

This transcript is the uncertified transcript of the California CDPH Human Stem Cell Research (HSCR) Advisory Committee meeting held on July 28, 2008. This transcript has not been reviewed for accuracy and has not been approved by the CDPH HSCR Advisory Committee.

STATE of CA

Moderator: Ms. Heidi Mergenthaler
July 28, 2008
3:00 pm PST

Coordinator: Okay. Thank you. Today's conference is being recorded. If you have any objections you may disconnect at this time. I will now turn the meeting over to Mr. Henry Greely. Thank you. You may begin.

Henry Greely: Thanks. Well, welcome everyone. Thanks very much for joining this meeting on a teleconference that was not originally scheduled. I think as you'll see, we have some good reasons to do it this way, since the alternative was waiting until our next scheduled regular meeting on October 1 to go into some matters that I think have some more urgency.

Why don't we do a roll call of everyone who is on currently, and then we can move to Agenda Item 2 -- Approval of meeting minutes from last meeting. This is Hank Greely from Stanford. I am here. Committee members, please announce yourselves.

Fred Gage: Fred Gage from the Salk Institute.

Bernard Lo: Bernie Lo from UCSF.

Samuel Cheshier: Sam Cheshier from Stanford.

David Magnus: David Magnus from Stanford.

Margaret McLean: Margaret McLean, Santa Clara.

Bertram Lubin: Bert Lubin, Oakland, California.

Henry Greely: Do we have any other committee members on? Okay how about the people from the state? Introduce yourselves please. (Unintelligible).

Shabbir Ahmad: Shabbir Ahmad.

Amber Christiansen: Amber Christiansen.

Heidi Mergenthaler: Heidi Mergenthaler.

Patricia Rodriguez: Patricia Rodriguez.

Henry Greely: And now members of the public.

(Lindsey Parham):(Lindsey Parham) with Program Medical Office, UCSF.

Woman: (Unintelligible) from Stanford.

Woman: (Unintelligible).

Henry Greely: I'm sorry. I think we may have gotten two people together there.

Marcy Darnovski: This is Marcy Darnovski from the Center for Genetics and Society.

Henry Greely: Okay.

Susan Stayn: Susan Stayn from Stanford.

Henry Greely: Okay.

Geoff Lomax: Geoff Lomax, California Institute for Regenerative Medicine.

(Laura Cavanaugh): (Laura Cavanaugh) from the University of California, San Francisco.

Henry Greely: Anybody else on this call? Alright, well sounds like somebody's coming on. I'll ask them to announce themselves, but I think we have a complete and I hope accurate list of who's on it right now.

And that concludes Agenda item number one, I think. Agenda Item 2 -- Approval of meeting minutes from December 5, 2007. Those meetings were in the packets we received. I think they were in the emails that were sent out. That was the meeting down in Los Angeles. Does anybody have any corrections, comments, objections, et cetera, about those meetings - about those minutes? Excuse me, who just joined?

Elliot Dorff: Hi. This is Elliot Dorff. I'm sorry I'm a few minutes late.

Henry Greely: Oh Hi Elliot. Welcome.

Elliot Dorff: Thank you.

Henry Greely: This meeting's being tape - tape recorded. Just thought you should know.

Elliot Dorff: Okay.

Henry Greely: Anybody have any objections, comments, corrections, et cetera to the minutes of the last meeting? You didn't miss much, Elliot.

Elliot Dorff: Okay.

Henry Greely: Hearing none, the Chair will entertain a motion to approve the minutes as written.

Man: So move.

Henry Greely: Is there a second?

Man: Second.

Henry Greely: All in favor say aye.

(All) Aye.

Henry Greely: Any objections? Any - all opposed say nay. Abstentions? I declare the minutes approved. Who just came on our call.

Radhika Rao: Hi, Hank. It's Radhika.

Henry Greely: Hi, Radhika. Welcome. This meeting's being taped.

Radhika Rao: Okay.

Henry Greely: Just thought you should know that.

Radhika Rao: Okay.

Henry Greely: Okay so we're now up to nine committee members. And Shabbir - Dr. Ahmad, you said you had a couple of quick announcements you wanted to make? Why don't you make those right now.

Shabbir Ahmad: Okay. It's just an update. We release the reporting forms end of May, so it has been June and July and they're due August 1. These reporting forms are in response to our 1260 where SCROs provide information on the stem cell research project - embryonic stem cell research project, and the second form is for assisted oocyte production for research.

