from "has agreed to assume the cost of."

Radhika Rao: Yeah.

Henry Greely: Right. Yeah.

Radhika Rao: So basically, it says...

Henry Greely: You're right.

((Crosstalk))

Radhika Rao: It's got to be covered but it doesn't say who's got to pay for it.

Henry Greely: Yeah. I agree that's superior to the language (unintelligible).

Man: Yeah.

Radhika Rao: So it's either the commercial entity or the research institution -- somebody...

((Crosstalk))

Henry Greely: Somebody has to. Somebody has to be on the hook.

Radhika Rao: Right.

Henry Greely: That also - the same sentence, and this also applies later to 8C, has been commented on by Senator - by the alliance. Our language, like the CIRM language, says “direct and proximate result” that SB 1260 just says “direct result.”

Radhika Rao: Right.

Henry Greely: Drops “proximate.” We talked about that at our last meeting. Given that SB 1260 is passed and it has the language on “direct,” I think we have to also drop the “and proximate” from those.

My own personal preference but - for 1260 would probably be to continue it. But given 1260, I think we have to drop it.

Anyone have thoughts on that?

Radhika Rao: I agree. So I think that we should maybe use the 1260 language here.

Henry Greely: Yeah.

Bernie, you were an advocate before for the “and proximate” language.

Bernard Lo: Well, right. I mean I think, as the letter from Senator Ortiz points out, we have to be in compliance with SB 1260 which is...

Henry Greely: Okay.

Bernard Lo: Legally binding. So I think that for these regulations which are - I'm sorry, for these guidelines, I think we do have to be consistent.

Henry Greely: Okay.

Bernard Lo: Institutions will have, you know, the job of reconciling.

Henry Greely: Right. So the CIRM-funded research, it's one rule; for the non-CIRM funded research; it's another, unless CIRM decides to become consistent with SB 1260 as a voluntary matter.

Shabbir Ahmad: Hank, this is Shabbir.

Henry Greely: Yes, Shabbir?

Shabbir Ahmad: We have extended time for teleconference up to 5 o'clock, so no rush, okay?

Henry Greely: Well, I hope we're done well before that, although I'm already - we're already 14 minutes late. But we started 10 minutes late.

Shabbir Ahmad: Duty to let you know, okay?

Henry Greely: But thank you, I appreciate it. I do think we'll be finished long before that. But I'm glad you've taken care of that.

So, we'll make that change, drop the "and proximate."

Now Page 16 Section 9, UCOP suggests we provide a definition of clinical trial to go in the definition section. Since this is our section added in our guidelines, nonexistent in CIRM about clinical trials. That struck me as perfectly understandable and appropriate suggestion.

David Magnus: This is David Magnus. I have a proposed definition.

((Crosstalk))

David Magnus: A scientifically designed and executed investigation of a medical intervention in humans that is aimed at determining the safety, efficacy, and pharmacological effect (including toxicity, side effects, incompatibilities, interactions) of the intervention. This includes Phases I, II, and III clinical trials under the FDA regulations.

Henry Greely: And did you just make that up or is that taken from somewhere?

David Magnus: I would save a whole bunch of different definitions and sort of put them all together to sort of - I thought this was a good one.

Henry Greely: Okay. Well, with the understanding that we're not going to try to approve that exact language. That certainly sounds like a good start. Nothing - might not approve that exact language. But it's not a knock on the language, I just don't think...

((Crosstalk))

Henry Greely: To do it. But yeah, okay.

Any objections to putting in a good definition of clinical trials and starting with David's starting point to get to a good definition of clinical trials?

Radhika Rao: No. And thanks to David for coming up with a definition.

Henry Greely: Yeah.

Radhika Rao: This is Radhika.

Bernard Lo: Yeah. Could I ask one of the lawyers, I guess I can review, Hank or Radhika or someone else to look at that and compare it to the FDA definition because I mean all these things probably will have to...

