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Moderator: Shabbir Ahmad
May 21, 2009
1:00 pm PST

Henry Greely: So with me, David Magnus and I along with Shabbir and Amber are here at room 283 in Stanford Law School. It's the physical home of this teleconference.

Then we've got two committee members here. We need seven for a quorum. Would the other committee members who are on the line identify themselves when I say your name rather than have you all talk at once. I think we've got Margaret on the line, is that correct?

Margaret McLean: That's correct.

Henry Greely: We have Bert Lubin on the line, correct?

Bertram Lubin: Correct.

Henry Greely: Sam Cheshier?

Sam Cheshier: I'm here.

Henry Greely: Elliot Dorff?

Elliot Dorff: Yes, I'm here.

Henry Greely: Radhika Rao?

Radhika Rao: Here.

Henry Greely: I believe that's seven. Any other committee members sneak in while I wasn't listening? Okay. In that case we have a quorum. I think we can get the meeting started.

Operator, if you would give your disclaimer and begin recording.

Coordinator: Thank you. I would like to inform all participants that today's conference is being recorded. If you have any objections you may disconnect at this time.

Thank you and you may begin.

Henry Greely: Thank you very much.

Well greetings, welcome and thanks to all of you for making time out of everybody's busy schedule to have this follow-up meeting.

This is I think in many respects a follow-up meeting to try to come up with language to approve principles that we need to specify, principles that we adopted in theory or in principle, ideas that we adopted in principle at our last couple of meetings.

Let me turn things over to our state tenders. I'm not sure whether - who wants to take it first.

Shabbir Ahmad: Shabbir, yes.

Henry Greely: Shabbir?

Shabbir Ahmad: I don't have much to say except that the California state government is facing a big budget deficit and after May 19 election we are now facing another \$21.3 billion deficit and it seems that there will be some major cuts in the program in the area of education, corrections, social services and health.

Other than that we are on, still on furloughs and staff layoffs are going on, so these are all the downer kind of news from the state. So other than that I don't have anything to add here.

Henry Greely: So we're making very good time but we're lost. Someone else just beeped in. Who just joined the call?

Otoniel Martinez-Maza: Hi. It's Oto Martinez at UCLA. I apologize for joining late.

Henry Greely: No problem. We just got started Oto. I think the next agenda item is approval of meeting minutes from February 20th of '09. These have been distributed to all of you. Are there any changes, corrections, revisions?

David Magnus: It is a very impressive job.

Henry Greely: Could everybody hear David there?

Woman: Yes.

Elliot Dorff: Yes.

Henry Greely: Okay, good. Is there a motion to approve the minutes?

Man: So moved.

Elliot Dorff: So moved.

Henry Greely: I'll take one of those motions. One of those (morable) motions as a second. All in favor say aye.

Elliot Dorff: Aye.

Woman: Aye

Man: Aye

Woman: Aye.

Henry Greely: Anybody opposed? Any abstentions?

Minutes are adopted unanimously.

Okay, so I think this may turn out, although David tells me I'm an optimist and I know I'm an optimist, it may turn out to be a quick meeting I hope.

We really only have two agenda items. One of which is coming up, is approving specific language to implement positions we've taken at our last couple of meetings.

And the other is one we're unfortunately, thanks to your chair's sloth, we really aren't going to be in a position to do anything terribly substantive, and that's the idea of comments on the NIH draft guidelines because those comments are due next Tuesday, May 26th.

So that's why I think we're not going to be able to do anything too substantive, but when we get there if we want to do something I've got an idea or two.

Let's start with the discussion and I hope approval of revisions to various sections. You will recall that we - there've been a couple things that have been troubling us.

Specifically we've been worried about some of the consent status of some of the older cell lines that are out there, as well as the question, more substantive, weighty question I think, of what iPS, what the role of SCROs should be with respect to our guidelines for induced pluripotent stem cells.

David Magnus has done, I think, an excellent job of trying to put into good language the positions that we reached agreement on and I'm going to turn things over to David right now.

I would just tell you that probably the better document, the best document to work from here is the one page double-sided document in your packets headed "Proposed amendments to CDPH Guidelines for Human Stem Cell Research," section 256, version number two and seven, that starts with section two definitions. David?

David Magnus: Thanks. So there were actually several different things we took up last time that are being addressed here.

One issue was the issue of iPSCs and the sense that partly because of our statutory authority, partly for just the reality of the ethical issues, we wanted to restrict the scope of what SCROs we're obligated to review to the issues that are seen as particularly arising fundamentally in application rather than in the derivation itself.

And so a number of changes have been proposed that would do that, although there is one other change to one section that somehow didn't get into the packet and that's also changing in section three, C and E changing the word "covered" to "pluripotent", also should have been included.

So if you take that change along with the other ones that are proposed in section five and section seven and section two, what those serve to do is essentially take off the table SCRO responsibility for review of the derivation of iPSC lines.

But still we would be responsible for reviewing the placement of cells that are derived from any pluripotent cell line into nonhuman animals, into nonhuman primates, into other humans, all the sorts of sensitive things that people wanted to maintain even if they are technically outside of our statutory authority.