So far we have received from five institutions or five SCRO committees about the research projects, none so far for assisted oocyte production for research. So this is just an update what's the status of reporting from Californian - California SCROs and programs - stem cell research programs.

The second update is that CIRM standards working group invited us to provide an update on the reporting forms to the committee members -- to the working group members. And I did that last Friday on July 25. I gave a very brief presentation that - why these forms are developed and what are the health and safety codes by which these are being implemented, and gave some samples - information from the forms.

Two issues came. And I think the committee members and others- they need to be aware of. One issue is we asked that any research project that is not fully funded by CIRM has to report - has to fill these forms. There was an issue at the meeting on July 25 by some members of the working group that it should be not only CIRM-funded but also CIRM-sponsored research projects. And those projects should not fill these forms.

So no decision has been taken. This is just an issue raised in that meeting. So we are moving forward as far as our reporting requirements are concerned, but this issue would be taken up by a select group from both working groups and some volunteer advisory committee members from the California Department of Public Health and some legal - other legal and privacy officers from both sides.

So they would start out like - about the definition of CIRM-funded or CIRM sponsored. That's a suggestion I gave at the meeting. The other concern, which is like we received during the public comment period, the concern is that these forms are asking too much confidential information about the donor of the AOP and the - if all these variables are put together, someone can identify who the donor is.

So I have given update to my legal consult. We will have some internal discussion on that, and then I will get back to the advisory committee members later that - how to handle these issues which are coming from CIRM standards, working group members.

So those are the two quick updates. And as you said, we will have October 1 in-person meeting. The details would be coming where and how and when, all those would be provided soon. Yes.

Henry Greely: But it will be in Northern California.

Shabbir Ahmad: Right. It would be in Northern California. Yes.

Henry Greely: Sorry Elliot.

Elliot Dorff: That's alright.

Henry Greely: And Rusty.

Elliot Dorff: Okay.

Henry Greely: Okay, thank you Dr. Ahmad. Anybody have any questions for him? Hearing none, let's move to the main agenda item for today.

Shabbir Ahmad: Okay, thank you.

Henry Greely: And I thought I'd lay out my understanding of this issue and why we're here and then open it to a general discussion by the committee, discussion by the public who are on board. And we may actually have occasion to ask Dr. Lomax a question or two about exactly what the CIRM - what he understands the CIRM regulation - regulatory change to mean.

But basically this is an issue raised by the ability to make induced pluripotent stem cells, taking somatic cells and reprogramming them to become pluripotent in ways that seems to - that seem to mimic even embryonic stem cells quite closely.

The issue here is whether the somatic cells that are used to generate those iPSCs and similar cell lines, need to be - need to have been donated with the same kind of special human embryonic stem cell specific consent that the National Academy standards, the CIRM regulations and the department guidelines require for donation of embryos, eggs, and sperm.

The - all of those bodies, including our recommendations to the department about its guidelines, included somatic cells along with embryos, eggs, and

sperm. At the time the NAS did this, I think the only perceived use of somatic cells in this context was for SCNT - somatic cell nuclear transfer, which is of course is an ethically sensitive and tricky issue.

The work on iPSCs, which has since been replicated either in its original or in modified forms by lots of different groups, makes these pluripotent cell lines without using embryos and without using somatic cell nuclear transfer.

Right now, as I understand it, it's mainly being used to explore how one transforms these into pluripotent cells, whether they're truly pluripotent, whether the gene transfer that's involved in them has - how that changes them from regular HESCs et cetera. In the long-term, I suppose it has potential for treatment implications -- being able to turn somebody's somatic cell into a pluripotent cell - may be an easier way of avoiding immune problems than anything else.

And it certainly has some potential -- or at least it's believed to have potential -- for studying specific diseases. So if you wanted to understand Huntington's disease better, maybe what you could do is make a pluripotent cell line from somebody with the Huntington's mutation, turn those pluripotent cells into brain cells, neuro cells, and other cells -- neurons and glial cells, et cetera, in an effort to understand better what happens.

The key thing about this approach for our purposes I think is it never involves an embryo, and it never involves -- or at least need not involve -- in this classic way, in the way of doing it that we're talking about, does not involve somatic cell nuclear transfer.

We had this - we had on our agenda for the December meeting talking about whether the guidelines should change in light of iPSCs, but we never reached

that agenda item because the forms took up so much time. Then we - were going to schedule a meeting this spring, which never happened. I feel remiss in this that we didn't act more quickly on this issue. The CIRM working group held a telephone conference call on this very issue exactly one year and one day ago -- on July 27, 2007.