Henry Greely: We will.

Bernard Lo: Comply with FDA regs for INDs.

Henry Greely: Yeah. FDA...

((Crosstalk))

Bernard Lo: Ensure that there's no...

Henry Greely: Even specifically defines clinical trials. But one way or the other...

((Crosstalk))

Henry Greely: Our definition will have Phase I clinical trial, Phase II clinical trial, and Phase III clinical trial. So that's one of the reasons why there's some slight variance in terms of how it's defined from institution to institution.

Bernard Lo: Okay.

Henry Greely: Yeah.

So Bernie, yes.

Woman: Yes.

Henry Greely: We'll look at the FDA and other definitions and use it to make sure that David's proposal is consistent.

Okay. We've now got a set of recommendations that are all relatively similar - - well, two recommendations relatively similar, one from the UCOP and one from Dr. Lo who is an employee of the UCOP or who works for an institution governed by the UCOP, both making comments about the delineation of functions between SCROs and IRBs.

The UCOP says, "Give careful consideration to delineation of functions between SCROs and IRBs. Some SCRO responsibilities overlap with traditional roles of IRBs. Institutions should retain flexibility to assign responsibility for certain aspects of review."

Bernie has suggested for IRB and SCRO responsibility, he suggests listing the elements of review and allowing the institutions to assure that review is carried out by a committee with appropriate expertise.

So they're a little bit different, but they're both concerned with the allocation of responsibility between SCROs and IRBs.

Comments?

David Magnus: Well, this is David Magnus. I think I actually disagree. There may be one exception. We had a substantial conversation last time at the meeting about why particular duties were being assigned to particular committees. And my major worry, in general, I think this is the way we've got it laid out -- gives responsibility to IRB for things that they're traditionally responsible for.

The areas of overlap that were identified between IRBs and SCROs that were identified by the University Council or the President's Office were once a week. We said that it was important for having the kind of expertise that a SCRO would provide to look at those kinds of questions about deciding whether or not it's really ready for primetime, whether or not a new stem cell intervention is really ready. And I think experience shows that that kind of expertise really is necessary.

And my worry is if you don't have the sort of delineation of responsibility, then it would be very easy for an institution to just say IRBs already do that, we don't need to have that extra review.

And in the one set of trials that we know of that would fall under these regulations that have already occurred we do know that that it was reviewed by two institutions that had SCROs and one that did not and the two institutions that had SCROs decided not to go forward with that trial and the one that did not decided to go forward. So I think it's actually important to keep the list of assignments the way that it is.

Bernard Lo: This is Bernie, if I could express a different view.

Henry Greely: Of course.

Bernard Lo: I think the problem is that, you know, SCROs are new, different institutions are organizing them differently, and I'm just concerned that some of the tasks actually could fall under one or the other depending on who's on the committee, what their new relationships are, and so forth.

And I, you know, again, I would sort of urge that you not be overly prescriptive, I mean, these after all are guidelines.

And I think it's important to make sure that certain points get considered by a body with appropriate expertise and I think that could happen in a lot of different ways. And I think to sort of assign tasks to bodies that may vary a lot from institution to institution, may not, you know, facilitate the development of things that work at the local level.

When we were developing CIRM regulations, we hear a lot of comments from research institutions who are still setting up SCROs and getting experience, how they're kind of having the communication crosstalk and interactions between their SCROs and IRBs. I think that's going to develop.

And I think, you know, one point of who is to say allow institutions to figure out what seems to work for them rather than sort of push them into a certain mold at the onset. I think what works at Stanford may not work at other institutions and will work at other institutions, may not work at UCSF.

Henry Greely: But two things: I think there's more flexibility in the way it's worded now because it doesn't say, for example, unlike the CIRM regs with regard to creation of stem cell, it doesn't require SCRO scientific review of those things, it simply requires that the SCROs guarantee that those things are

taking place. So if they think that there's another mechanism, it's just saying where the buck stops.