But it would exclude the issues around derivation, partly because while derivation of iPSCs might have issues that are worth thinking about they're not very dissimilar from the kinds of issues that IRBs are used to dealing with with tissue procurement more generally.

And there's also other existing guidance for investigators and for IRBs when thinking about those issues.

Henry Greely: Right, and of course they avoid the ethical issues around status of the embryo or the status of gametes.

David Magnus: Right.

Henry Greely: That has driven so much of the controversy around human embryonic stem cells.

David Magnus: Right.

Henry Greely: So David, if I can walk through this, if I've got it right, if we look first at section two in the proposed amendments, what we've done there, what you've suggested there, is to redefine covered stem cells to make it clear that it's a culture derived human pluripotent stem cell, human pluripotent cell, stem cell?

Elliot Dorff: I think the word cell there is not supposed to be there.

Henry Greely: No?

David Magnus: Yes.

Henry Greely: (Unintelligible).

Woman: Take out the first cell.

Henry Greely: Okay. Population derived from an embryo or product of SCNT, that it's capable of blah, blah, blah. The difference there is the addition of the language from an embryo or product of SCNT since pluripotent stem cells, induced pluripotent stem cells won't be from either of those.

This excludes them from the definition of covered cell lines. Then with respect to section five, SCRO committee review and notification, we've put in there in D and in F, involving the use of pluripotent cells rather than the use of covered stem, covered cells.

David Magnus: Right.

Henry Greely: To make it clear that when you're dealing with putting these cells into animals or into humans, into nonhuman animals or into human animals, iPSCs are covered.

Similarly on guideline three, and this is the addition that David realized wasn't included. It didn't get onto the sheet that you've got. That was on three C and E, so three C is the introduction of stem cells into nonhuman primate embryos.

Currently it says from a covered stem cell line the proposal would be to amend that to say from a pluripotent...

David Magnus: Right.

Henry Greely: Human pluripotent stem cell line into nonhuman primate embryos. And E is the breeding prohibition, breeding any animals, any animal into which stem cells from a covered stem cell line having been introduced. Again, change covered stem cell line into human pluripotent stem cell line in order to make it clear that iPSCs are covered by those prohibitions.

And I think the other change on section seven, if you turn your sheet of amendments over, this was to, David, refresh my recollection about why the change was on seven?

David Magnus: It added the word embryonic. When reviewing the proposal to derive new human stem cell lines, now it says new human embryonic stem cell lines.

Henry Greely: Right. So because we're stripping - so because we don't think we, the SCROS need to review the derivation of iPSCs...

David Magnus: Actually, seven as it was worded it's even broader than that and even technically could apply to deriving stem cell lines from fetal tissue. So it's actually extremely broad the way it was originally written.

Henry Greely: So all of those amendments basically go to this idea of limiting SCRO oversight of iPSCs to the things where people seem concerned about iPSCs, about ethical issues of iPSCs, notably their placement into animals, nonhuman animals and their placement into human animals, but not having SCRO oversight elsewhere.

Is there any discussion about that? I think if we break this down and take that first and then move on to section six changes. Any discussion about those changes dealing with iPSCs?

Elliot Dorff: This is Elliot. I agree with everything David has done here and I think it's well done and thank you, David, for, you know, taking the responsibility to do it.

What I'm a little bit worried about and here I'm not a professional in this field, so I mean I have to hear from the people on the call who are, what I'm a little bit worried about is that the distinctions that we're making are going to get lost

in the regulations and I think that kind of an introductory paragraph along the lines of what Hank just said, namely that, you know these regulations cover - to the effect of something like this.

These regulations cover human embryonic stem cells but they also cover pluripotent cells that are derived in other ways. And so where the concerns are about derivation are less, but where there are still concerns about their usage.

And so, you know, it's basically a kind of introductory paragraph to clue people in from the very beginning that what they're about to see are regulations that apply to both kinds of cells so that they don't - so these distinctions don't get lost in the details.

I think you'll have people doing things that, you know, are - they think are permissible because of some section in these rules where as it turns out they're not permissible or the other way around.

Henry Greely: Elliot, I think that's an excellent idea. I think we could probably do that through a preface to the public notice.

Elliot Dorff: Exactly right. Good.

Henry Greely: The preface says here's why we're doing this.

Elliot Dorff: Right.

Bertram Lubin: Well, I was going to ask along - this is Bert - I was going to ask along the same lines. We've been working on pluripotent cells that we get from the placenta. So that would neatly fit into these same categories.

Elliot Dorff: Right.

Henry Greely: Right. It's that they're not embryonic. So they don't - we're not concerned with derivation to the same extent that we are with embryonic cells.

Bertram Lubin: Right.

David Magnus: And the reason why this is important is that under the existing guidelines the actual derivation would have had to accord to all the full informed consent requirements for derivation which aren't - isn't really appropriate for that kind of derivation work.

Henry Greely: The amendment at section seven takes care of that.