CIRM proposed regulations went through their regulatory process and those regulations became effective. Regulatory changes became effective on June 29. So since June 29, the new CIRM regulations have governed the use of somatic cells for these purposes and CIRM-funded research, but our guidelines have not changed.

The most relevant CIRM changes are in section 100080 and 100090. Unfortunately we sent you 80 and 100 instead, but Heidi sent along as an email with an attachment the changes or the new language in 100090. So you should have those

The change in 80 was to add Section A3, which says, "Acceptable research materials will include stem cell lines that are derived from non-identifiable human somatic cells under the following two conditions -- the derivation did not result from somatic cell nuclear transfer or from the creation or use of the human embryo, and the somatic cells are -- deidentified in a way consistent with the Office of Human Research Protection Guidance on appropriate - the identification of cells."

Basically they're either anonymous or they are not easily or readily linkable. Not easily or - the identities are not easily or readily ascertainable by anybody else. And that's what CIRM proposed and that got passed.

Section 100090 has also been amended. It now says in Part B, that its Part A doesn't apply to CIRM-funded research intended to derive a covered cell line from somatic cells when the SCRO committee has determined that the requirements of 80, A3-A and A3-B have been met. Let me go back and explain what I just said, which I didn't say very well.

Section 90 deals with additional requirements for CIRM-funded derivation. 90A, which was all of 90-4 said that the requirements of A2 must have been met, which includes - and that the requirements for anything subsequent of Section 100100 Subdivision B for informed consent must be met.

Now the one is 100100 Subdivision B is the detailed stem cell specific consent requirements of the regulations stemming from the NAS guidelines and copied by or paralleled by our guidelines. So those are the things that say when you're doing informed consent for stem cell work, you've got to tell people it may be used indefinitely, that there may be genetic modifications, that the cells may be put into non-human animals, et cetera, et cetera.

Under the amendment to 90 and the amendment to 80, you don't have to have that kind of specific inform - as I understand them, you don't have to have that kind of specific informed consent in order to either derive nuclear potent cell lines using IPSC using somatic cells or in order to use cell lines - pluripotent cell lines derived from somatic cells as long as those somatic cells were - are unidentifiable and were - what's the other part? And didn't result from the use of an embryo or from SCNT.

So that, as I understand it, is the CIRM change. We have not made a change or recommended the department make a change in its guidelines. So the department's guidelines would still require that if you wanted to turn a somatic cell into an IPSC line, that somatic cell would have had to have been

taken from the donor with an informed consent that - if it's new that met the requirements - the full stem cell consent requirements -- laid out in Section 100100.

Why this is important is that lots of people are very interested in this new method of deriving pluripotent cells. There's an awful lot of research and excitement about the research going on. And A, many people want to use older, well established cell lines to try to do these transformations or derivations for using like, let's say fibroblast lines purchased from ATCC, been around for a long time, that are well characterized that are well understood, but were not donated with the kind of consent that we require for specific stem cell research.

So I think the driving force behind this in reading the minutes of last year's meeting of the working group of the CIRM working group was to use these older well established cell lines for which the full kind of consent required by the CIRM regulations was not taken and was not available.

There is also the issue of getting new cells and using them and it's not entirely clear to me what the CIRM regulations say about newly acquired somatic cells, but I think for our purposes we have to think about should we change - should we recommend that the department change its guidelines to parallel the CIRM guidelines with respect to somatic cells that have previously been acquired as well as with respect to somatic cells that may be acquired in the future and used for this purpose.

As we all know, you know, our preference, as we have stated it, has been to try to be as parallel as possible to the CIRM regulations given our somewhat slightly different legal environment. It's not completely possible to do that,

but to be as similar as possible to avoid making life more difficult for California researchers and for the research that's been done.

The argument I think for exempting these kinds of cells is that they don't raise the same kinds of ethical problems for donors that donating an embryo, donating eggs, donating sperm, that donating materials that will be used for somatic cell nuclear transfer or used to create an embryo, do. It - there is no embryo involved in this research. There are no eggs, no sperm, nothing that can be called cloning that's involved in this research in and of itself.

So the thought is that makes - that reasonable donors would be much less concerned about their materials being used for these purposes. So that's sort of my take on this. I'm happy to invite other members of the committee to comment on it.

Elliot Dorff: I agree with the drift of what -- this is Elliot talking. I agree with the drift of what you've been saying -- that we should change our regulations and the way that CIRM did because of the very reasons that you just mentioned. I mean I think the concerns that we had for requiring informed consent when we were talking about embryos, just simply don't exist with somatic cells in the same way.