And the reason why I think that's still important is - especially for this particular area. My worry would be that there might be institutions that would be inclined to say well, these are really all IRB issues and we're just going to let our IRB handle it when the IRBs really don't have the kind of expertise that's really needed for the first clinical trials and...

((Crosstalk))

Bernard Lo: Right. Suppose that they could always appoint ad hoc members, they could sort of invite two or three members to the SCRO to come to their (unintelligible) -- lots of ways of gaining expertise. And I would suggest we leave it open to IRB to make sure they have that expertise rather than automatically saying it's got to go a different committee.

Henry Greely: So Bernie, you would eliminate any requirement that a SCRO necessarily be involved in clinical trials of covered stem cells?

Bernard Lo: Well, I think - the point, I think, we want to make - no, I think the point I want to make is that someone's got to do scientific review and the SCRO is likely to be (unintelligible) to have that expertise rather than IRB. But again, if someone's been having SCROs, you know, the majority of members being non-scientists, it may not have that expertise.

So I think that pointing is that someone needs to have - that institutions to have that expertise. And the presumption, I think, that they usually - the SCRO have more advantage than the IRB and has much more expertise with the consent stuff and things like that.

Henry Greely: But the CIRM requires that SCROs do scientific review.

Bernard Lo: Right.

Henry Greely: So, because they're likely to have expertise, doesn't it make sense to have them do the job that's required for the group that has that expertise?

Bernard Lo: Well, but, you know, but I think my problem there is you have two with one thing, the SCROs got to do these and IBR has to do these.

((Crosstalk))

Henry Greely: SCRO have to assure that these have been...

((Crosstalk))

Bernard Lo: Able to be done by the other committee at some institute.

Henry Greely: Yeah.

((Crosstalk))

Man: Doesn't have to do them. The SCRO has to guarantee that they've been done.

Henry Greely: It actually says the SCRO shall require that investigators provide, provide, evaluate, provide, et cetera.

Man: Right.

Henry Greely: I do think David's right that the SCRO doesn't necessarily have to do it.

How about this, guys?

I do think both Bernie and the AC - UCOP are right in urging us to allow institutions to be efficient and to carefully figure out and not try to impose too strong...

Bernard Lo: Procrustes.

Henry Greely: Procrustes and Procrustean bed.

Anyway, not get too micro managerial on this, but at the same time, I would be reluctant to have SCROs completely - to have them involved in all human stem cell research except clinical trial research.

We could add a sentence here encouraging institutions to come up with innovative and flexible ways to integrate the SCRO and IRB functions. But I'd be reluctant to write SCROs, write SCROs out of clinical trial review entirely.

Bernie, does that help from your perspective?

Bernard Lo: Yeah. I mean I think - yeah, I think (unintelligible). These are recommendations.

Henry Greely: Right.

Bernard Lo: Right. So that...

Henry Greely: So from your perspective, if UCSF doesn't like them, you could always ignore them.

Bernard Lo: Right. I would, you know, I guess I would sort of favor an approach that gives more flexibility. And I think it's fine that they disclose - got at least, you know, sign off or review or carry out parts that - of the review that are - that - for which it has, you know, more expertise.

((Crosstalk))

Bernard Lo: The IRB has to do that.

Henry Greely: I think there's space here.

David and Bernie, I think I can write something that will - that you both will find acceptable.

David Magnus: Yeah.

Henry Greely: I'd just say one more time: I tried to make it more flexible by not saying that SCROs had to carry out those things...

David Magnus: Yes.

Henry Greely: Simply make sure that those things took place. But we can make that a little more clear, I think.

Let me - my suggestion is - I try to write something that makes clear the flexibility that David thinks - that David has put into this in ways that make Bernie and the UCOP's concerns less pressing.

David Magnus: Can I just add one other concern I've got about this?

I don't think we should make it so flexible that the thing that Bernie and I both agree on is that there needs to be that scientific expertise...