Radhika Rao: But, David - this is Radhika - for section seven when you're talking about voluntary informed consent it applies to human embryonic stem cell lines. We also meant to include cloned embryos, didn't we?

David Magnus: The way we defined...

Radhika Rao: Because earlier you defined in the definitions, covered stem cell line means derived from an embryo or product of SCNT...

David Magnus: Right. That's right.

Radhika Rao: So does that - would that include - would human embryonic stem cell lines include lines derived from SCNT?

David Magnus: We could make that derived new covered stem cell line, would that be - would that solve that problem?

Radhika Rao: I think that would be - I think that would solve the problem.

Henry Greely: I think that would...

David Magnus: Let's do that.

Henry Greely: I think that would be a good spot. It also prevents us from using new terms.

David Magnus: Exactly.

Radhika Rao: Yes, so instead of using embryonic stem cells lines in section seven you can just hearken back to section two and do covered stem cell lines.

Henry Greely: Right, good idea. So strike on the amendment to section seven, strike embryonic stem cell lines and substitute...

David Magnus: Covered.

Henry Greely: ...covered stem cell line.

David Magnus: Good idea.

Henry Greely: Other comments?

Geoff Lomax: Could I just ask for a clarification there? This is Geoff.

Henry Greely: Sure.

Geoff Lomax: In what you just said is there a distinction between covered cells in the definition and covered - what did you just say? Covered embryonic?

Henry Greely: No, covered stem cell lines.

Geoff Lomax: So covered stem cell lines...

David Magnus: The word embryonic is now out in section seven.

But in the definition of covered, that now is restricted to either essentially embryonic, pluripotent cells...

Geoff Lomax: Got it. Got it.

So the question is covered cells, which is defined - is that term - is there any - is that term relevant any more in this document because if it is not, and I don't know the answer to it, but if taking that definition, that term out would be helpful.

I'm finding it kind of confusing and I'm just wondering if it's necessary anymore given the modifications you're now proposing?

Henry Greely: Well, the covered cells does get you, via the addition of cells differentiated from covered cell lines.

Geoff Lomax: The problem is I think in all the sections where you require something now you've replaced it with the term pluripotent.

David Magnus: I think that's true for most of them.

Geoff Lomax: You might want to check that. We don't have to solve that but you might want to be aware of that because it's creating a bit of confusion.

Henry Greely: Okay.

Geoff Lomax: So you might just want to check that. There may be sections where it is an operable term still, but you may have just - I don't know.

Henry Greely: Right, I understand. And I also, yes, think that we're not going to be able to nail that down right now.

David Magnus: Yes, and I think Radhika's example in section seven is one case where that works, where it is actually helpful to be able to say that to make sure we capture SCNT.

Henry Greely: Other comments on this from committee members or from members of the public on the line about the issue of amendments to deal with iPSCs? Public, this is a comment period for you, but you don't have to say anything. Okay. Let's take a look then at section six.

David Magnus: Okay, so section six originally what I had wanted to do, the current system is a little complicated because on the one hand the existing CIRM regulations recognize any lines that have been approved by a recognized authority.

At the same time other cell lines that don't have that approval have to meet higher standards and the reality is what that means in practice is there are some cell lines that actually had better consent than some of the lines that are actually officially on the bank but are not allowable.

Also of concern to me, especially in regard to some of those lines, I know the existence of some cell lines that were created prior to the NAS guidelines outside the state of California or Massachusetts, both of which have had rules on the books for some time requiring IRB approval.

And that means if it was done before then IRB approval for de-identified and working with de-identified embryos was not considered human subjects research and in fact the 2002 OHRP guidance document says they were not - IRB approval was not required.

The CIRM regulations require IRB oversight but it's hard to see what going to an IRB and having them tell you this isn't human research so we're not going to review it really gets you compared to some lines that were created at the same time where say a company just decided not to do this.

We also had talked about that as a problem in terms of consistency, thinking about the BresaGen lines and other lines which really didn't necessarily meet all the full standards.

Initially I wanted to create a pretty radical new way of looking at things given the feedback we got at the meeting by some folks and afterwards, as well as Bernie's suggestion that maybe the best way to handle some of these issues is to actually simply publish or put on the Web site some of the existing literature about how SCROs ought to be thinking about reviewing particular cell lines even if they've got approval.

And given the desirability of paralleling CIRM as much as possible I decided to, rather than restrict the scope of what we would allow beyond what CIRM allows, to make a few different changes.

One to make our language more in keeping with the CIRM language so it actually explicitly talks about allowing things to be seen as acceptable if they're approved by a recognized authority, and then I also - that's one thing that I did.

Second thing I did was I added to the list of recognized authorities essentially CIRM itself since CIRM now has a process by which they can approve lines. I've added CIRM as itself a recognized authority.

And then the other thing, I obviously restricted since we've taken iPSC derivation off the table, I've taken all of that out of section six, given what we've already dealt with.

And then another change that I added was to better harmonize between lines that happen to be approved by recognized authority and others that are equally or more ethically derived but don't happen to have that feature.