And so both in the substance and also in terms of just simply being in conformity with CIRM, I think we should change our regulations in the same way to make it - to make them the same.

Henry Greely: Other comments?

Bertram Lubin: This is Bert from Oakland. I completely agree with both of you. And I think the potential for drug development that's personalized or related to a

particular individual is great with this technology. And that restrictions that we had before with embryonic tissues don't exist with this. And I think this - I think we should definitely make a change.

Man: (Unintelligible).

Henry Greely: Now let me add one thing before asking anybody else to say (it). One thing that does bother me about this -- I think that people actually are doing this research now in California. There's even some publications that seem to indicate that, which means consciously or not they're violating the guidelines.

Now what the consequences -- legal and otherwise -- of violating the guidelines are isn't clear, but all other things being equal, I'd like to have practice and guidelines in conformity. That doesn't mean we should always change the guidelines because people are violating them, but it's a concern.

Man: Right.

Henry Greely: Other comments from committee members?

Bernard Lo: Hi this is Bernie Lo. I also agree with you and the previous two members that we should alter the CDPH guidelines.

Henry Greely: I didn't actually take a position on it.

Bernard Lo: Okay. Well I was...

Henry Greely: (Unintelligible) think that. But okay.

Bernard Lo: ...I'll agree with the previous (unintelligible) people. And I just want to point out, it's making a consistent not just with CIRM but with the common rule as interpreted by the federal agencies.

Henry Greely: Right.

Bernard Lo: The scientists in California who are doing this kind of research are following what they understand which in fact they're told are the federal regulations for human subjects experiments which do exclude this sort of deidentified or unidentifiable use of existing biological material. I also support changing the - our guidelines to be consistent with CIRM.

I just want to point out something that I think may not be apparent, which there is exclusion from the detailed consent requirements doesn't apply if the somatic cell is going to be a used to create an embryo or SCNT. So I think there are protections against (unintelligible) sensitive kinds of research that are not implicated for the IPS (unintelligible) changes (unintelligible).

Henry Greely: Right. that's quite clear in the - 10008 - well it's clear in the (unintelligible). you got it. Other comments.

Fred Gage: Hi this is Rusty Gage. I fully agree that we should modify these to be consistent with CIRM's measured proposal.

Henry Greely: Rusty, how exciting and important is this research do you think, as one of our scientist members?

Fred Gage: Right. This is very important. There are - there's at least one paper coming out in Science very shortly on human IPS for a disease, demonstrating that from an - a freshly isolated biopsy, ES like cells can be generated from that

individual in-vitro, and they can be induced to differentiate into specific lineages. And...

Henry Greely: I'll watch for it.

Fred Gage: ...so it's here. And that's not from California.

Henry Greely: Okay.

Fred Gage: This is a - this is going to be potentially very, very useful and will be something that will actually facilitate and support the objective of the California initiative.

Henry Greely: Okay. Let's see, Radhika, Margaret, David and any other committee members I'm forgetting?

David Magnus: I - obviously I'm in favor of this as well. I think your point also about the - what actual practice is. It's not just that people are going to flaunt it, it's that in practice given how easy it is - turns out to be in terms of different possibilities for doing genetic manipulation. It's in practice impossible to enforce, because graduate students are working on this on different cell lines and fiddling around with different genes to see whether or not they can induce pluripotency. So I think in practice it's just not possible to enforce this, and it's not desirable to enforce it.

Radhika Rao: Hank?

Henry Greely: Yes.

Radhika Rao: This is Radhika. I am also in favor of this. But I also have a question too. And perhaps it's in there and I didn't see it clearly enough. So this would mean that if you've used them already available somatic cell in - and induce it to become pluripotent, then you wouldn't have to follow the same informed consent requirements. But what if you do it in the future?

Henry Greely: That's an excellent question and one I had intended to raise, because it's not quite clear to me what the CIRM regulations says about that. To the extent its human subjects research to take the cell from somebody...

Radhika Rao: Right.

Henry Greely: ...presumably still got IRB considerations under the common rule. Let me...

Radhika Rao: Right. but it's not the same level of informed consent that we've been requiring.

Henry Greely: Right.

Radhika Rao: And do we want to make a differentiation between already existing cells and future, you know, (unintelligible) cells?