Henry Greely: Yes.

David Magnus: To really do an adequate review. And my biggest worry is that if you make it too flexible, you'll have a review that's carried out by entities, institutional entities that lack that expertise. And I think that's a real risk.

((Crosstalk))

Bertram Lubin: I agree with that. This is Bert. I mean I think when we discussed this before the IRB, in general, is not an expert in stem cells -- in any kind of stem cells necessarily, but certainly not embryonic stem cells -- and that's what I thought the SCRO was certainly got to be providing that resource before the IRB looked at it.

So it sounds like, Hank, you have a handle on what - to try to address all of this.

Henry Greely: Let me give it a shot.

Again, pending whatever we hear from members of the public in the public comment section. But my current intent would be to try to come up with a language that will address - will retain the parts that David, I think, appropriately thinks are important while addressing and clarifying some of the issues for the UCOP and for Bernie.

I hear no objection to letting me try to do some more writing.

Man: Absolutely.

Henry Greely: Boy. Yeah. I need a better chairman of this committee.

Man: You're doing a great job.

Henry Greely: Yeah, yeah.

Next comment, also from Bernie. And this I think is - we're - we don't have very many comments left and few of them are substantive. This is one of the substantive ones: consider adding a requirement to register clinical trials in the registry such as [clinicaltrials.gov](http://clinicaltrials.gov).

Sounds good to me, but I can't say that I've - I'm deeply familiar with [clinicaltrials.gov](http://clinicaltrials.gov) or with the - any possible implications of this requirement.

Comments from anyone? Bernie or anyone else?

Bernard Lo: No. Well, let me just explain that there's a lot of concern that if there's a clinical trial that started and it has negative results, you know, it gets buried.

And the idea of a clinical trials registry is it needs to know what trials get started, they have to be registered at the onset, you can't publish the article now without its being registered in any journal, plus necessary forced disclosure of negative results. But at least it gives people a sense of what's been tried - what trials have been started.

clinicaltrials.gov is the NIH Web site. There's, you know, this is a work in progress, people are going to be trying to develop other sites. WHO has recommended parameters of what needs to be included in the Web site. And there will be information about, you know, the disease, the type of, you know, the target population enrolled.

There's obviously a lot of concern about what you have to disclose about the intervention and trade secrets concerns. But I think there's a push now to say that some basic information can't be labeled proprietary and kept totally out of the public domain at the onset and I think this would be - again, these are recommendations not requirements, but I think it would be the nice step towards sort of having more transparency in what's been tried.

((Crosstalk))

Henry Greely: Any objections?

Man: Sounds great.

Radhika Rao: No, I like it. Hank, this is Radhika. But I'm just thinking that all of those other data reporting suggestions about clinical trials, so do we want to include some - I mean, do we want to include this requirement to register clinical trials now and then later consider adding those, or do you want to do it all in one section?

Henry Greely: Well, you know, unless anybody has any objections to the registration, I think that sounds like something non-controversial and something we could add at this point. The others, I think, need to be on the agenda for our next meeting because they strike me as some case is substantially more...

Radhika Rao: Onerous.

Henry Greely: Uncertain as to whether they're a good idea or not. But I, you know, as I say, I'm not deeply familiar with this registry idea.

Does anybody have any objections to the idea of the registry?

Radhika Rao: No. I certainly don't have an objection.

Henry Greely: And Bernie, I take it that the registry itself does not require submission of detailed information about the trial other than just the fact that the trial's being done.

Bernard Lo: Right. I mean what information has to be submitted is being hotly debated. And instantly process and this cloning is pushing for publication of results as well as just registration of the trial at the onset. So I think we'll see some changes here.

And I think, again, we should write something that's not so prescriptive that it doesn't allow other things to change as they evolve. But I think it'd be nice to have something saying we want people to know what's being - what clinical trials are starting up.

Henry Greely: Any objection to that?