I added section three which basically says if the lines were created prior to the NAS guidelines but were derived in accord with all the other sections for ethical derivation except being overseen by an IRB, that a SCRO would be able to approve that if the investigator's provided sufficient scientific rationale for the use of the line.

There's been - there are two minor amendments to this that I would like for us add. One is a suggestion that Geoff Lomax just made, which is in if you look at 2B, this is under 6-2B where it says, "donors of human gametes or embryos did not receive valuable consideration," Geoff has suggested essentially that we add something like for participation in research.

The words, "for participation in research," after consideration so that it's clear that it's the payment for research that's prohibited, not incidental payment associated with IVF that might have predated any kind of issues around donation for research.

And then I would also like, this is just an artifact of an earlier - a different version of it when I was working on, if we could delete the words, "as defined in section 2K."

Henry Greely: That's in 6A-2B.

Margaret McLean: Yes, I'm lost in the documents right now, David. Can you...

Henry Greely: Okay, so...

Margaret McLean: ...help me find this?

Henry Greely: That front and back document? That one Proposed Amendments? It's one page front and back.

Margaret McLean: Right.

Henry Greely: Okay. We're talking about section six which starts on the front page, goes over to the back page and the two changes in addition to what's on that piece of paper, two changes that David has suggested are on the back page under 2B.

Margaret McLean: All right, thank you.

Henry Greely: Add after, at the end of the first sentence "for participation in research."

David Magnus: For participation in research.

Henry Greely: And then in the second sentence strike out "as defined in section 2K." It was - nobody can figure out what 2K was about.

So, you know, again, this is the sort of issue that we've talked about earlier with respect to what acceptable derivation of acceptable stem cells are. I think it comports to the conclusions we reached, but of course, the language might be improvable.

Any comments from panel members, from committee members on this set of amendments - oh, let me add one more there.

David Magnus: Right.

Henry Greely: Again, on the back page under three, 3B, "derived prior to the publication of the NAS guidelines," apparently it says paren (2005). As soon as I get back to my office and my computer and I do something I should have done before this, I'd like to say paren (April whatever it was, 2005) to specify the date of publication of the NAS guidelines.

That I think probably would not be a controversial suggestion.

Elliot Dorff: Hank, this is Elliot. Don't we describe - don't the guidelines describe at some point what are acceptable payments? I mean, I think I don't know that 2K is a place to do it, whatever that is, but I think we somewhere in these guidelines we did talk about what are acceptable payments. And it might be a good idea to refer to whatever that is.

David Magnus: It's 2K of the definitions.

Elliot Dorff: Oh, so it really is 2K.

David Magnus: And let's keep it. That's why I had it there.

Elliot Dorff: Oh, there we go. It's right on page two.

Henry Greely: It's close textual reading, so...

Elliot Dorff: That's right. So as I say, in section two...

Henry Greely: Okay.

Elliot Dorff: Section two paragraph K.

David Magnus: Okay, that's what it actually said before I said, "Let's erase it." So let's just leave it there.

Elliot Dorff: Fine.

David Magnus: I guess I knew what I was doing when I had it in there in the first place.

Elliot Dorff: Good.

Henry Greely: If you knew what you were doing it doesn't count if you later forgot that you knew what you were doing.

Elliot Dorff: There's the professor talking.

Henry Greely: Other comments? Any other comments? I heard somebody beep.

Gregory Stock: Yes, it was Greg Stock. I just joined you. I got held up on some other things.

Henry Greely: Hi, Greg. Welcome.

Gregory Stock: Yes.

Henry Greely: We were discussing the proposed amendments, some of which have gotten slightly but non-controversially re-amended. We finished the discussion of how to deal with the amendments that limit SCROs required jurisdiction over iPSCs, induced pluripotent stem cells.

And we are, I think, nearing the completion of our discussion of the amendments dealing with the consent, what's acceptably derived.

Gregory Stock: Okay.

Henry Greely: And if you're looking at your packet, Greg, the piece of paper you most want to look at is the one page front and back headed Proposed Amendments to CDPH Guidelines for Human Stem Cell Research.

Gregory Stock: Okay, got it.

Henry Greely: (Unintelligible). So, other comments on the section 6 amendment?

Radhika Rao: I have one comment. This is Radhika. But it's not really major, it's just the language seems a little - "recognized by an authorized authority?" It's a little awkward but then I was looking at it's exactly identical to the CIRM language, but I like the way that David was describing it as approved by a recognized authority, but it's totally trivial.

I mean, it's a minor change, so if we want to keep it parallel with CIRM we can do this "authorized authority" even though that seems a bit redundant.

Henry Greely: Yes, it's sort of like being acceptably acceptable.

Radhika Rao: Right.

David Magnus: I'm happy to diverge from the language of CIRM in that way because I agree that it's not felicitous. So I'd be happy to say a recognized authority.

Henry Greely: Does our guest from CIRM wish to defend the felicity of authorized authority?

Geoff Lomax: Not at all. I think plain English is always an advantage.

