

This transcript is the uncertified transcript of the California CDPH Human Stem Cell Research (HSCR) Advisory Committee meeting held on September 24, 2007. This transcript has not been reviewed for accuracy and has not been approved by the CDPH HSCR Advisory Committee.

STATE OF CA-DHCS (US)

**Moderator: Shabbir Ahmad
September 24, 2007
2:00 pm PST**

Coordinator: Welcome and thank you for standing by. At this time all participants are in a listen only mode. During the question and answer session please press star 1 on your touchtone phone.

Today's conference is being recorded. If you have any objections you may disconnect at this time. Now I will turn the meeting over to Mr. Shabbir Ahmad. Thank you, you may begin.

Henry Greely: Thank you, Dr. Ahmad, thank you all for coming. Welcome, it's good to see all of you. It's been awhile. Thanks for coming to this meeting. I have a sense that we may not need the full three hours planned. I hope no one will end up objecting seriously to that. But there are some important - this important issue about the meeting that I want to start by asking Dr. Ahmad to explain.

Shabbir Ahmad: Shabbir Ahmad. The intent of the meeting (unintelligible) said that there are two requirements in 1260 - SB 1260 that the SCRO committees report to the department about the projects they have reviewed over the year. And the second requirement is about the demographics and effects of oocyte donation for research.

So the department staff who are working in the stem cell unit they have the consultation within the department and with others and developed two forms for this committee to consider so that we can post these forms on our web page so that the public can start giving us their comments or to the committee - their comments. What need to be add - what need to be added, what need to be deleted. So that's (unintelligible).

Now the issue with today's meeting, and that is an honest mistake on our part and I fully take the responsibility. These forms they have not been posted on our Web page. Although meeting notice laws but for some reason they did not go over the Web page. There are many reasons that I can go over but just to be brief.

So I have talked to Professor Greely these forms can be discussed with the committee. Today's call we will record suggestions from the committee and then we will update these forms and post them on our Web page for public comments and then in the next meeting the committee can make decisions on these forms. Whether they should be adopted or changed in light of public comments.

So that's comment I want to make at the start of the meeting. And the second meeting if the committee is available I think that we are thinking sometime in November.

Henry Greely: So if I understand this properly as a result of legal requirements having to do with California's meeting laws this is not an official meeting in the sense that we cannot take any action. Not sure anyone would complain if we approved the minutes at the last meeting. But even that might be iffy. But I don't think we can act at this meeting, but we can talk at this meeting. There was notice of

the meeting that went out but not notice of the specific documents that were part of Agenda Item 5.

So we'll talk, we'll discuss. We'll also discuss Agenda Item 6, remaining items from our December meeting. I think we never did end up setting up the update on clinical trials, I believe. So we have a relatively short agenda as it is. And as it turns out it's an advisory agenda - it's a discussion meeting only. And we're sorry for the fact that that's the way it's turned out. But also sorry of course to the members of the public and the others who didn't get a full opportunity to comment on the agenda because it wasn't posted.

You will of course have that opportunity before we have a decision meeting probably in November. So any comments on that?

David Magnus: Can we approve the minutes or not?

Henry Greely: We can try. I don't know that it would be illegal for us to - well, you know. Let's - before we approve minutes let's make sure we have for the recording purposes at least everybody who's here so why don't the committee members and staff say hello. Say hello to each other as well. And do we have any committee members on the phone as far as we know?

Is Rusty on the phone? Dr. Gage? Rusty if you're there hit whatever you were supposed to hit and say hello.

Anyway, I'm Hank Greely. Happy to be here. Radhika why don't you go next.

Radhika Rao: Radhika Rao here as well.

Alex Lucas: Alex Lucas. I'm here instead of Bert Lubin.

Elliot Dorff: I'm Elliot Dorff. I just wanted to take this opportunity to mention that my university has merged with Brandeis-Bardin Institute and we now have a new name and a new email address. The regular address is the same and so is the phone number. But it's the American Jewish University it's called now. And so we couldn't use AJU.edu because that's Andrew Jackson University. So we're...

Man: Andrew Jackson University.

Elliot Dorff: That's right, in Birmingham, Alabama. I never heard of it before. But anyway, I looked it up. But it's Edorff@ajula.edu.

Henry Greely: A-j-u-l-a...

Elliot Dorff: L-a- dot edu. As of October 1, the uj one won't work anymore.

Henry Greely: Okay, thank you Elliot.

David Magnus: David Magnus from Stanford and number 3.

Sam Cheshier: Sam Cheshier from Stanford.

Pat Rodriguez: Pat Rodriguez from the Department of Public Health.

Cindy Chambers: Cindy Chambers, Department of Public Health.

Shabbir Ahmad: Shabbir Ahmad, Department of Public Health.

Otoniel Martinez-Maza: Oto Martinez-Maza, UCLA.

Bernard Lo: Bernard Lo, UCSF. I want to thank CHORI and Bert Lubin who's not here for having a meeting in my own backyard (unintelligible).

Henry Greely: You'd of had trouble crossing the bridge.

Margaret McLean: Margaret McLean, Santa Clara University.

Henry Greely: I think we've gone through the committee and staff. Rusty if you're on - is it star 61? Star 1 to say something.

Well currently I guess we'll assume that Rusty's not on until we hear from him. I also want to thank Bert and the Children's Hospital of Oakland Research Institute for hosting us yet again. It's always such a nice facility to come to in this beautiful room. And relatively central at least for those of us in Northern California. This is particularly nice of Bert because we scheduled the meeting at a time that we knew he could not make.

Not out of any desire to shut Bert out but because as you might guess scheduling this group makes herding cats look easy and this was the date on which we could get the - that we could have the smallest number of people absent, still a non-trivial number of people who weren't able to be here. But we really appreciate Bert opening CHORI for us even on a day when he can't be here.

Alex Lucas: Well I want to welcome you...

Coordinator: Excuse me, we do have Rusty Gage online.

Man: Good...

Fred Gage: Can you hear me?

Henry Greely: Yes, hi how are you?

Fred Gage: Hi I've been here I just was unsuccessful at logging in so I thank the Operator for doing that.

Henry Greely: Okay, well.

Fred Gage: Good to be here.

Henry Greely: The phone system makes even scientists confused, right?

Fred Gage: Right, exactly.

Henry Greely: Okay. So we've got the welcome and introductions. Why don't we put up for tentative approval the minutes. And if it turns out it's concluded that we can't even approve minutes at this meeting then this action will have been null and void. But I don't think it will hurt anything. Does anybody have any changes in the minutes?

David Magnus: I was extremely impressed at how thorough they were.

Henry Greely: And frightening, actually.

Man: Yeah.

Henry Greely: Is there a motion to approve the minutes?

Man: Moved.

Henry Greely: Second?

Woman: Second.

Henry Greely: All in favor say, 'Aye'.

((Crosstalk))

Man: Aye.

Woman: Aye.

Henry Greely: Opposed, Nay.

Abstension? Rusty?

Fred Gage: Yes, approved.

Henry Greely: Good, thank you. So the meeting- the minutes are approved if and to the extent legally possible.

So Shabbir would you give us the report on the guidelines and the committee?

((Crosstalk))

Henry Greely: I thought about having them come around later but I suppose that it certainly can't hurt. So members of the public - I think you've got to come closer so we can make sure we can get you on tape. Is there a mic right at the end?

Come on up and tell us, if you wish, who you are. I don't think we require you to but we encourage you to.

Jesse Reynolds: Yeah thanks, hi. I'm Jesse Reynolds from the Center for Genetics and Society. And I do want to say certainly the Center has appreciated the opportunity - the ongoing opportunity that we've had to provide input into the discussions in these meetings. We do want to express our concern that the meeting was not noticed in a manner that has allowed us at this time for this meeting.

We do recognize this may have occurred from simple mistake and that no decisions are to be taken. But I suppose I just want to express this concern for the record and we're continuing to work with you.

Henry Greely: The record reflects it.

Jesse Reynolds: Thank you.

Henry Greely: Anybody else? Come on up and say hello.

Ellen Auriti: Hi. Ellen Auriti from the University of California Office to the President. Glad to have the opportunity to be here.

Henry Greely: Ellen. Don't all rush the microphone at once, folks.

Geoffrey Lomax: Good afternoon, Geoff Lomax with CIRM.

Henry Greely: Thank you Geoff.

There are several other people in the room who are not coming forward.
Anybody else on the phone who wants to identify themselves? And is able to
successfully negotiate the message for doing so?