((Crosstalk))

Bertram Lubin: This is Bert. Do you think we're ready to do this, Bernie?

Bernard Lo: To?

Bertram Lubin: To put - I mean - I don't - I mean I understand the intent of publicizing or notifying all the clinical trials, but it seems like there's a long way to go before we would get to that - get to where we want that to be.

((Crosstalk))

Bernard Lo: Well, I mean, as David mentioned, there is one clinical trial of stem cells is they're fetally derived not embryonically derived. It's actually taking it from a company in California that's being carried out in different states. Geron keeps saying they want to go to the FDA for approval for stem cell trial for spinal cord injuries sometime next year.

So I think, you know, people talk, I don't know. But the timeline for sort of actually starting a clinical trial may be closer than we - some time soon.

Bertram Lubin: Okay. But are you referring now in these clinical trials to embryonic stem cells trials?

Bernard Lo: Well again, I would...

Henry Greely: It's covered cells under...

Bernard Lo: Covered cells. So they would be - not - it has to be, you know, the sort of cord blood issues that, you know, you're (unintelligible). But it'd still be a good idea, I think, but wouldn't necessarily be under covered cells.

Bertram Lubin: Okay. Wouldn't mind the cord blood ones, I think they're pretty straightforward. But I'm just asking that as a question.

Henry Greely: And the covered cells are...

((Crosstalk))

Henry Greely: Pluripotent stem cells or cells differentiated from pluripotent stem cells. It's a covered cell under our definition of cells from covered cell lines or cells differentiated from cells from covered cell lines - covered stem cell lines. Covered stem cell lines means a culture-derived even pluripotent stem cell population that's capable of blah, blah, blah.

Bernard Lo: So it's not adult stem cells or not cord blood stem cells.

((Crosstalk))

Bertram Lubin: Okay.

Henry Greely: Unless you guys manage to find some pluripotent cells and cord blood cells.

Bernard Lo: Work on culturing out.

Bertram Lubin: Right. We're trying.

Henry Greely: Okay. Page 17 Line 15, a Bernie Lo suggestion, changing the wording from - to "donors of biological materials used to produce the covered cells." I think that should be non-controversial.

Basically, Bernie, I think you're pointing out that the language we've got now just talks about biological materials used in the trial -- oocyte, sperm somatic cells -- and this might...

Bernard Lo: It's...

((Crosstalk))

Henry Greely: It's broader. It needs to be a little broader.

This strikes me as a very good recommendation.

Man: Yeah.

Henry Greely: Page 18 Line 2...

Man: Yeah.

Henry Greely: UCOP wants us to change "involved" to "that involve."

Man: Yeah.

Henry Greely: Looks good to me.

Page 18 Line 8, Bernie suggests inserting the word "adequate" before "data safety monitoring board."

Man: Yeah.

Henry Greely: We say, "IRB shall require that any clinical trials involving hESCs and their derivatives shall have an adequate data safety monitoring board" - shall have a "data safety monitoring board" and this would change to it "an adequate data safety monitoring board."

Any objection to that?

Radhika Rao: Certainly didn't want them inadequate.

Henry Greely: Indeed.

Radhika Rao: Data safety monitoring board.

Henry Greely: I think that's a good suggestion.

Then we've got at 18 - page - Line 21...

Man: 45 CFR Part 8 46.

Henry Greely: It's a typo that CIRM managed to cut out.

Page 21 Line 1, CIRM cut out "additional." Again, these are purely typographical. In addition, the "following additional requirements," so they cut out one of the - they cut out the "additional," which I think we should do.

UCOP suggests that on the following line which refers to Subdivision 1 of this regulation that we be clear what we're talking about. Another good suggestion.

Man: I had no clue when I went back and looked at what Subdivision A was referring to.

Henry Greely: Yeah. Neither did I. So we'll have to fix that.

Line 23 on that - the CIRM regulation has changed from “research will not benefit them or any other individuals” to “the research is not intended to benefit.” I think a good suggestion. We’re not guaranteeing it won’t benefit them.