Radhika Rao: So you could change it to approved by a recognized authority as opposed to recognized by an authorized authority.

Geoff Lomax: Yes.

David Magnus: Why don't we just say the stem cell line is recognized by - oh yes, this is just ugly, isn't it?

((Crosstalk))

David Magnus: How about is recognized by a...

Radhika Rao: How about an established authority?

Henry Greely: What we do mean, as Radhika says, we mean approved, not just recognized.

Radhika Rao: Right, approved by, yes.

David Magnus: If we don't say approved then they might write register, license, sometimes they're...

Henry Greely: Yes, but recognized doesn't...

David Magnus: So what's a generic word for approved or licensed or...

Henry Greely: I would go with approved actually.

David Magnus: Okay, so stem cell line is approved...

Henry Greely: ...by a recognized authority.

David Magnus: ...by a recognized authority. To recognize - to be approved...

Henry Greely: I've got recognized...

David Magnus: Approved by a recognized authority the stem cell line must be and then everything else that follows.

Henry Greely: Yes, and then we've got some other (verbs).

David Magnus: Yes right. So that sounds slightly more felicitous than CIRM's language.

Henry Greely: Nyah, nyah, nyah. He said felicitously. Other comments, any comments from members of the public?

Geoff Lomax: One point, this is Geoff again, for A1F I don't think you want - it's not technically right to say it's derived in accordance with? I think it's something like found to be - that's an exemption process and the ICOC is required to make a finding.

Henry Greely: Okay.

Geoff Lomax: So it's a finding type of situation not a condition, not a sort of condition of derivation.

David Magnus: So it has been found to be acceptable in accordance with...

Henry Greely: Well, there's a problem with...

Geoff Lomax: Yes, you can - I think you just have to tweak that or have a staff or a finding. I mean the other thing that I'm...

Henry Greely: Yes, the finding is made by the ICOC not by CIRM more generally.

((Crosstalk))

David Magnus: How about if we say it has been approved by CIRM in accordance with California Code of Regulation, blah, blah, blah.

Geoff Lomax: I think that's more accurate. Yes, I think that's fine. I mean that sounds right. There's probably something wrong with it but who knows what. The other thing just to put out there and this may have to get picked up at a later date, we are also trying to - we are now in the process of a procedure for documenting overall.

For lines that we have funded the derivation of - we are in the process of sort of verifying their provenance through the oversight committee at the institution where they were derived.

And that there will be another level, that that will - we will - the end product will be a list of lines for which we've, you know, been able to establish they've been derived in accordance with our regulations.

David Magnus: That's a great - as soon as that happens we would want anything that's approved by CIRM to be - to count as having been approved by a recognized authority.

Geoff Lomax: Now, I don't know if you actually need a regulation for that because once you've - it really constitutes - once someone's established that then you may be able to just cite the list. I don't know. So it's something to think about.

I don't think we can tackle it here today. We should probably finish and get our - make sure we're - we can post a list of these lines, but I think that's something that should happen very shortly here. We're very far along in that process.

Henry Greely: Great. That would be a helpful thing, I think, to the entire community.

Geoff Lomax: Right.

Henry Greely: Other public comments? Okay, any other member or public comments generally about these amendments? I think we've talked about all of the amendments and I'm about to propose that we're ready for a vote unless somebody else has something to say?

Radhika Rao: One more thing, this is Radhika, on the section that Geoff was just talking about, section six A1F, "derived in accordance with the California Code of Regulations or whatever the CIRM.

Henry Greely: Right.

Radhika Rao: If you look at the CIRM parallel section it says "be derived in accordance with California Code of Regulations section 100090, not 100081.

David Magnus: Correct. They have nothing to do with one another. This F is just basically to add CIRM as a recognized authority. Their addition of their F - it's not clear to me why that belongs under there in the CIRM regulations and so I left that out because it didn't seem to me to be appropriate to be there.

So if - so we're doing two things. We're dropping that requirement which I don't think belongs there and we're adding a new thing which is basically allowing the CIRM process of approval to count as being approved by a...

Radhika Rao: Recognized authority.

David Magnus: ...recognized authority.

Radhika Rao: Okay, I think I understand. So that was kind of an additional provision for CIRM.

David Magnus: Correct.

Radhika Rao: But we are including everything that's been approved by CIRM.

David Magnus: Correct.

Radhika Rao: And so that's why the difference in the numbers?

David Magnus: Right. The 1081, the 100081 section is the section that creates the process by which the ICOC can approve lines through the petition process.

Radhika Rao: Okay.

Henry Greely: And it's the grandfathering.

David Magnus: Obviously CIRM doesn't have to add that into their own regulations, as recognized as an approved authority because it's handled by this other regulation. But we have to add that in if we want to count the things that have gone through that process in CIRM.

Radhika Rao: But don't we want to include all lines that are approved by CIRM, not just those that are grandfathered by CIRM?

David Magnus: These aren't grandfathered. These are ones that have gone through a petition process.

Radhika Rao: Okay.