Coordinator: If there is please press star 1.

Henry Greely: Thank you Operator. We're hearing no one at this point. Back to you Dr.
Ahmad.

Shabbir Ahmad: Thank you very much and I again apologize for this oversight on our part. I
have a few updates, fyi's before I go into the guidelines and these meetings in
detail.

As most of you know that California Department of Health Services has been
split into two departments. There is California Department of Public Health
now as of July 1. And the other department is California Department of Health
Care Services.

Health Care Services is mostly Medi-Cal, Medicare and Public Health is
everything dealing with infectious the public health issues. The management
in the Department of Public Health the transition from one department to two
department has been very smooth although there are some bumps here and
there in the road but, you know, for this big organization the move from one
organization to two organizations so you can imagine some of the issues. But
so far it has been fairly good.

The second announcement I have is Dr. Susann Steinberg who was my boss,
she has gone on extended leave. She was the Chief of Maternal, Child and
Adolescent Health Division and the department has asked me to step in to be

the acting for at least six months. So we will see where she's coming back or not we will update you at that time.

So regarding the human stem cell research guidelines- in end of last year Professor Greely provided final recommendations to the department. We submitted that to the director office, the director signed it, it went to the agency and we are putting - we have actually the package as an fyi for the agency. But the guidelines have been approved and by the director of the Department of Public Health. And they have been posted on the web page of the department. And the site is (www.mcah.dhs.ca.gov) then it you can - it can lead you to stem cell projects.

I just want to give also a heads up they are having some discussions within the department. There are two bills which relate to cord blood banking, -- AB 34 and SB 962. Both bills have been gone through the Senate and Assembly and they are now enrolled. I will give one copy to Professor Greely.

If they are signed by the Governor as the law then this committee may have some additional responsibility of providing some assistance and technical and recommendations on cord blood banking to the department. So this is just a heads up. We don't know whether they would be - these bills would be signed or not. But it's just - you can actually go to the California legislation site and you can download these enrolled bills. They are AB 34, Portantino and SB 962, Senator Migden.

Henry Greely: Actually I'll go download them and send them around.

Shabbir Ahmad: We can send the link to everybody. Now the 1260 has two requirements among the other. But the main requirements...

Henry Greely: Now Shabbir you're beginning to move into the discussion on the reporting forms or is this still general introduction...

Shabbir Ahmad: Reporting forms.

Henry Greely: Why don't we hold that.

Shabbir Ahmad: Okay.

Henry Greely: Are you done with your report on the guidelines and committee status?

Shabbir Ahmad: That is correct.

Henry Greely: Comments, questions? I would note by the way what I provided within my role as humble scribe trying to figure out and write down what we decided at our last teleconference meeting. And also in some back and forth negotiation with the lawyers for the department over what could or, should - which tense and mood of various verbs -- should, could, might, may, shall -- be used with respect to it. But I wasn't trying to do anything - make any substantive decisions as final (unintelligible) hand. But that's now been out for awhile.

Any other questions or comments for Dr. Ahmad?

Radhika Rao: Just a question on the committee status. This is Radhika Rao. We are now committee - does it say how long? Does the department know how long we are to stay in effect?

Shabbir Ahmad: In the (context) in December 31, 2006 the program, the stem cell research program, and the California Department of Health Services at that time, now

the California Department of Public Health. The program decided to extend the committee for another three years.

Radhika Rao: Three?

Henry Greely: Two?

Shabbir Ahmad: Two or three. I do not - we can check the records. I think it was two years if I remember or recall correctly. So that - it can be extended again. Although you know this is not a mandate but it was the department strongly feels the need of this highly technical nature of the stem cell research. So we need some advice from this very advisory committee.

Henry Greely: But should the department every change its mind there's nothing to keep it from abolishing the committee.

Shabbir Ahmad: I - that is correct. But I don't see any...

Henry Greely: I just don't want people feeling too secure that we have a tenure position here. I think it's also the case that you asked all members of the previous committee whether they wanted to continue on. Did everyone?

Shabbir Ahmad: That is correct. Everyone agreed, or at least nobody objected.

Henry Greely: Okay. At some point I mean I don't think people have or should have signed on perpetuity here. So some point we'll come up with another graceful time when it's other things demand your attention more seriously you can say, 'served my term, thanks, see you later'. Because I know the compensation for this is highly attractive. You'll notice that the pay was raised - was doubled between the previous committee and this from zero to two times zero. But we

do appreciate the fact that people are willing to take the time to do the reading, to attend, to attend on telephone and otherwise be available for this.

Shabbir Ahmad: The Department thank you for that and the committee members. One other thing as I mentioned related to the committee, if cord blood bills are signed and the committee feels that we want to have some working group having some more expertise on cord blood collection and banking. Luckily we have Dr. Lubin who's an expert on cord blood so we can expand that working group and that's in front of the committee at that time.

Henry Greely: And I'm sure Bert agrees with all of this, and his representative.

Man: Unintelligible.

Henry Greely: Thank you. All right, other questions for Shabbir?

Coordinator: Excuse me, this is the coordinator. We did have two parties star 1 to announce themselves.

Henry Greely: Okay.

Coordinator: The first is Shannon Smith Crowley, your line is open.

Shannon Smith Crowley: Oh, I was just announcing myself.

Henry Greely: Okay, could you announce yourself again? I didn't catch your name.

Shannon Smith Crowley: Shannon Smith Crowley with the American College of Obstetrics and Gynecologist.

Henry Greely: Thank you.

Susan Fogel: Susan Fogel with the Pro-Choice Alliance for Responsible Research.

Henry Greely: That's Susan Fogel?

Susan Fogel: Yes.

Henry Greely: Okay, you didn't come through very clearly but I thought I got it.

Susan Fogel: Yes, thank you. Can I just - I just wanted to note one thing which is because this is a public meeting it's my understanding that there should be an opportunity for public comment even though this is not a legal meeting. In general there should be an opportunity for public comment after each agenda item as opposed to at the end of the meeting. Or at the discretion of the members of the committee. So that would be helpful if you would provide that opportunity at each juncture.

Henry Greely: Well all right, I have no objection to that. I'm sorry that we missed it. Do you care to comment on the welcome and introduction?

Susan Fogel: Welcome.

Henry Greely: Report on guidelines and committee status? No? Okay.

Susan Fogel: No, thank you.

Henry Greely: We'll move onto Agenda Item number 4 which is the report from the California Institute for Regenerative Medicine. And we are happy to have with us Geoff Lomax from the Institute to tell us what's going on at CIRM.

Geoffrey Lomax: Thank you. Geoff Lomax, CIRM. I - we were requested, there was a fairly specific request so in terms in some of the specific questions that were raised. We provided an update, you know, in writing which you all should have in the packet and available to the public.

So I'll just quickly touch on a few areas and reiterate what's on the written summary and if you all have any more detailed questions I'm happy to make myself available to address any of those questions.

There was a question concerning the status of the funding program which to date we've authorized approximately \$208 million dollars in funding and the breakdown there is in the training grants program, the Seed Program or Scientific Excellence through Exploration and Development. Our comprehensive grants program that we approved earlier this year by the ICOC and the shared laboratory grant.

There are two additional major programs now in the pipeline, if you will, that's major facilities and faculty awards. Which are for new (facul) in the area, stem cell research and both those awards they are available to our Web site as are the previous RFAs.

There was a specific question regarding our community's of science response initiative which is identified in the CIRM strategic plan. And at this time we have not developed specific applications pursuant to that initiative. However as sort of touch on the moment we are in a kind of a very exciting transition period at CIRM so I think part of it as we move through that transition period into early next year based on our strategic plan I expect those types of initiatives - that initiative in particular will be one that will develop and emerge.

And as always we welcome input on initiatives, particularly as they relate to our strategic plan. And certainly any thoughts this committee might have on how we can develop that initiative would be well received by the institute.

Later, two weeks time, we are now going to move on to the bond sales. Just to let you know we're moving forward with a \$250 million bond sale in next month in October and that is - will allow us to be moving forward on the grants program so we're very excited about that and expect to hopefully have a larger announcement on that next week.

Again, I referred to the transition at CIRM two weeks ago Alan Trounsoun from Australia was announced as our new president and we had the opportunity to interact with Alan for a couple of days and it was I think very exciting. Speaking personally I was particularly impressed by his - the depth of his clinical experience and I think his interest really in- he really views in sort of clinical end points as the ultimate measures of success in stem cell research. And that was very invigorating to get a chance to meet him and sort of get a sense of his vision for the institute.