And then Page 22 Lines 4 and 5, CIRM cut out that sentence from its recordkeeping section, the - 22, 4, and 5. The sentence said that “Stem cells developed from their oocytes will be grown in the lab,” et cetera.

I better double check that to make sure that that’s not in SB 1260. But I don’t think it is. So I think that’s something that we might as well comply with CIRM or be consistent with CIRM on.

Questions about that? Comments?

So overall, any other comments on the draft guidelines before we open it up to the very long-suffering and patient members of the public, if there are any still listening to my words?

So to summarize, we’ve gone through this: Most of these recommendations, most of the comments we’re adopting. A couple of them we’ve specifically rejected, they’re not very many, and there are maybe five or six where we need to try some language on in order to see if these will work out.

Well, we’ll try a language to incorporate the thrust - to respond to the thrust of the comment, to adopt the thrust to the comment.

That’s where I think we are in that language. I’ll be drafting some of it. Some of it, David has volunteered to do a definition.

But I think the way I'd expect to proceed is to send the whole thing back around via email to everyone. So I don't - I hope there'll be nothing controversial in it. Let's just give everybody a chance to look at it before we send it to the department. Okay?

Woman: Okay.

Bernard Lo: Hank, I've got a procedural question. Does this need to go out again for public comment or not?

Henry Greely: You know, I don't think so because I'm not even sure that it had to go out legally for public comment at all. Not only is it not a regulation, it's not a guideline.

Bernard Lo: Right.

Henry Greely: It's a recommendation for a guideline.

My understanding is we've put it out for public comment not because we were legally required to but because we were interested in it, because we wanted to hear what the public had to say. The department was interested in it. We were interested in it.

So, you know, that can be - certainly be corrected by the state's lawyers, but I don't think we have to go back for public comment again since we're not even making the guidelines, just making recommendations about the guidelines.

And also, frankly, I don't know that we're making any changes that are -- at least at this stage -- that are all that substantial. We're making some that are

very useful and important -- some typographical, some clarifying, one or two additions. But by and large, I think these changes are relatively minor.

Other comments?

Well, then let's go to the public discussion, and I'll ask our teleconference moderator/coordinator to open this up to the public.

I will, I guess, ask for all public listeners who are eager to speak not to all shout your names at once because I don't know how many of you there will be. But if you're interested in speaking, say so shortly after the thing comes up and I'll establish a list and take you in some appropriate order.

So can we have the listen-only turn-to-speak as well please?

Coordinator: Actually, we can take them one at a time if you'd like.

Henry Greely: Well, but how do we know who went on?

Coordinator: I will announce them by name.

Henry Greely: Okay. So you can do that? Great.

Coordinator: I can.

At this time, if you do have a question or a comment, to press star-1 on your touchtone phone. I'll announce you by name when your line is open.

It's star-1 if you have a question or a comment.

We'll give it a moment or two for our first question.

Henry Greely: I see. So you can handle this on a person-by-person basis, not open it up to everyone all at once.

Coordinator: I can do either one.

Henry Greely: Got it. I like your way.

Coordinator: All right.

If you do have a question or a comment, to press star-1.

Our first question or comment comes from Emily Galpern.

Go ahead, Emily, your line is open.

Emily Galpern: Hi. I just first want to thank the committee for all the work that you've done on putting these recommendations together, particularly in light of many different things you had to consider with CIRM regulations and SB 1260 as a statute now.

So, our primary comments had been around making sure that the department guidelines would be obviously consistent with 1260 and just wanting to focus on that now that it was signed by the governor. And so, we're glad that all those were taken care of during this call.

The only thing, I think, I wanted to highlight was in terms of the professional or financial stake issue. I just wanted to point out - I know that in the summary of comments cut from CIRM regulations, and then suggesting it be

cut from the DHS guidelines, that it refers to the membership of SCRO committee. But I just also wanted to point out in your consideration of this that SB 1260 does talk about financial and professional conflict of interest in terms of the physician or surgeon performing assisted - performing the egg retrieval process, not having a financial interest in the outcome of the research. That's Section 125344.