Henry Greely: So let me kick that over to either Dr. Lo as a member of the working group at CIRM or Dr. Lomax from CIRM. What do you guys understand the current CIRM regulation to say with respect to newly collected cells - somatic cells to be used for this purpose?

Geoff Lomax: You want me to take a shot at that, Bernie? I guess I'm on then. It's...

Henry Greely: Sounds like it.

Geoff Lomax: I need to go back and, you know, track this exactly. So I'll say this with a slight caveat of, you know, I'm subject to - I'd need to go back and look at this, but I believe the way it - we've tried to construct this is that if you were collecting those somatic cells with our funding, with the intent of deriving a covered stem cell line...

Woman: Yes.

Geoff Lomax: ...then our full consent provisions kick in. Where there's a sort of quote/unquote gap, which I think you were alluding to in your question, would be if those - if someone else were to procure the lines and they were sitting in a bank somewhere and they met the criteria that Hank described, then they are actually available for use.

So for example there was nothing in the provision that said, you know, subject to some cut-off date, because that's what you would need to sort of capture this - that contingency. So what we're trying to do is very much get our funded researchers to use the more detailed consent, particularly when they're collecting any somatic cell embryo or gamete for the purpose of deriving a line.

But where the sort of reach gets more difficult is that materials that may enter sort of a bank or repository outside of our funding stream it just gets a little bit challenging to sort of dictate to the rest of the world.

Henry Greely: So Geoff if I understand you, would it be then if a CIRM-funded researcher says, "You know, I really need some somatic cells from somebody with Huntington's disease..."

Geoff Lomax: Yes.

Henry Greely: ...and goes out and says, "I'm going to find somebody with Huntington's disease to get some somatic cells so I can make an iPSC." They would fall under the full requirements of 100100B.

Geoff Lomax: That's how I've been advising grantees that had that question, yes.

Henry Greely: But if somebody were to say, "Gee, I could really use a Huntington's cell. Ah, my buddy, you know, Jane who works on Huntington's has a bunch of Huntington cells already available. I'm going to get them from her. I'm going to get them from her or from ATCC or I'm going to go them from someplace else," then it wouldn't fall under 100100B?

Geoff Lomax: Correct.

Henry Greely: Okay.

Geoff Lomax: Not if they met the conditions that you described earlier.

Henry Greely: Right. Right.

Fred Gage: Can I interject then, because I'm - this is Rusty again. Why - let me just look at it from another direction. From the perspective of the scientists, there are populations of patients with - that have been very, very well characterized for their disease with a range of phenotypes with MRIs and blood samples and genetic information that, for which there were no cell lines of their skin ever made or any other kind of tissue.

But would be ideal for - this range of patients would be ideal for IPS so that you could actually begin to examine the variability in population within a particular gene disease.

Am I understanding that this is going to make that much more difficult to do than if you just by chance somebody had made lines earlier. Am I missing something?

Henry Greely: Geoff, I think that's a question for you.

Geoff Lomax: Well not necessarily because I mean if - I mean the way it's set up is it presumes for the most part that most of the individuals who have - if you've got living individuals and you know who they are and they're well characterized, presumably you'd be able to consent them, because the value of those materials sort of either therapeutically or clinically would be that they're not anonymized, and you can get back to a donor and, you know, get consent.

So ideally one would want to get consent.

Henry Greely: Even apart from the anonymization, if you're going to get something from a new person, I mean to get something new from an existing living person, you're going to have to consent them as a result of the common rule.

Man: Right.

Man: Yes.

Henry Greely: And if you're going to have to consent them anyway Rusty, I think as I understand what Geoff has said what this means is if you're consenting them for IPSC purposes you need to use a stem cell consent form and not an

ordinary every day consent form. So I don't think you'd be requirements - I don't think this requires you -- as I understand it -- to consent to do consent when you otherwise wouldn't, but it may change - it may require you to use a longer form.

Man: Right.

Henry Greely: And is that terribly problematic?

Fred Gage: I'm not...

Henry Greely: It's a hassle. (I know).

Fred Gage: It's a hassle. And I just want to know why. I can understand...

Henry Greely: Yes.

Fred Gage: ...that you would do that and you would make that rule, but what is - where's the concern?

Geoff Lomax: Well this is again - it's interesting though -- keep in mind this is where it is interesting when you're sort of looking at the scope of the state regulations versus CIRM regulations.

I mean this requirements falls on our grantees and the working group felt it was reasonable to consent to a certain level, particularly since we're funding for the researcher to do that. It wouldn't rule out the use of materials that have - that could make it a more generic standard, which materials, you know, still could be used. Or - so it's - and so it - again the catch is, it's - where the point

of who's performing the procurement and the point of procurement of the, you know, original somatic cells.