So with that said I thought maybe we could spend a tiny bit of time on the regulatory development, given that I think that may be of interest to the committee. And we are actually in a phase where we are going to be proposing amendments to our regulations. We hopefully, the proposed revisions will go into the office of administrative law this week or next week at the latest.

But we - starting with our standards working group and then going to the ICOC we've had the standards working group recommend and the ICOC

subsequently approve a series of amendments for the regulations that would accomplish three sort of major objectives.

The first is to expand lists of authorized cell lines that could be used by CIRM funded researchers. And specifically these would be stem cell lines derived under the Japanese guidelines. So we've - I think that will help facilitate exchange and reduce the level of review required among grantees.

In a second amendment we've effectively removed some language that were put into the regulations describing allowable costs for cell lines. It was determined that that language was actually redundant with language in Proposition 71 but it wasn't - it didn't overlap perfectly so what we were getting was a lot of questions about what was the difference when there really was no intended difference. So what we've done is we've gone back into the regulations and removed some language and then referred the grantees instead to the actual portion of the Health and Safety Code which now is now getting - Proposition 71 is being incorporated into. So we're going straight back to the authorized language.

And then the third part which I think from the standpoint of sort of practical research is the most substantive modification is the ability to authorize the use of human somatic cells in stem cell line derivation experiments. As I expect folks are aware there was a number of papers published this summer and the gist of the science there was it may be possible to generate a pluripotent stem cell line from the genetically programming of a somatic cell.

And the way the consent requirements were constructed and some of the requirements were constructed in the original regulations it was effectively impossible to perform that experiment on a pre-existing somatic cell line. A reprogramming experiment. The problem became that I think the working

group thought was a critical issue was that a number of well characterized somatic cell lines are in the scientific research stream. Those cell lines by nature of the fact that they've been well characterized and they served - they'd been in the basis for early research in this area- to not allow them to be used by CIRM funded researchers would severely undermine the opportunities to advance the science.

But I think what we effectively was the - where the working group came down is while they still have there's a number of mechanisms in the regulations to promote strong consent strictly with new collection of materials. It would be advisable to allow the use of pre-existing somatic cell lines in research.

So the amendments which you all have copies of there - the three sort of substantive policy considerations are the ones I've just mentioned. In addition we did -- and this is kind of a psychological thing -- I know people when people open up the regulations there's also a number of other edits. Particularly in the informed consent section. That was just since we were noticing the regulations since they were going to be open for public comment there was also a sense that some things could be worded more clearly.

And so in our section 101, 100 when one gets past 100, 100B there's a lot of edits in there. I would suggest those edits are entirely editorial and not substantive. Although that's just the value of the public comment period. We had some comments indicating that they could actually be interpreted substantive so we tried to kind of balance that. I say public comment that wasn't technically a public comment period.

What we do traditionally is when we're proposing updates to regulations in advance of the formal public comment period we also push the regulations out and enable comments. That's actually encouraged by the office of

administrative law to get interested parties comments in early. And we did pick up a couple of things that were sources of confusion.

So in the end I think we have something hopefully now when it goes through the office administrative law process the policy objectives as compared to sort of the editorial changes are now clearly delineated and we hope that will be effective. And again certainly comments and feedback from the committee are welcome. Anyone can take advantage of the office administrative law process.

And again, I'm available. I think the other issue is given that we've made a substantive change to our rules it then begs the question to what extent you all want to evaluate those changes in the context to stay timely.

Henry Greely: Thank you Geoff. Just to be clear the changes are on this five page double-sided document marked at the bottom CIRM-rev 08-29-07.

Geoffrey Lomax: That's right. And we've done a tiny bit of cleaning up since then but since that document really reflects the first round of major changes I thought that was the most useful document to the committee at this time. And we've cleaned up a couple of things since then so when the formal document goes out under the office of administrative law process there'll be some slight deviation from that document. But fairly minor.

Henry Greely: Your current thinking is that will go out when?

Geoffrey Lomax: My hope is that we will notice it - we will get it in tomorrow. Which I believe frees it up for Friday notice of this week. Although we're one lawyer short this week so there's always a question of person power and whether that will actually happen this week.

Henry Greely: Questions from the committee for (unintelligible).

Elliot Dorff: I noticed that on Page 9 your regulation says - number 2 at the bottom of the page on the left-hand side. A donor must have the opportunity to oppose restrictions on future use of donated material.

This is - what I'm wondering is our - what we have here is and our in the guidelines for human stem cell research pursuant to health and safety code 125, 118, our paragraph is actually much less clear about that. It's on Page 12 number 14 on ours. Its says that donors have been offered an opportunity to document their preferences regarding the future uses of their donated materials and that the consent process is fully toward whether donors have objections to any specific forms of research to ensure that their wishes are honored.

But it doesn't say that their wishes have to be honored. All right, in other words they can express their preferences but that's very different from having the opportunity to impose restriction on the future use of their donated materials.

So, I mean, I think we have to decide whether we're going to go with the language that's in CIRM or whether we're going to stick to a kind of wishy-washy standard that, you know, they can express their preferences but who knows what the researchers are going to do with them.

Henry Greely: I think they're really two separate points in which you've just said. One is it's useful for us to be as similar as we possibly can to the CIRM given that the statute that governs both entities aren't exactly the same but are broadly similar. There is an advantage in uniformity in general. There's also the

substantive question even if we didn't feel the urge to uniformity whether we wanted to be more strong than our current language is.

I don't frankly remember the discussions we had about the language in our guidelines. Whether we intended it to be mandatory or advisory certainly the current language doesn't make it mandatory.

Radhika Rao: I think our current language tracks the former language of CIRM...

Henry Greely: Okay.

Radhika Rao: Because if you look at the text that was edited out on Page 9, you know, it's very similar. We could choose to offer donors an opportunity to document their preference. And the last sentence- researcher may choose to use materials only from donors who agree to all future uses(unintelligible).

Geoffrey Lomax: Yeah I will - that is one section again in the final thing we published, we have modified that slightly. We did have a few comments back. The substance of the comment was simply that we don't want to go through the process of offering the opportunity to preclude things if our ultimate sort of policy in that particular case is we just want to take unrestrictive donations.

We clarified it again to say that they could sort of the first - the sort of entry point to the conversations could be we're looking for unrestricted donors and that could be sort of decision point that people could at that point aren't open to that they just would not ask them to be donors. So and that the existing wording was perceived as requiring you to go through the entire process and then getting to the end and deciding not going to take the donation.

So again there's been another addition. I may have it in my briefcase, I do apologize. I could check that. So the final language we're going to propose will be slightly different than this. And that's what I alluded to earlier that this is close but not exact and...

Man: Substantively different do you think?

Geoffrey Lomax: I would have to - I'd have to go look. I may have it. I need to check, I can do that if it's helpful.

Man: I see a nod from the audience. Ellen do you have a recollection?

Ellen Auriti: (Unintelligible).

Man: Okay.

Elliot Dorff: (Unintelligible) makes sense only if you have a plethora of donors. Right, if you don't have a lot of donors, and remember these people aren't being paid. It seems to me you at least want to offer them the opportunity to make these kinds of restrictions if they're willing to donate under those restrictions.

Geoff Lomax: Yes and this isn't just for oocyte donation, it includes embryo donation as well. And so I would suggest there the opportunity for donation is reasonable and I think there's a lot of more availability then the situation with fresh oocyte donation where things are zero at the moment.

So it's - I think it was just a practical consideration that addressed the reality in the sort of clinical setting where if you didn't want to go through a long consent process if the sort of first order consideration. That simply we need

unrestricted - you know, in order for this research proposal to work we need unrestricted donations.

Elliot Dorff: But how long would the consent process be? I mean, it's either I'm willing to donate them for this, this or this? Right? There's basically three or four different kinds of research and if they check all of the above that's fine but if they only check three of the above?

Geoff Lomax: That's right. And I think the concern is that for the researchers proposing do the derivation the notion that they have - they are then responsible for ensuring those wishes are held up to perpetuity. They don't want to be in the situation of having to be responsible for that obligation. They just think it's logistically impossible to ensure that - make that promise. So they're - they it sort of unrestrictive donation or not at all.

Because logistics and the reality of how materials travel in the research stream at some point something could go wrong and they feel they're on the hook at that point.

Elliot Dorff: Well then we would have to change 14 in the other direction.