And then, under Section 125341 that the physician or surgeon - and if their immediate family has any professional interest in the outcome of the research or of the procedure that they disclose it.

So I just wanted to point that out.

Henry Greely: Okay.

Emily Galpern: That that's included in SB 1260.

And in terms of the specific additions to data collection under recordkeeping, I'm glad that the committee will be considering that and I think we could -- ourselves and the Pro-Choice Alliance and Senator Ortiz' office -- could weigh in more once you have further discussion about that issue at your next meeting.

And we had just suggested keeping in the - Page 4 Lines 7 through 19 as CIRM had it in their regulations just as a marker because of the importance of making sure that genetic modification of human embryos doesn't happen. But I understand that committee members felt it went beyond the purview of your mandate.

I just want to say that was why, you know, we thought - because I did include in the CIRM regulations and also because it is something that potentially can happen and is very related to the process of research planning. I thought that it was - be something to highlight to include, but understand the committee's decision.

Henry Greely: Thank you for your comment.

And we should - I suppose I should note you are the author of the comments from the Center for Genetics and Society.

Emily Galpern: Right.

Henry Greely: Which we have received.

As I understand the point about the financial and professional stake, what's cut - what we're cutting out of our guidelines because it's cut out of the CIRM guidelines, you also - I think you mentioned only with the SCRO members, but we'll go back and take another look to make sure we're not getting the implications that SB 1260 requirements that deal with the physicians and other professionals involved in oocyte retrieval don't - somehow don't apply.

Emily Galpern: Right. That was why I wanted to bring it up.

And just the last thing I wanted to say. Nicole Vasquez from Senator Ortiz' office was on the call earlier but had to go to another meeting. I just wanted to let folks know.

Henry Greely: Okay. Thank you.

Emily Galpern: Yeah.

Henry Greely: Next.

Coordinator: And if you have a question or a comment, to press star-1 on your touchtone phone. I'll announce you by name when your line is open -- star-1.

Any questions or any comments from anyone to press star-1.

Henry Greely: We may have outlasted the patience of our Ellen Auriti or whoever else is here from UCOP. I was confident that Ellen would have some comments.

Coordinator: If you have a comment, to press star-1.

Henry Greely: Not necessarily outlasted the patience, but outlasted the time they've allowed for it since we're now 45 minutes later than originally scheduled, for which I apologize.

Radhika Rao: Okay.

((Crosstalk))

Radhika Rao: This is Radhika. On that last point that Emily Galpern made about the professional or financial conflict of interest...

Henry Greely: Right.

Radhika Rao: I think we were changing the language to be consistent with CIRM and they were getting rid of the "professional or financial stake" and just using "conflict of interest."

Henry Greely: Right.

Radhika Rao: Because SB 1260 uses the “financial or professional.” So maybe we could do something like “a conflict of interest, including...”

Henry Greely: Right. Although...

((Crosstalk))

Radhika Rao: “...or financial.”

Henry Greely: Yeah. The 1260 is applying to the doctor or other professionals involved in the oocyte...

Radhika Rao: The oocyte retrieval.

Henry Greely: Retrieval process and our guideline is applying to SCRO members.

Radhika Rao: Okay.

Henry Greely: But I do think we need to make sure that our guidelines don't get read--this goes back to the things that several of you have mentioned. We don't want to make people think that if they comply with our guidelines that means they don't have to comply with other things that are in SB 1260 that aren't specifically addressed by our guidelines.

Radhika Rao: Right.

Henry Greely: We're not immunizing anybody - we can't and wouldn't want to immunize anybody from requirements of 1260 in areas that we're not -- well, period.

Shabbir Ahmad: Hank, this is Shabbir.