And we're trying to set it up in a way - if you're doing the initial procurement of the somatic cells, to really do it with the most effective consent possible. And we think that's entirely reasonable and sort of consistent with the ethical conduct of research.

Henry Greely: And I suppose one could argue that although there are no embryos involved and there is no SCNT involved, so the most sensitive issues are not involved in this, you are still making from somebody a pluripotent line with their DNA, with their genome, that has potentially unexpected and unpredictable long-term consequences for them, both positive and perhaps maybe negative.

So maybe that's the way in which reasonable subject might have - a reason why a reasonable subject might have higher concern about this than some other forms.

Fred Gage: I think that makes sense. I think it's somehow it's including that -I'm just speaking here in a voice not necessarily of my own exclusively...

Henry Greely: Oh.

Fred Gage: ...but if I (unintelligible) of those that I'm representing. And it's going to be another, you know, people are going to wonder why there...

Henry Greely: Correct.

Fred Gage: ...(unintelligible) hurdle. So...

Henry Greely: Right.

Fred Gage: ...that being said, I - there - I see a loophole.

Henry Greely: Yes.

Fred Gage: And that is that you get your IRB to consent in stages. So you get your IRB to consent for biopsy...

Henry Greely: Ah.

Fred Gage: ...(unintelligible) cell lines, and then you make your cell lines. Now you've got your cell lines and you go through a second step. Now the cell lines are already there to do - say something else. You want to do genetics, you want to do something (unintelligible) because blood's not always the best genetic material to do your...

Henry Greely: Yes.

Fred Gage: ...genetic analysis on, so you could stage this.

And I'm not saying that anybody would do this...

Henry Greely: Right.

Fred Gage: ...but am I wrong in thinking that that could happen?

David Magnus: But wouldn't that be more work than just putting in a paragraph in the consent form that says...

Fred Gage: Yes.

David Magnus: ...you know, this may be put in animals, it may be genetically modified, it may be kept for many years? I mean wouldn't it be just easier to just put a paragraph...

Fred Gage: I guess.

David Magnus: ...have - that's boiler plate into the consent forms?

Bertram Lubin: Well isn't this -- this is Bert -- isn't this what people are thinking about when they develop these repositories of samples from disease - related to particular disease conditions to try to be as comprehensive as possible when consent is obtained so that you don't have to go back...

Henry Greely: Yes.

Bertram Lubin: ...if a new thing comes up that you want to use this repository for? I mean I think that would make the most sense for this, rather than say I develop something and somebody in Atlanta wanted to use a line that I've developed from a sickle cell patient who had a particular mild disease versus sickle cell patient who had a severe disease because they had something new.

Would I have to go back to those two patients who had those two phenotypic variations and get requests to permit this to go to Atlanta? I mean that's a question I guess.

Radhika Rao: This is Radhika speaking. That's kind of one of the reasons why I raised this issue, because I thought in terms of lines - in terms of somatic cells that already exist maybe, you know, we want to ease up on the informed consent

requirements. But if we're talking about withdrawing new samples of somatic cells and then in the future creating a precedent for what's going to happen, maybe we want to keep the informed consent requirements because exactly as Bert said, you don't know what might be - what it might be used for later.

Henry Greely: And as I understand from Geoff's comment, his understanding of the regulations is that they would require the special broad stem cell consent if the person doing the extraction receiving the donation of the cells intended at that time to use them for derivation of a new iPSC line. But not if they had - if a different person or they had some different intent. Right Geoff?

Geoff Lomax: Yes. again, we tend to look at it a little bit more in the context...

Henry Greely: Right.

Geoff Lomax: ...of what is the funded proposal (unintelligible).

Henry Greely: Right. You regulate proposals and grantees.

Geoff Lomax: Yes. So I mean we're - so I think kind of functionally it's left sort of speculative. It's like there's a proposal, we're going to collect some cells, we're going to do this with them for the purpose of that experiment. So...

Henry Greely: Right.

Geoff Lomax: ...we figure in that case you clearly - yes, that's a terrific opportunity to, you know, get - do a bang up job on the consent side, so why not do it.

Henry Greely: Okay.

Geoff Lomax: And then there's other - I mean you - again, there's some other scenarios where materials can get utilized by sort of a different standard on sort of the consent side. And that's consistent with the national academy's acceptably derived standards. So it, you know, there's gradations of this, but obviously yes we're trying to get as much as we can on the front end for our funded research where there's procurement of material.