Henry Greely: You know, we actually have an opportunity to have at least two bites at the apple here. And the requirement I think to have one we could make comments as a committee to your proposed regulation. Along as anyone in the public either individual committee members could make comments as members of the public. Or a committee as a whole as members of the public could make comments during your notice period.

And then once you've adopted anything then I think presumptively any changes you make need to go on our agenda to be considered in terms of

whether we want to, or can, there may be statutory issues that keep us from doing everything you do. But any time you make a change we need to consider it in terms of whether we want to revise the guidelines.

Clearly that latter one will come into play. It may well be that we'll want to comment either individually or collectively on your proposed regulations. And Elliot I get the feeling that you're troubled by the limitation - elimination of the choice there.

Elliot Dorff: Right, exactly.

Radhika Rao: It seems to me it's sort of a yes or no situation. Either you can donate unrestricted or we don't want your donation.

Geoff Lomax: I think it depends. You could have a very limited research protocol. You could have a donor where they're donating for something very narrow and very restrictive. We're not precluding it, but I think the comments we heard is if we're going to be in the business of stem cell line derivation and the purpose of that derivation is really we're in the business of enhancing the pool of stem cell lines available for basic research. And that's, you know, an objective we're funding at this point in time.

And anyone doing that derivation does not - doesn't want to be in the position of policing the use of the cell lines.

Bernard Lo: If I could step into (unintelligible). Before we put in that provision allowing researchers to only take donations with (unintelligible) researchers came and said that's what I would like to do for reasons that we described. That says I'm not sure reading the regulations that I'm allowed to do that and I don't want to (unintelligible) complicated process without being sure

(unintelligible). So we put that in to give the option. We're not saying that researchers may only take those kinds of donations they can certainly choose (unintelligible) to allay the fears of researchers that that would be permitted (unintelligible) it's meant to be permissive and clarifying rather than suggest that it would be preferable

Henry Greely: So allay the fears of researchers that they would be required that they give (unintelligible).

Bernard Lo: No, no. The fear of researchers was if they wanted to only accept donations from donors who were not placing any restrictions. They were not clear from the previous version that that was permissible (unintelligible)...

David Magnus: Right. We are - we have a lot of discussions with our attorneys about that issue who some of them thought that they were obligated to give people the option which practically for reasons articulated made no sense for a lot of the protocols that we're doing. But I think most researchers will probably not want materials that have those kinds of restrictions on them.

Samuel Cheshier: From a practical standpoint. I would think more materials that are unrestricted. We have no idea in the future what science are going to be done to these cells. And if in the future someone wants to find it morally objective to use that particular donation for X,Y,Z science then by allowing them to say what I want and what I don't want in the beginning gives them opportunity in the future to come back and pull their donation out of the pool.

Henry Greely: Withdraw from research.

Samuel Cheshier: Right. But the other thing is why can't you just write the language that says you can have this or have that. (Unintelligible) may choose statement here.

Henry Greely: So we don't have the precise language that's going to go in. Geoff do you remember when the comment period is likely to close? Is it 60 days, 90 days?

Geoff Lomax: I believe it's a 30 day comment period followed by a 15 day if we republish. But it hasn't opened yet. So there's - and then what we do as soon as the comment period opens I think most of you all are on the interested parties list so we push out the...

Henry Greely: What I'm thinking about is as individuals we could all comment during the comment period. Collectively we can't I think comment as a group until our next official meeting which probably won't be within - certainly won't be within 30 days. And may or may not be within 45 days. But that's - okay, well we'll see the actual language distributed to the committee. Get a sense of whether this committee wants to I think try to figure out a way to pursue it collectively or whether committee members want to pursue it individually.

And of course I suppose it's always possible for a majority of committee members acting individually to jointly submit an opinion in their role as individual citizens. So we may be able to figure - if there is interest in the committee. We don't know that yet, we haven't seen the precise language. If there's interest in the committee in commenting substantively on the proposed regulation I bet we can figure out a way to do it.

Other questions for Geoff?

I have one Geoff. You're modifying this to take into account to safe harbor the Japanese lines - lines approved under the Japanese process. Have you figured out what you're going to do about the safe harbor for the British line

now that HFEA may be creating some lines that would appear to me to arguably violate California law?

Geoff Lomax: Would this be the egg sharing scenario you were referring to?

Henry Greely: Yes. So let me - this is the one where people who are going in for clinical purposes for IVF, women who are allowing their eggs to be harvested can get a deep discount. I think its 50% off? If they allow some of their eggs to be used for stem cell research which without wanting to give a formal legal opinion appears to me to quite likely violate California law.

Radhika Rao: And where's this happening?

Henry Greely: The UK has announced that they will approve it. Although I don't know, have they actually approved any specific licenses for it?

David Magnus: I think in northern England.

Radhika Rao: Presumably it's approved then under the regulations. Because it says...

Henry Greely: Right. The current...

David Magnus: There's a contradiction in the regulations. The current regulations imply (unintelligible) stem cell bank. Actually it's not a restriction yet but...

((Crosstalk))

Henry Greely: Both in the stem cell bank and things that are created under license from HFEA and these presumably would be both.

David Magnus: Right, but that hasn't happened yet.

Radhika Rao: It hasn't yet happened but it could happen in the future.

Henry Greely: Geoff, you guys have any thoughts on how you'll deal with it?

Geoff Lomax: Yeah, we will - this is where, you know, our best friend is the process. I mean, we have a set of regulations on the book. They were recommended by the standards working group. We have the benefit of the, as we said, there are no lines in existence at this time. And my sense is in terms of just checking about where things are headed in terms of licensing is that we -this is not, we're not going to end up on next year and suddenly have these fines.

And so, you know, we have received a series of sort of comments and feedback on the regulations in a variety of areas and we're trying to sort of work through some of the issues. Which is sort of reflected in this document. And this is one we're well aware of. And so in the event we don't necessarily need to wait until lines are derived I think this is one of those issues we need to take back to our working group. We need to discuss this issue.

There is the comment has come up from others and I've began to sort of work the kind of documentation and do a treatment of the issue. Which we do with all these issues and we bring them before the working group. So I think we'll use the working group process and again it's going to be one of those that combined with some legal opinion perhaps in this case from some of our lawyers and we'll go from there.

Henry Greely: Is it believed that this will also be an issue for us? I think it's pretty clear our guidelines...

David Magnus: (Unintelligible) violates SB 1260.

Henry Greely: Right, and I think it's - I remember the Prop 71 language there's likely to be a problem there as well. But the 1260 language I think is - which applies to us but not to you.

Man: Crystal clear.

Henry Greely: Yeah, Section 6 of our guidelines -- 6B and 6C -- refer to the United Kingdom stem cell bank or the United Kingdom HFEA.

David Magnus: Again, even when they create the lines and the six month gap (unintelligible) time they distribute the line, that's not going to happen right away.

Henry Greely: That's something to keep our eyes open for.

Other comments or questions for Geoff from the committee? Anyone in the public wish to comment or question Geoff either here in person or here through the conference call?

Coordinator: Once again, on the phone press star 1.

Henry Greely: Yes. Please come forward so we can record you. Audio only, as far as I know.

Charis Thompson: Hi, this is Charis Thompson from UC Berkeley. It seems to me that it might be wise to begin pushing some to move toward dropping listing individual countries because of the problem of leaving some out and bringing some in for (unintelligible) and also for other reasons to do with good science and good ethics.

At the same time as not allowing any country to continue to have blanket clearance, (unintelligible) approved by HFEA (unintelligible). Thank you.

Henry Greely: That's a good point to consider. There's certainly some advantages in having a blanket clearance. Having a safe harbor in terms of not having to reinvent the wheel with every new stem cell coming through a country. But there are the potential disadvantages as well if those countries shift their standards away from those permissible in or desired by California. Elliot and then David.

Elliot Dorff: Is there a process by which countries can have their own stem cell lines approved. I mean what like for example Israel created stem cell lines. (Unintelligible) If they wanted those to be available in California, how would they go about doing that?

Henry Greely: Presumably at this point California institutions would have to make a determination whether they were in each case acceptably derived. David?

David Magnus: It's also important to remember that UK stem cell banks does not just include UK stem cells. So they actually have a very thorough process of letting stem cell lines they get from other countries as well. So one easy way for any body is with - the ideal thing would be to have some kind of authority that would be reliable to ensure that cell lines are ethically derived. And then use that for the basis of doing this.

And actually one question I have for Geoff is whether or not CIRM is considering planning on taking on that role?