Henry Greely: Yes, grandfathering was my fault, my mistake.

Radhika Rao: Okay. So this new section, 100081 will include all lines that have been approved by CIRM one way or another?

David Magnus: No, just right now the only way CIRM approves a line currently...

Radhika Rao: Is it goes through...

David Magnus: ...is through this petition process.

Radhika Rao: Okay.

Henry Greely: But Geoff has said that they may very soon have a list of lines that...

Radhika Rao: That they funded.

David Magnus: ...they derived in accordance with the CIRM regulations.

Radhika Rao: Okay. That's what I was thinking of.

Henry Greely: Right. And once they have that we can I think refer to it.

David Magnus: I'm also not sure if we need to because such by definition because of the regulations that CIRM requires...

Henry Greely: Yes.

David Magnus: ...anything that meets that standard automatically meets 6A-2 and so since everything on that list would also be by definition ethically approved by this...

Radhika Rao: Right, right.

David Magnus: ...and so it would be satisfied in any case.

Henry Greely: Exactly. Did someone just come on?

Susan Fogel: Hi, it's Susan Fogel from the Pro-Choice Alliance for Responsible Research.

Henry Greely: Hello, Susan.

Susan Fogel: Good afternoon.

Henry Greely: You've reached us right at what I think is about the end of our first substantive agenda item, the amendments. I'm about to call...

Geoff Lomax: Hank, I - sorry, it's Geoff again.

Henry Greely: Yes?

Geoff Lomax: This is the danger of sending this stuff out; we actually read it. I did have a question...

Henry Greely: Only you, Geoff.

Geoff Lomax: There is - there was a slight change in the standard for research introducing cells into animals and I don't - I think you skipped over it, but is that section now, if I understand it correctly, that any differentiated cells from a human pluripotent stem cell line would require review by the stem cell oversight committee? Am I understanding that correctly?

David Magnus: That is what was suggested by - that the group wanted last time. If it was derived from a pluripotent cell my understanding that is in fact the common SCRO practice.

Geoff Lomax: But it no longer has pluripotent potential or even researcher potential?

Henry Greely: Do we even know whether it has pluripotent potential if it's derived from a pluripotent cell?

David Magnus: That's the issue.

Bertram Lubin: It would have to. Why would it be put in there in the animal model if it didn't have that?

Geoff Lomax: Well, the way it's written it reads like any downstream products of a pluripotent of, say, a human embryonic stem cell line going to animals now requires a review by the oversight committee. That seems like a fairly significant expansion in scope.

Henry Greely: My recollection with that was the Stanford SCRO has been doing and the reason that motivated this were a concern both about as a practical matter how well do we know that a bolus of derived cells, only derived cells doesn't include any remaining pluripotent cells?

And also at this stage, although the science may make this clearer, how confident are we that cells that are derived from these scientifically manipulated embryonic or pluripotent, induced pluripotent cells will stay derived and might not revert?

Geoff Lomax: Okay.

((Crosstalk))

Geoff Lomax: So is this clear? I just wanted to make sure you had a clear intent here of you recognize the scope of this and, you know, that's good to know.

David Magnus: I'd be interested to know if other SCROs don't do that in practice, but in practice that's what we do. If they're derived from pluripotent cells we require SCRO review. It would be interesting to know if other SCROS, and I know that Mike from San Diego's on the line.

Mike Kalichman: Yes.

David Magnus: Mike, do you guys review all of those?

Mike Kalichman: So, at this point we aren't demanding investigators send us those things but when it comes up we deal with it. So whatever comes out of pluripotent stem cells.

Man: Oh, really?

Mike Kalichman: So there is no announced policy about what we're doing.

Otoniel Martinez-Masa: This is Oto at UCLA. I'm on our SCRO here and I think that generally we would review that here.

Bertram Lubin: Yes, and I think at Berkeley they would review it as well. Hello?

Henry Greely: Yes, thank you.

David Magnus: Thanks.

Henry Greely: Okay, other comments from committee members or public? Not hearing any I think I'll call for a vote on this amendment and subsequent, well, first I need

somebody to make a motion to approve the amendments as amended in the course of our conversation.

David Magnus: So moved.

Henry Greely: David so moves. Is there a second?

Elliot Dorff: Second.

Henry Greely: We've had discussion. Any further discussion? All in favor signify by saying aye.

Elliot Dorff: Aye.

Radhika Rao: Aye.

Margaret McLean: Aye.

Man: Aye.

Henry Greely: All opposed, nay. Any abstentions? (Abst)?

Okay, the motion passes unanimously.

We will get a written version of this that we have - as we have tinkered with it today. I think between David, Amber and Shabbir and I we should be able to come up with that.

There was also a request that we have a little preface and I'll write up a paragraph or so on that. It won't be part of the proposed guideline changes but will explain the guideline changes.

We'll circulate that back out just for your information, but it is certainly my hope and expectation that we will accurately reflect today's conversation and the amendments made to the amendments.