Henry Greely: Got it.

David Magnus: (Unintelligible) Can I say I think that actually it - the distinction that CIRM made in their regulatory approach though may make have some virtue to it. I mean I think the elements of the informed consent form would be good to be in there for donors going forward, because it's pretty comprehensive. It covers things that we know some people do care about. There are some people who do object to the idea of - or would object to the idea of pluripotent cells derived from their cells being put into non-human animals. And this would cover that.

And so it seems like it's a really good optimally good consent form. And so if somebody's intending to do this kind of research, iPSC research -- it seems like putting out a guideline that endorses that as the standard to SCROs and IRBs it seems to be is a good and worthy idea.

But I think going as far as making it a requirements going forward for any new cell lines, that to me seems to presumptuous because if people in Atlanta are creating cell lines, if people from anywhere are creating cell lines or procuring tissue from groups of patients that will have a broad range of usage and they have informed consent for a fairly broad range of usage, but it's not optimal from our point of view that it doesn't cover every single element of

the consent form. Maybe it doesn't state that they're going to be kept for many years.

Though - may be merely implied, but it's not explicitly stated, then it seem to me saying, "You can't use any cells from those sources," is too restrictive to researchers. So I think saying if you know you're - that you're doing this kind of research and you're going to be getting informed consent anyway, why not do a very, very good job?

But if the cells are out there somewhere, then, you know, then requiring that they meet every single element of the consent process I think is asking too much.

Henry Greely: Yes. I don't think we've heard from Margaret or Sam. I want to - you don't have to say anything, but I want to make sure you have an opportunity to comment.

Samuel Cheshier: Yes, I - this is Sam. I tend to agree with allowing the cells that have already been derived to be used. But I'm a person who actually gets consent from patients for use of their particular research and from a logistic standpoint it doesn't add any work at all to explain, you know, one more point regarding future use of the cells.

So that certainly, at least in my (unintelligible) a barrier.

Henry Greely: Good. Thank you. Margaret?

Margaret McLean: Yes. this is Margaret. Radhika actually asked my question but it was a good one for (unintelligible) how much conversation this generated. I do think that there is an ethically relevant difference between, you know, those cells

that have already been procured and the procurement of new cells with the intent of forming, you know, new iPSC lines.

And so our conversation that those ought to have different levels of rigor in their informed consent processes, I'm in agreement that we ought to probably lighten up on, you know, on, you know, the necessary consent for those cells that already exist, but, you know, going forward as it's been said with, you know, cells specifically derived to create new cell lines, we ought to have a more robust informed consent process consistent with what we discussed previously.

Henry Greely: Okay. Committee members, I'd like to - and unless some of - unless one of you has a really urgent thing, I'd like to give the public listeners a chance to comment here. Anybody need to jump in right now? No? Anybody from the public want to say anything? Geoff, Marcy, others?

Woman: No thank you.

Henry Greely: Okay. Well back to the committee. Any further comments on this? So, you know, I think committee meetings and particularly conference calls, are not the world's best places to try drafting language. And I don't propose - I don't suggest - in fact I strongly suggest that we don't try to draft specific language here.

But I think we probably - it sounds to me like we could get - like we might be willing to accept a motion that we recommend to the department that it amend the guidelines to be consistent with the CIRM regulatory changes such that existing cell lines don't need the special stem cell consent. Existing somatic cells don't need the special use in - the use of existing cells or lines derived from existing cells don't require the special consent that's consistent with the

CIRM interpretation that if you have new - if you're newly collecting somatic cells for this purpose, the special consent requirements should apply.

Man: (Unintelligible).

Henry Greely: Is that a fair statement of where we are?

Elliot Dorff: Yes. Elliot Dorff. So moved.

Henry Greely: Okay. Well Elliot thank you, but anybody want to amend that as - I'm open to friendly amendments if I didn't capture it correctly.

David Magnus: Why not just say we move that we mirror the language of the CIRM regulations?

Henry Greely: I actually like mine a little better because frankly that - in reading the CIRM regulations, the distinction that Geoff drew between existing and new cells didn't really jump out at me.

David Magnus: Well I don't think that's what we're saying, though. I think we're not saying it's a difference between existing and new cells. I think it's the difference between cells that are being created specifically for iPSCs versus cell lines or tissues that occur from a bank without regard to date.