Geoff Lomax: I think – sort of two comments. Yeah, I think for the genesis' for the safe harbor is - was in part we've done a fair amount of follow up with the

institutions and I think it's reasonable to say at this point the single most - the greatest point of friction or cost in the system is the verification of stem cell lines and the subsequent uncertainty even though one has gone through the verification process.

And I think the typical issue is less the payment issue at this point in time and more the quality of consent and sort of subjective decision on what constitutes consent. So the objective of the sort of safe harbor was to try to reduce that friction in the system. And everybody who's been listed in our regulations to date has been by both reviewing the national legislation in terms of substance in the regulation or law or whatever the case. And discussion with individuals in the country responsible for the lot.

So we feel that we have a legal sort of framework that matches up with the intent of our regulations. And we've had the opportunity to kind of dig a little deeper through, you know, direct conversation. So that's certainly the intent and reminder that our objective is to advance the science under certain and high ethical standards and try to find that balance one often ends up in a policy space that maybe often feels a bit less than perfect. But it's where you arrive when you're trying to fit the policy to the activity at hand.

So, you know, that's how we got there. And then there was a second piece to the question which I'm now forgetting.

David Magnus: (Unintelligible) either take it on directly...

((Crosstalk))

Geoff Lomax: That's right. So I think there is - certainly, again back to the strategic plan and conversations I have approached them. It certainly contemplating a stem cell

bank which could play that role. And we're just not there yet, but I think that is something that increasingly - there is a lot of good reason to sort of play that role. It probably wouldn't be as directly, it probably would be through some banking entity. Either physical or virtual that we fund to sort of take that one. And we want them then - their sort of certification to carry the weight of law.

In that case it may very well be at that point in time. We could reconfigure the regulations in a way where we weren't simply listing countries. That certainly could be a reasonable outcome. Where, you know, we're really trying to - we're moving in real time here and trying to again balance the objectives of good ethical - good ethics with advancing the science.

And again, sometimes those policy instruments may appear a bit imperfect I guess the point I like trying to make - we also hopefully in terms of, through example showing our sort of desire to revise things as we can. And quickly as possible suggesting that we would continue to do so. So it's - we are where we are because the process has led us here but that process is not going to end. It's going to keep moving forward and I again, we've got a good working group to work with. We've got the right set of mechanisms in terms of process and the bank is also a good idea so I wouldn't rule any of that out.

Henry Greely: (Unintelligible) it seems too clear an opportunity for it not to be picked up by someone to have a broad certifying authority - that could both certify but could also certify with some caveats and say for this particular cell line this sort of reimbursement was made and you should take that into account whether or not it meets your state or your ESCROs or your national standards.

David Magnus: Which HFEA is going to do. They are actually going to have a clear distinction between in their cell lines. They do a pretty good job, so.

Henry Greely: Okay, any other questions for Dr. Lomax?

Geoff, thank you for coming. You're certainly welcome to stay for the rest, thank you for your report. And thank you to CIRM to sending you to us.

So hearing no other public comment on this agenda item we move to Agenda Item number 5. Discussion and feedback on proposed reporting forms. Dr. Ahmad, I'll ask you to kick this off.

Shabbir Ahmad: There are two main requirements which are (unintelligible) SB 1260 you have a copy in your packet and Section 125119.3 The (unintelligible) stem cell research committee that has reviewed human embryonic stem cell research pursuant to Section 125119 shall report to the department annually on the number of human embryonic stem cell research projects that the stem cell research oversight committee has reviewed and the status and disposition of each of these projects. Including the information collected pursuant to Section 125432 and these gives us some detail about what needs to be reported.

And the next is 125119.5B. The department shall provide a biennial review to the legislature on human embryonic stem cell research activity. These biennial reviews shall be compiled from the reports of the stem cell researchers activity.

So we have given the first try to develop a form within the department but this is just a suggestion as I mentioned earlier to the advisory committee here. That these forms - these are the suggested forms for SCRO committees to report to the department on the stem cell research projects they have reviewed. So this would be open for discussion today among the members and if they'll have to be some major changes, additions, omissions, modifications we will note those and develop the right form and put it on our web page for public

comment. And then during the next meeting the committee would take a decision on this.

The second one is on the - if we go back to 1260, Section 125C42 that is from the research program. The research project or the research program that involves assisted oocyte production or any alternative method-this is on Page 7. Or any other method of oocyte retrieval shall ensure that a written record is established and maintained to include but not be limited to all of the following components. And then it gives the demographics and (unintelligible) on every oocyte how it is obtained and how it is disposed. The record on adverse health outcomes and then the department has to get this report and develop an aggregate information for public use for public information. And that department has to put this on their web site for information to the public.

And for that purpose we so that (unintelligible) form in your packet should – it says State of California Human Oocyte Retrieval Mandates. The subtitle it says - so this is again developed internally by the department and it's from the assistance from the Ob/Gyn consultant within the department. And we tried to capture what is the detail given in the law and some additional information. So this is also in front of the committee today for discussion. And if the information needs to be changed or deleted or something is wrong with it we need to know that.

So these are two items for discussion that may begin. The other two forms (unintelligible) those are just produced as a guideline. One is the informed consent form checklist for research involving human oocyte retrieval. And these are some guidelines, checklists. This is just an aide. And then there's a comparison of what type of research whether (SCRO) approve or IRB reviewer approve needed. And I would actually request the committee to look

at this form if we have done this right or if there needs to be some corrections made to this one page. (Unintelligible) SCRO and IRB approval.

So back to you.

Henry Greely: Thank you. So we really will not be taking any action on this today but if you've got thoughts on any of these forms this would be a good time to air them out. I suggest that we start with that we take the forms one at a time, if that's okay with people. And start with the shorter one. The stem cell research oversight committee reporting form. Three pages stapled together. Dr. Magnus?

David Magnus: So one thing it's just the matter of scope. So a language change here SB 1260 though in the preamble it requires that SCROs review all human stem cell research. In the body of the text where it actually concludes all the reporting requirements it only actually specifies the requirements who were reporting human embryonic stem cells.

So I would suggest that for this reporting form we amend where it says human stem cells to the human embryonic stem cells. That would - otherwise the number of things that would have to be obligated to be reported by the SCROs would be much, much larger and I think unmanageable.

Henry Greely: David looking at Page 2 of this form on this checklist down at the bottom on stem cell information would you also include pluripotent cells? Which are governed by our guidelines as if they're embryonic. For some purposes derivatives of pluripotent cells or HESC's.

David Magnus: The SB 1260 only requires that reporting of embryonic stem cell research so I would suggest that we restrict it to the language of SB 1260. Only requires this be done for human embryonic stem cell research.

Henry Greely: Although that continues to require some conclusion about the appropriate treatment for research involving cells derived from...

David Magnus: Right, I think that would be reasonable to have included that. But it's - but...

Henry Greely: I take it David and I both serve on the Stanford ESCRO and we got a report at our last meeting on Friday that we had something like 35 protocols approved administratively...

David Magnus: In the last month.

Henry Greely: None of which involved embryonic stem cells or derivatives from embryonic stem cells. They were all adult stem cells research which does have to go through it but it's not clear that it has the same sort of interest as to require reporting. The statutes I think you're right - I'm sure you're right, says reporting only for embryonic. The committee could recommend to or the department could decide to as to reporting beyond what the statute requires but I'm not sure there's any good reason to require reporting in this detail on human adult stem cell research. Right?

Bernie?

Bernard Lo: Two points. First, with regard to (human stem cells or embryonic stem cells) no one knows what derivative stem cell (unintelligible) modification of some cell? Is it a protein (unintelligible). And there's no definition from NIH (unintelligible). Like you said, if we are going to require reporting we have to

be very clear as to what we (unintelligible). Having said that I would not be in favor of expanding reporting requirements to include things other than embryonic stem cells. If you look at both the language of SB 1260 and Senator Ortiz's letter dated November 2006. I think it's clear that the intention was to make sure the concerns about the health, well-being, safety, and decision-making (unintelligible) who might be involved in either stem cell research or oocyte donation were protected. And I think adult stem cell research does not raise those kinds of issues and I'm not clear that research with derivatives of stem cells once the lines have been derived from embryos or oocytes implicates those kinds of concerns.

I think what David was recommending is that we draw reporting guidelines from a clear statutory mandate under SB 1260 (unintelligible) very very circumspect about extending beyond that without clear rationale as to why we're doing it and clear understanding about what the burdens are for that extra reporting. I think there are certainly good reasons to have reporting when certain issues (unintelligible) require more data but there's no real ethical concern (unintelligible) might become a burden.