Second agenda item, the NIH guidelines. As I'm sure you all know the NIH has come up with proposed guidelines for stem cell research. They've sought comments. The deadline for comments is next Tuesday, May 26th.

A number of individuals and groups have been circulating at comments, some of which I think already have been formally submitted. Some of which will be submitted by the 26th.

Now, CIRM has had comments. The group of prominent ethicists working on these issues including our, absent today from this call, colleague, Bernie Lo, (Alta Charo), (Jonathan Moreno) and others have circulated some comments.

Stanford SCRO has some comments that it's ready to make. A variety of different groups have made comments. I think it's fair to say that most of those comments have focused on two major points.

One, the limitation under the federal guidelines of federal funding to research done on existing or to be created stem cell lines that were made from embryos created for reproductive purposes, and the other is some concerns about the consent and other ethical requirements for lines that were created in the past.

The first one I think is fairly straightforward. It's also, I suspect, highly unlikely to change from the federal government's perspective. The administration's, I believe, political assessment of what was most prudent in terms of federal funding.

The second can get quite technical in terms of what specific amendments should be made. Now if you had a diligent chair we probably would have started the process - would have gotten through a process of trying to come up with some comments as soon as the NIH draft came out.

But you don't and it's now May 21st and May 26th is a short time away and I don't think we can reasonably - I don't think I can reasonably ask or expect us to draft comments on this phone call.

But, you know, we may be able to make a broader - we may want to make a broader statement just saying that, you know, we think the broader kind of restriction is unfortunate, inappropriate, something like that, and the consent requirements or ethical requirements for already existing lines requires greater thought.

This doesn't actually help NIH very much, but it puts us on the same side as CIRM and a variety of other commentators on these issues. Having said that, let me throw it open to people's comments. David, you look like you want to say something?

David Magnus: Well, I think we could - we have two options it seems to me. One is to make some kind of statement of a few very broad principles as you sort of suggest, stating something like, you know, we regret the restriction on - to not allow NIH funding of cell lines derived from embryos that were created specifically for research.

Two; that as a matter of principle, we think that any cell lines that were created in accord with the generally accepted ethical standards for consent and oversight at the time should be allowable.

And three; that because of that there needs to be some kind of mechanism for grandfathering in older lines that don't accord with these standards that were espoused by the NIH. So something like that which are fairly broad principles is one option.

The other option would be to see whether or not people would look at the CIRM statements, are comfortable enough with that that we could join CIRM or simply reiterate CIRM's comments or something close to that so that our voice would be added to the voice of the sort of specific concerns that were raised by - and specific suggestions that were raised by CIRM.

Henry Greely: Although the CIRM comments were not circulated to us, is that correct, at least not in the hard copy packet?

You know it occurs to me, David, from hearing what you said at first, another way, a very general way to do this which is also clearly within positions we've already taken, is to say we think California both through the CIRM and the CDPH guidelines has gotten it right in terms of what should be funded and what kind of research should be funded.

And we think the NIH should give more consideration to adopting the California position. That would both expand beyond reproductive embryos and deal with the kinds of issues around the ethics of the pre-existing lines that both CIRM and us have - CIRM and we?

Radhika Rao: CIRM and we.

Henry Greely: CIRM and we. We and CIRM...

Radhika Rao: Yes.

Henry Greely: ...have thought out over the last several months and years. So other thoughts on this and, you know, we don't have to do anything. I mean, to be honest, I think the chance that hearing from our committee will be the decisive blow that changes minds at NIH is not zero, but probably not substantially greater than zero. And so, thoughts?

Radhika Rao: I like the second approach, Hank, the one that you just mentioned of basically saying that we think that NIH should at least look at the example of California and, you know, we've got regulations saying what should be permitted, that we've worked on.

Margaret McLean: Yes, this is Margaret. I'm going to agree with Radhika on this to just point them in the, you know, in the direction of what we've done here over the period of years rather than over the period of a few weeks and, you know, suggest a serious consideration of the work that's gone on about, you know, regulatory structure and guidelines here.

Bernie Lubin: I like that as well.

David Magnus: Yes, I think that's a good idea, too. What I'm hearing politically is that the approach that we and CIRM have taken, of having the idea of essentially grandfathering in through the mechanism of recognized approval by a recognized authority is one that NIH is not inclined to go with.

At least that's what I've heard, but that doesn't mean we shouldn't push them since as you say, we've got collectively a lot of experience in the state of California and have come to the conclusion that this is a good way to go.

Henry Greely: Other thoughts from committee members?

Elliot Dorff: This is Elliot. I agree completely. I mean I think the Beltway in Washington needs to hear what California's doing.

Henry Greely: Thoughts from the public or committee members who haven't gotten their two cents in yet? Okay, so it sounds like the committee is open to a motion that we send by Tuesday a letter, comments to the NIH suggesting, in commenting on their guidelines, suggesting that they should consider seriously changing their guidelines to be in - to follow the California approach taken by CIRM and taken by us.

I think that we should be able to actually circulate for some wordsmithing or tinkering a draft on that before Tuesday. I can't guarantee that everybody's comments would be fully discussed and incorporated, but does that sound like an appropriate way to proceed?