Henry Greely: That's fair, but even that distinction didn't really jump out at me from the CIRM regulatory change. So I liked my motion - I like my wording because it made clear that we're concerned about that. If we just tried to copy over the CIRM language, that might not come through.

Man: (Unintelligible) I...

Woman: I like Hank's wording as well.

Man: I like Hank's wording as well.

Man: Right. That's fine.

Radhika Rao: This is Radhika. I like Hank's wording, and I think it's better actually because I think the CIRM wording doesn't quite apply to us because...

Henry Greely: Yes.

Radhika Rao: ...as Geoff was saying, it's really the proposal. And CIRM funding, and we don't have that. So we can't say to somebody, you know, that we're funding you and if you intend to, you know, derive a stem cell line, then you have to follow the special consent procedures.

Fred Gage: Do we need to have any preamble to this explaining why we are changing or do we just change it?

Henry Greely: Well we don't change anything. We just make a recommendation to...

Fred Gage: Yes, yes, yes.

Henry Greely: ...the department.

Man: (Unintelligible).

Henry Greely: And I think the transcript of this meeting should make that clear. If the department wants a write-up, I'm sure that I or somebody can write something

up and send it around to the committee for blessing. But I think the transcript should make it clear. The committee - the department probably will want to put some sort of preamble about why it's doing this.

Shabbir Ahmad: Yes, we can put it together when we submit the recommendation from the advisory committee for - and approval process within the department. But we would need a actual wording of the regulation that need to be included. Not regulation -- guidelines that need to be included...

Henry Greely: Right.

Shabbir Ahmad: ...in the guidelines.

Henry Greely: And I...

Shabbir Ahmad: ...(unintelligible) committee.

Henry Greely: ...think some of us would be happy to work with you at that, but I don't think the teleconference is the right place to try to work out that wording. So...

Shabbir Ahmad: Oh yes (unintelligible).

Henry Greely: ...for this meeting I think we pass the resolution about what our intent is, and then I or others - and others would be - would try to suggest some wording that would capture that intent.

Shabbir Ahmad: Thank you.

Henry Greely: Is that okay?

Shabbir Ahmad: That's fine. Thank you.

Henry Greely: Elliot, you willing to say so moved again?

Elliot Dorff: Yes, absolutely. So moved.

Henry Greely: Is there a second?

Man: Sec

Woman: Second.

Henry Greely: Is there any further discussion? Any discussion? Hearing none, let me call for a vote. All in favor signify by saying aye.

Man: Aye.

(All): Aye.

Henry Greely: All opposed. Any abstentions? The motion passes unanimously. That's our agenda item for today. We will meet on October 1. I do want to say one thing about one issue that's come up. I thought about trying to put it on the agenda for this, but it was too soon. We didn't have enough time I thought and the situation's still a little fluid.

Rob Streiffer from the University of Wisconsin published a really interesting piece in the Hastings Center Report just I think last month. He got from NIH through the Freedom of Information Act because they wouldn't give them over any other way, the consent forms that were used supposedly, according to the NIH, as the basis of the NIH approved cell lines.

His article in analyzing that, found some real reasons to - what he viewed -- and I agree with him -- as real reasons to be concerned about the consents from the Cellartis lines addition the BresaGen lines. I think this is something that SCROs around the state and ESCROs around the country. Need to take seriously, will be taking seriously, and I think it's something that unless other intervening events happen between now and October 1, will probably be on our October 1 agenda.

Fundamentally, the BresaGen consent was not a research consent. It was a clinical consent with one sentence about research, and it said it would only use embryos that were multiply fertilized, eggs that were multiply fertilized or embryos that had ceased all development. The Cellartis consent said they were going to use - they might use some of the embryos to study how long cells could be kept alive in culture and as soon as those studies were done, they would destroy the cells.

So there's a concern with both of these that they really never got consent for making embryonic stem cell lines in a pretty fundamental way. I'm not suggesting we discuss that or decide that at all today, but I wanted to raise it to you as something that's going on that I think we are likely to see again on, and even before October 1.

Any other comments from anybody? Well committee members, Department of Public Health. What are you again?

Shabbir Ahmad: California Department of Public Health.

Man: There we go.

Henry Greely: California - former DHS people. Now California Department of Public Health people and members of the public, thank you very much for participating in this teleconference, which I would note, is going to conclude two minutes early if someone will move to adjourn.

Man: I move to adjourn.

Henry Greely: Is there a second?

Woman: Second.

Man: I second.

Henry Greely: All those in favor hang up.

Man: Bye.

Henry Greely: Thanks guys.

END