Radhika Rao: But one point is in requiring reporting I think you have to make clear like Bernie said what an embryo is if you're only going to require (unintelligible) embryonic stem cell research. Because some people think parthenotes don't count as embryos but it seems clear from the concerns manifest in 1260 that they should because they involve oocytes.

So I mean I guess would we just say only reporting required for human embryonic stem cell research and leave it blank and leave it to be interpreted or should we specify that research on stem cells if they were to be derived from a parthenote would be included.

David Magnus: We'd have to - we'll have to be very clear about what sorts of things are included but it seems reasonable to include SCNT those sorts of things.

Henry Greely: If the driving source behind this as I think much of this comes from concern about embryos and oocytes then you could think of defining it in terms of something derived either from an embryo or from oocyte and the oocyte would take into consideration parthenogenesis, SCNT... I guess those are the main ones. I mean, reprogramming wouldn't fall under that. The reprogramming with the somatic cell doesn't raise concerns about the female donor and the oocyte retrieval. Of course we don't know whether it can be done in humans yet, anyway.

Elliot Dorff: (Unintelligible) sperm? Does that come under the same-for those that are worried about oocytes are they also worried about sperm?

Henry Greely: (Unintelligible) Anybody know more details on the science? I don't remember.

Bernard Lo: People are trying to work on it.

Henry Greely: No I don't think any body has done it yet in humans.

((Crosstalk))

Radhika Rao: I think Charis has a comment.

Henry Greely: Charis?

Charis Thompson: (Procurement issues regarding testicular sperm cells has already come up as an issue).

Henry Greely: Right. Although, perhaps if you're getting sperm progenitor cells from the testes I don't know of any health or discomfort issues raised in the traditional method of sperm donation. But you're right (unintelligible).

Bernard Lo: One other point the way this is written it includes human pluripotent cells and again if it becomes possible to use (reprogramming). All those lines would need to be included under (unintelligible) format. Again I think the donations of somatic cells will include questions about consent (unintelligible) level of concern about safety (unintelligible).

Henry Greely: Although we do include pluripotent cells that are put into the central nervous system, right? In our guidelines...

David Magnus: Right. (Unintelligible) CIRM guidelines as well so we might want to make a similar kind of exception (unintelligible) for that kind of research to be reported to the state department.

Henry Greely: So to sum up this part of the discussion I think we're - we've got concerns about the breadth. We think the breadth should be narrowly tailored to the reasons for the reporting requirements. And that adult stem cell research at the very least probably doesn't - shouldn't require the same sort of reporting. And this department should think carefully about how to define what specific kinds of research one's to report on, right?

And they will be certainly - SCROs will have to continue to review adult stem cell research. This doesn't go to the substantive requirement for review but only to the requirement to reporting and the detail of reporting to the state. Baring in mind that we'll have another meeting at which to discuss this and

that people can certainly also submit comments via email up to me to have brought up at the next meeting.

Other comments on this form?

Fred Gage: Yeah, this is Rusty. Can you hear me?

Henry Greely: Yeah, hi Rusty.

Fred Gage: Yeah I really like the direction of this conversation and I lost a little bit there at the end but I would highlight the fact that this whole discussion about derivatives should be addressed and probably dropped if at all possible because it's really not clear what derivatives mean. And as it is now it's quite inclusive and some people are interpreting it as much as to mean photographs taken of stem cells. And the data collected from that.

So I like the idea that was discussing the intent, the original intent, of having this in the first place rather than the progression as to how tightly this could be designed.

Henry Greely: Okay, I think the term derivatives really entered into all of this debate because of the Bush policy and it's very limited in implementing language courtesy of the NIH through their FAQ's. Which talked about no funding for research with cell lines and the derivatives except those that are approved. And the derivative language has not been defined by the Federal government. But of course that doesn't necessarily mean that for state purposes we have to use (unintelligible).

Fred Gage: Right, I agree.

David Magnus: I agree derivatives is very vague. I think there was some (unintelligible) using it for certain kinds of research where the goal is to use HESC's to create differentiated cells that will then be reintroduced into the body that is commonly referred as HESC research. So Geron for example potentially - potential clinical trials as an HESC clinical trial. So it seems to me that the differentiated cells that are derived from- through embryonic stem cells might fall within the range of something that would be legitimate. Especially if their - if that characterized by the researcher themselves as HESC research.

But I think going beyond that would be difficult.

Henry Greely: It would be self derived from protein taken from factors (unintelligible)...

((Crosstalk))

Henry Greely: This actually came up at our ESCRO somebody wanted to use hemangioplasts derived from Federal line. We had to decide whether it fell within our ESCRO jurisdiction or not. We decided that at least current for the moment we would take jurisdiction of it in part because of this uncertainty about the derivatives.

Also in part because, you know, 100 billion of these cells would anyone tell us that they weren't undifferentiated HESCs still in that bowl of cells to be transplanted. (Unintelligible). Oto?

Otoniel Martinez-Maza: I have one comment regarding this reporting. It seems to require much more information than is specified in the statute. I'm just curious as to what the rationale for that was? It seems to create an unnecessary reporting load on ESCROs. And it's unclear to me why this particular information is required.

Henry Greely: Dr. Ahmad do you want to speak to that?

Shabbir Ahmad: As I said this is like an effort, first effort the department put together. This may be too much already in the form. If the committee decision and recommendation that would come out of this meeting what would be asked in the end. This is like various items, not all inclusive, but various items that can be asked about the project. So this is not I think final but it's just a suggestion to the committee to react to and say what needs to be included what not to be included.

Otoniel Martinez-Maza: My preference would be a more minimalistic approach in that if you look at the language of 125119.3 it really only requires reporting the number of projects to be reviewed, the status and disposition, and any unanticipated problems in the action (unintelligible) to respond to these. But if you look at this particular reporting form there's all kinds of things about collaborators, initiation to mandate the project there are things that may actually be difficult to find. I think it would put a heavy administrative burden on committees that are already rather taxed.

Henry Greely: Maybe this committee might want to - the department might want to think about two versions for further discussion. One that is limited solely to the requirement of the statute and one that includes other things that the department thinks might be useful and we could discuss at our next meeting. What, if anything, beyond the bare statutory requirements in 125119.3 A and B that's worth including.

Otoniel Martinez-Maza: One more comment. Perhaps the reason that some of this information is requested is to cover reporting requirements for AOP Procedures involving that which it's really at this time at any rate a very small minority of the total projects that SCROs are reviewing.

Henry Greely: (Unintelligible) sunset of review mandates.

Otoniel Martinez-Maza: So perhaps a form for those AOPs including projects that (unintelligible) simpler point for regular human embryonic stem cell projects (unintelligible)appropriate.

Henry Greely: Any other comments on the stem cell research oversight committee reporting form? The general one, not the assisted oocyte procurement form.

David Magnus: Can we distribute this to SCROs to get commentary and feedback as we go forward?

((Crosstalk))

David Magnus: That would be great.

Henry Greely: All right. Comments on the oocyte retrieval form? (Unintelligible) the more substantial form. The five pager headed State of California Human Oocyte Retrieval Mandates. Second page says facility and clinic information, IRB information. Third page is written record of research donors involved. A lot of demographic information. I mean, substantially it's not entirely out of the language of 1260 which does go into some significant detail.

Next page is Items 11-19 are oocyte procurement. Twenty through 31 are adverse health outcomes followed by more adverse health outcomes, question about medical expenses coverage covered. And the last page is (unintelligible) okay. Margaret McLean?

Margaret McLean: I just have a question. Who would fill out this form in your...

Shabbir Ahmad: The language in 1260 is research program or projects. Now this could be programs in that the department or the (unintelligible). That's the interpretation, I don't know what you would think (unintelligible) call (unintelligible).

Pat Rodriguez: So are you referring to 125119.3?

Shabbir Ahmad: No, this is 125342 Page 7. (Unintelligible). A research program or project

Henry Greely: Shall ensure that a written record is established.

Margaret McLean: One of my concerns is how this is a very expensive data set and how, you know, on the grounds that's going to be put together and by whom. That may dictate, you know, how this form is actually constructed. Or that's one way or the other way to think about it is it's, you know, if we have a form that's (unintelligible) X,Y, and Z then you figure out who's responsibility it is. It doesn't - I can't, I don't read law very often and I can't see in here that there's any indicator as there is for, you know, for the first form where it's clear that that should be the SCRO committee that does that.