Elliot Dorff: Yes.

Man: Yes.

Henry Greely: Motion to that effect?

Elliot Dorff: This is Elliot. I'm - so moved. I mean if you want me to articulate it, yes, that we...

Henry Greely: I think that we understand each other.

Elliot Dorff: Okay.

Henry Greely: Okay, it's been moved and seconded. Any further discussion?

Hearing none I'll call for a vote. All in favor signify by saying aye.

Man: Aye.

Woman: Aye.

Man: Aye.

Henry Greely: Any opposed? Any abstentions?

Okay, well that completes our agenda.

Is there anything else anybody wanted to add?

Dr. Ahmad, anything you want to add?

Shabbir Ahmad: (Unintelligible).

Henry Greely: Okay. I mean I do think - I hope that California will continue to have a department of public health.

((Crosstalk))

Shabbir Ahmad: That would be, yes.

Henry Greely: It's one of those situations where it hurts so bad I think all you can do is laugh, but the state budget crisis is only a laughing matter because otherwise we'd be too filled with fears to do anything.

And again, I want to thank very deeply the state employees who continue to work hard for less money and less pay and less recognition and less security and less of everything than they have been in the past.

It is a - this is far beyond the jurisdiction of this committee, but I think our budgeting system in this state just is not working, and we've got to get this fixed somehow.

So the reason I say all that is not just to thank them but to point out that that leads to some significant uncertainty about when our next meeting will be, whether we will have a next meeting, whether there will be a department of health to report to, et cetera.

Shabbir Ahmad: This is Shabbir. I don't see that there will be any, at least in the discussions or what we have been asked last week or are being asked this week, that there is any mention of the advisory committee funding or anything like that.

So I don't see any reason that this committee would not move forward, so it would go forward, but you do not know until it is done.

Henry Greely: Right. Between our committee and vaccinating 1 million kids...

Shabbir Ahmad: Kids.

Henry Greely: I would go with the vaccination myself.

Shabbir Ahmad: We don't have - the committee funding are very minor funds so it's very insubstantial, yes.

Henry Greely: But anyway, I trust that I'm sure the state folks will be in touch with us about future things. Does anybody else have any thoughts or ideas for future agenda items, any new business you want to bring up at this point? David.

David Magnus: I actually do have one suggestion. Following up on Bernie's suggestion that he made at the last meeting, I think it would be very helpful if we could put, start to collect for the Web site the sort of key articles that would help serve as guidance for investigators and for SCROs.

So things like Bernie's recent article about how to address provenance issues. There's a similar article that (Jeremy Sugarman) wrote, the Rob Streiffer article itself, I think all of these would be very helpful. If we could start to collect those on a regular basis and have those, the, you know, contact information to those articles on the Web.

We can't have the actual articles themselves posted because of copyright, so that that can serve as useful guidance without actually having to have formal...

Henry Greely: So the operative part of that is suggestion to all committee members to send all such articles to Amber?

David Magnus: Yes.

Henry Greely: Okay. Good idea.

Shabbir Ahmad: We will do that. Yes.

Henry Greely: Okay, other thoughts?

Bertram Lubin: I'm wondering whether there's - this may not be the - what our committee's supposed to be doing, but I'm just curious if we took a look at therapies that were generated as a consequence of our stem cell activities in the state and what the outcomes have been in humans?

Is that too far down the line to think about? Is that not appropriate for our committee?

Henry Greely: (Unintelligible). You know, that's an interesting issue. I don't know that - I think at least with respect to embryonic or pluripotent stem cells there are no such therapies yet.

David Magnus: Well, trials.

Henry Greely: There's the trial that's announced that should be starting soon, but I think when we reach that stage that may well be something that's useful for our committee to talk about and think about.

Bertram Lubin: I would like to hear that if we get - if when we reach that stage.

Man: Yes.

Henry Greely: Yes. Other thoughts? Well folks, you may have an indolent chair in many respects, but...

Elliot Dorff: We have a very good chair, Hank.

Henry Greely: But I am about to suggest that we can adjourn this meeting 28 minutes before originally scheduled if no one has any grave objection to not taking the entire 90 minutes, the chair will entertain a motion to adjourn.

Man: Moved.

Henry Greely: Moved. Is there a second?

Margaret McLean: Second.

Radhika Rao: Seconded.

Henry Greely: Okay, all in favor say aye.

Radhika Rao: Aye.

Margaret McLean: Aye.

Elliot Dorff: Aye.

Man: Aye.

Henry Greely: Opposed? Abstentions? You who oppose or abstain can stay on for another 28 minutes.

((Crosstalk))

Bertram Lubin: Hank, stay on the line. We can discuss that other...

Henry Greely: Thank you all very much.

Elliot Dorff: Thank you.

Man: Thanks.

Margaret McLean: Thanks, Hank.

Elliot Dorff: Right, bye.

Radhika Rao: Bye.

Margaret McLean: Bye.

END