Do you want to know who else is like on the public participants' side?

Henry Greely: Well, is there anybody else in the public - nobody else in the public participant side has asked to comment, is that right? We've had nobody else press star-1?

Coordinator: No questions or comments at this time.

Henry Greely: Okay.

Coordinator: If you do have a question or comment, to press star-1.

Shabbir Ahmad: Are there any who does not have any comment but they are there?

Henry Greely: You know, I suppose it's fair for people to be anonymous members of the public...

((Crosstalk))

Henry Greely: People show up at public meetings, we don't ask them to identify themselves unless they're talking.

Coordinator: Okay. If you'd like, I can open the entire conference and they - I have to identify them.

Henry Greely: Well, we will let them identify themselves if they talk.

Coordinator: Okay, very good.

Henry Greely: But I'm just - so Dr. Ahmad, don't think we need to have a reading of or a listing of who has been listening. If they want to listen without their identities known, I think that's...

Shabbir Ahmad: That's fine.

Henry Greely: Fine. So...

David Magnus: Hank?

Henry Greely: Yes?

David Magnus: David Magnus.

In spite of the fact that UCOP Office of the President is not present, I would recommend that for now we adopt their proposal in terms of the change of the language about confidentiality to language about privacy.

Henry Greely: Yes. I'm in favor of that now. I mean...

Radhika Rao: Me too. This is Radhika.

Henry Greely: Yeah.

Radhika Rao: I thought their language was better.

Henry Greely: Okay. Well, I think we've given enough time for anybody to press star-1.

So, at this point, let me ask the committee members again, anybody want to say anything more about Agenda Item 2: Discussion of proposed guidelines?

I'll try to...

((Crosstalk))

Bernard Lo: Thank you, Hank for running a nice meeting and getting us through all of them.

Henry Greely: Well, we're not quite done yet. But I do think - I'll try to turn around another version of this sometime in the next couple of weeks. We're getting into a busy time of year, but I'll try to get it out before very long. No guarantees and specific dates.

I'll also deal with - talk with the department about their time preferences on this.

We do also - so, I'll declare Agenda Item 2 closed. We get to Agenda Item 3: New business.

The only thing I can think of is it appears that we will be continuing and we will have more meetings. We already have one agenda item for our next meeting -- the proposed additional disclosure, data collection and disclosure items from three of the commenters.

If you have additional agenda items for our next meeting, you can state them now or send them in to me or to Shabbir or both of us, preferably. Otherwise, any other new business?

Radhika Rao: Well, Hank, will these guidelines then - do they need to be done by the end of the year now or is that deadline no longer, you know, do we no longer need to comply with it?

Shabbir Ahmad: This is Shabbir. We will prefer that.

Henry Greely: I'll work to try to have that happen. It's not clear to me legally that they have to be, but it certainly would be - it would eliminate one possible question, if we got them out before the first.

David Magnus: And it seems to me given that SB 1260 goes into effect and sort is predicated on the existence of these guidelines.

Henry Greely: It would be a good thing.

David Magnus: We can always make changes to it later, but there should be some guidelines in place for them.

Henry Greely: I think it would be a good thing. And we'll work to try to make that happen. I just have to crack the whip on whoever the poor sucker is who has to do the rewriting.

Okay. I take it there's no other new business. In that case, I do want to thank you all for sticking with it for so long. I know teleconferences are a drag. I'm sorry this went on longer than we advertised and longer than I expected. But I think it's been another useful and productive meeting.

You're a great committee. Thanks to all of you.

The chair will entertain a motion to adjourn.

Radhika Rao: So moved.

Henry Greely: Is there a second?

Elizabeth Blackburn: Second.

Henry Greely: All in favor signify by hanging up.

Thank you very much.

((Crosstalk))

Henry Greely: Happy holidays to you all.

Man: Happy holidays to you, Hank.

Man: Bye.

Man: Bye.

Woman: Bye.

END