This is not clear...

((Crosstalk))

David Magnus: It can't be done by the SCRO I don't think. (Unintelligible). The investigators have to have access to the patient information...

Woman: Right.

Pat Rodriguez: But there's no specific language in the statutes that describes what a program or a project will be then it's kind of up to guidelines or regulations to add that definition if the statute itself isn't clear. And that would be helpful to get comments from the group as to what is a practical application of that. Who really would be doing that.

Henry Greely: I suppose that you might tie it to whoever is the responsible person on the protocol that has to go through the IRB for oocyte procurements.

David Magnus: I'd say you might want to - be kind of interesting to making it somewhat flexible. We're heading towards a model where for oocyte procurement and embryo procurement other than each individual PI doing their own process. We're trying to create a centralized system and then the PI sort of come and get that stuff from the centralized program. And then in that case it might make sense for that centralized program to be doing it as opposed to the individual PI on the particular protocol.

Henry Greely: This is a classic example though of legal passive voice. The actual reporting requirement is buried in 125342B1. Information included in the written record dot, dot, dot shall be reported to the State Department of Health Services with no indication of who shall do the reporting. Passive voice is dangerous.

Bernard Lo: Two issues I'd like to raise. One is I think the idea of some sort of reporting of complications is an excellent idea including the required to give us a sense of (unintelligible) activity. However I think we need to be more precise (unintelligible) page- item 23-31 on page 4...

Henry Greely: Oh it goes on to Page 37...

Bernard Lo: (Unintelligible) so, you know, is nausea after anesthesia to be reported, what exactly do we mean by ovarian hyperstimulation? There was excellent workshop at the IOM that CIRM sponsored that clarified the medical risks of oocyte donation for (unintelligible) research. And one person's definition of ovarian hyperstimulation is (unintelligible) I think we don't want to - I think we really want to get at adverse events that are more than... That are more on the serious side.

(Unintelligible) we don't want one organization reporting everything that happens. In other words they should only be including the ones that are serious. But I think we need to pay more attention. All of these- mood swings after anesthesia...

((Crosstalk))

Bernard Lo: That's one set of issue. Second issue I wanted to raise is one of patient confidentiality. There are probably going to be very very few oocyte donors. And even if we don't have a (identifier) It's going to be very likely that people can be reidentified on the basis of one through ten. If there are only two or three donors and only one of them was a college graduate and only one of them spoke, you know, Arabic that person can be identified (unintelligible). So again I think it's important to balance the benefits of the reporting versus what I'm concerned about and that's potential to re-identify people because it's an unusual very small number.

Henry Greely: Are you concerned about the possibility of reidentification based solely on the data that's reported to the department or based on what the department then releases?

This is the department is told in the statute to aggregate the data and release it in a way that doesn't provide personally identifiable identification. Although the term personally identifiable information may not be quite the same as truly re-identifiable.

Shabbir Ahmad: But he has a point with the department (unintelligible) logical term anything which is less than five are not reported because by looking at (various characteristics) things like that, yes. So I think that's a very important question and very good question how to handle that. Whether the department should consider reporting or not reporting if it is less than five donors in a year.

Henry Greely: So again there's two different reports that we have to be careful to keep separate. There's the report to the department and then there's the report by the department to the public as well as subsection B2 of 125342 on Page 7 of the SB 1260 copy you have. Further says the department should provide public access to information in a manner that is understandable shall be available to the public. I'm not sure how that - I think that's connected to the information discussed in B1.

That says this information shall be reported to the State Department of Health Services which shall aggregate the data and make it publically available- I see set forth in paragraph two in a manner that does not reveal personally identifiable information about the subject.

So the department clearly has an obligation under the statute to report but to report in a way that doesn't make - doesn't reveal personally identifiable information about the subject. I think part of what Bernie was saying with which I concur entirely is you got to be quite sensitive to what that means. Particularly these days the possibility of re-identification in any research that has a rich data set at all are substantial.

Bernard Lo: (Unintelligible) stakes are higher. The risk to an oocyte donor to be re-identified (is high-psycho-social).

Henry Greely: However, sub-section 8 does require a report - a record of all adverse health incomes. I'm sorry, a record of all adverse outcome, including but not limited to incidences and degrees of severity resulting from the assisted oocyte procurement. So I think I agree with you Bernie that it would have been better if it had said serious adverse events or serious consequences but the statute says all adverse health outcomes...

Bernard Lo: And in the reporting we should make sure everyone's got the same idea of what counts as a serious adverse event. Otherwise if we try to aggregate data and people are using different criteria...

Henry Greely: Well what counts as an adverse health outcome because serious doesn't appear in the statute.

Bernard Lo: But in terms of we - our form distinguishes different degrees of severity...

((Crosstalk))

Shabbir Ahmad: (Unintelligible) use this as a guidance (unintelligible) conditions and put it on the form. I will provide a copy to all the committee members next time (unintelligible)...

Man: Send it electronically...

Elliot Dorff: Along those lines one thing you could simply do is give examples of in each one of these cases which constitutes as severe and what constitutes, you know,

(moderate), and what constitutes as mild. So that for instance, could be met so that you would have some of each symptoms even if you can't exactly define the degree of severity in each one of these cases. Just again some clear examples of what would be severe and what would be, you know, mild.

On the other hand I think that would help. Two very little things but it would be good to have page numbers on this form. And then the second little thing is on 16 and 17 there's no room for answering the questions.

Shabbir Ahmad: The forms would be designed later (unintelligible)...

Elliot Dorff: That's fine just I mean you're going to need to have - you're listing the drugs that's not going to go in those little boxes, okay? And if you're going to have an alternative method that's certainly not going to go in those little boxes.

The other thing that I was thinking of in terms of these forms is that if you're in number 11 how much was the donor reimbursed for direct expenses related to donating her oocytes. That's what's legal. Do you want to put in what's also illegal? Did the donor receive any other reimbursement? Something like that? Or do you want to just leave it the way it is?

David Magnus: I'm worried that that would be an invitation to misunderstanding because they might assume that if you're asking the question that it's okay that they mean...

((Crosstalk))

David Magnus: (Unintelligible) bus fare doesn't count as the expense or they mean - you know what I mean?

Man: Right.

David Magnus: It's probably better to leave it out.

Henry Greely: I could be wrong but unless it's someplace other than 125342 I don't see a requirement to list reimbursement. It might be a good thing to do, but it's not as far as I can tell under 125342A1 which is demographics, 2 which is information regarding every oocyte that has been donated or used, and 3 record of all adverse health outcomes.

David Magnus: So it seems to me in thinking about the adverse health outcomes we could decide how that should be done in a lot of different ways. But I like the approach people are saying of distinguishing between sort of mild, more serious - some way of defining that so that we can lump together some of the routine things without having to go into so much detail.

The second comment I have I guess I want to go against what the approach that you're advocating of giving examples because I think that's an invitation of misinterpretation. And instead I would recommend that we try to get something that can be operationalized (sic) as clearly as possible. So for example, the defining of a serious adverse event as something that requires hospitalization or find discreet concrete measurable things that can be included that would be ways of capturing and defining it into categories without having it open to individual interpretation. Things that can be objectively defined.

And then the third comment I have is a problem that I'm going to have to go through SB 1260 again in more detail and also think about this. Which is clearly everybody has in mind in all of this are research donors. People who are coming forward and donating oocytes just for research. So far we're

offered oocytes that were actually collecting that I believe USF is collecting as well are not from research donors. They're from clinical donors and they're providing oocytes that are failed to fertilize or something like that that are excess from a reproductive event.

Now (unintelligible) IVF. I think we have to have some way of recognizing the distinction between these two groups because the way we think about risk and everything else are going to be very different for somebody who's donating materials that would otherwise be discarded and there's no additional risks to the donor from something where there's risks of undergoing the procedure.

Otoniel Martinez-Maza: (Unintelligible) on that comment. If you read the language in the statute it actually as the subject that defines only those people who are undergoing AOP for research purposes...

David Magnus: So we should make sure that that's included in this so that this by definition the failed to fertilize eggs that are used for research they should not be filling out these forms.

Otoniel Martinez-Maza: In fact if you look at the third paragraph the first line. If your facility or project has collected oocytes that were or will be used - I mean potentially anyone undergoing this for clinical reasons would have it used so that should be changed to reflect more closely the research definition.

((Crosstalk))

Otoniel Martinez-Maza: On the draft form...

Man: On the draft...

Otoniel Martinez-Maza: It says if your facility or project...

Henry Greely: On the front page of the...

Otoniel Martinez-Maza: Potentially if any clinically - any of these procedures done for clinical reasons could potentially be in the future. So one might then think you have to report everything or every single AOP would be...

Man: Right.

Henry Greely: Well we really got three different structures here. On the one hand we've got the statutory requirements for reporting which I think was clearly done in order to get a database of the extended adverse effects to be able to assess the risks and the dangers that actually follow this kind of procurement.

We've got the concerns that the privacy of the subjects themselves which is certainly non-trivial. And then we've got concerns about the regulatory burden, the implementing of this at the institutional level. And balancing those three different sets of demands within the language of the statute is going to be tricky.

David Magnus: (Unintelligible) statute is good in terms of making that distinction between research donors and (unintelligible) that's helpful.

Henry Greely: But yeah, it's subjects. It's the definition of subjects in the statute.

Other comments from the committee on this form? Other comments from the committee on the first form, or the issue of forms in general?

I think in terms of the other two, the checklist and the short form you gave us I think that's - we can take comments on that or comments can come subsequently as well. Elliot?.

Elliot Dorff: On the informed consent form checklist - well...

First of all my mother was an English teacher so 6,7, and 8, whom to contact with questions, not who to contact, whom to contact. Okay because (unintelligible) More substantively on 13, I'm sorry 12. Is there language that's asked the subject to waive her legal rights to what? I think I understand what you have in mind but it's not clear from the form.

Henry Greely: Although actually it's not clear from the federal regulation that bans her legal rights either.

David Magnus: (Unintelligible) legal council won't let us do that so it's not - I mean you can't have a consent form that says that.

Henry Greely: Well I know but the checklist is to make sure that your legal council didn't flip something.

David Magnus: But that's not something special about stem cell research. I mean none of our consent forms can ask people to waive their legal rights.

Henry Greely: But none of this is special. I mean, this front page looks like it's classic common rule requirements. Statements of the study involves research etcetera.

Elliot Dorff: Right. I don't know what you have in mind for 12 but if it's legal to put it in then it should also be explicit...

Henry Greely: I think he was just tracking the language of regulation which is itself completely unclear about what legal rights should be...

David Magnus: That's a strange - actually I'd say is the checklist, what's odd about this is you're right. This looks more like 45CFR46 in our guidelines. So I would suggest that if we're going to have a checklist we should include within our checklist the sorts of things that belong...

Henry Greely: Yeah, but that's on Pages 2 and 3...

David Magnus: That's where the oocyte procurement requirements are also subject to requirements for embryo procurement...

Henry Greely: Yeah okay, right.

David Magnus: And so we should make sure we got all those included. We've actually started developing a checklist like that at Stanford so we could probably provide that so we've got something like that has to be done as every SCRO has to look at that we could probably use.

Elliot Dorff: And the next page number 1, again my mother here E.G. comma, okay. But I think more substantively I think medically accurate summary of health and consumer issues associated with assisted oocyte or any alternative method of oocyte retrieval - this is to the patient? Is this in language I would - in language understandable by people not trained in medicine? I mean, is this a checklist for people talking to potential donors? And if so then it ought to be, I mean, even what I just read out loud may not be understandable to people who are not in medicine.

So I think if you really want to have consent it's got to be in language that people can understand. And probably the last thing is -- it goes back to what I was talking about before on the third page number 11-- donors should be offered an opportunity to document their preferences regarding future uses of their donated material. And I wrote in sort of sarcastically, in the likelihood that those wishes will be followed. Again I don't know, depending on what the ultimate regulation is, whether this line should be here at all. Or if so then you have to spell out what the restrictions are that the person's making.

Man: (Unintelligible)...

Elliot Dorff: Yes, that's right.

Henry Greely: And we'll also I think end up revisiting that (substantive) question as well.

Man: Right.

Henry Greely: Comments from the public on - Rusty do you have anything that you want to say? Committee member not physically present.

Fred Gage: Conversation I think...

Man: (Unintelligible) on the telephone...

Fred Gage: Can you hear me?

Henry Greely: Yeah.

Fred Gage: Okay, I just was saying that I'm following the conversation and it seems like this whole idea trying to reduce the size of these forms is a good one. But

clearly there are some requirements that are needed. But brevity will be helpful where possible. That's it

Henry Greely: Okay, thank you. Public comments?

Charis Thompson: Charis Thompson from UC Berkeley. One person you might consider for the reporting - giving the reporting requirements to is whoever the (SARTS) reporter is for the clinical setting for deriving- for extracting the eggs. And there's an opportunity for you in these guidelines to put, even if they're not mandatory they're not code, to put some things that would be good for the health of oocyte donors.

One of them might be age in parity restriction. That's two different ones. I see you have categories 19 and under. That's years before you can have a drink. So if there are any long term effects on fertility for example it's not a good idea for making people research donors at that age. So...

Henry Greely: So you're suggesting that we revise the guidelines to have some substantive constraints? This is just a reporting form itself.

Charis Thompson: I know, but you might say if you do by any chance. Something that might encourage people. I know that you're trying to follow what is the California law but there could be something where you could suggest or maybe not even give the category of 19 and under, for example.

Henry Greely: In the expectation that that would lead people to think they shouldn't use 19 and under, not in the expectation that that would lead them to ignore age in parity. Dropping it could have (unintelligible) consequences.

Charis Thompson: No, I mean I understand that.

Henry Greely: Okay.

Charis Thompson: It's just, you know, some of us have been trying very hard to get parity in age restrictions and also (dose) restrictions you don't need the same dosage of (denatiris) and not (unintelligible) purposes as well as number of times you can donate, restrictions on all of those things. But seriously concerned about potential long term effects of these drugs.

Radhika Rao: What is parity?

Charis Thompson: Well if you haven't had your children yet if there is any chance that it's going to - it's possible you don't want to have children which you should be free to go ahead and donate without having children. But perhaps you have to sign that you feel that way. So just think it would actually protect the health of the oocyte donors as opposed to making it as research friendly as possible even though I understand the motivation for doing that.

Henry Greely: I think I understand those comments but I think the committee should think of them both as possibilities for effecting the reporting requirements. That's something else I might want to take up as substantive (unintelligible) guidelines. I think your goal there is really substantive than it really is reporting. Other comments from the public? From the public online or on the phone?

Coordinator: I do not show any comments at this time.

Henry Greely: Okay, then I think we're done with Agenda Item 5. Which moves us to Agenda Item 6, the remaining issues from the December 5 HSCR advisory committee meeting -- public comments on the guidelines. This again is only

discussion at this meeting. And I think as I recall the main thing we pushed over last time for further consideration were some of the questions really about data collection, what should be revealed, specifically some of the things suggested by then Senator Ortiz and some of the other public commenter's such as any positive - any results positive or negative from non-CIRM funded research or clinical trials. Adverse reactions in clinical trials - a lot of these were clinical trials but not entirely.

Anybody want to speak to those issues? Or anything else for that matter that we had left undone at our last meeting?

Elliot Dorff: Just a question. What we have on hand is this as a result of or in response to the things that we got from the president's office University of California and from Senator Ortiz and so on another - are those changes tracked in here already or are they not in here?

Henry Greely: In the guidelines?

Elliot Dorff: In the guidelines that we...

Henry Greely: The ones that we decided at our December 5 teleconference to adopt are already on here. There were a few that we - some we adopted and some rejected. And some we said we need to think some more about this. The current Agenda Item is for the ones where we said we need to think some more about this. And...

Shabbir Ahmad: The minutes from the meeting have the details about what was adopted (Unintelligible).

Henry Greely: It really would have been a good idea for me to look at that more closely for this. Because I have to confess I do not have firmly in mind what we put over. Somebody help here?

Shabbir Ahmad: There's a list of public comments (Unintelligible). Summarized.

Henry Greely: Yeah it was the - I think it was issues about reporting and as I recall it was there's the list of data collection in reporting requirements that appears in largely similar language in the letter we got from the Pro-Choice Alliance for Responsible Research and the letter we got from Senator Ortiz's office. And I suspect though I don't have it right in front of me, perhaps the letter from the Genetics and Society - Center for Genetics and Society as well.

If we've got those letters I think we are talking - so if you look at the Pro-Choice Alliance for Responsible Research I think on the second page of that we're looking mainly at 1 through 9. My recollection - as I recall one of the things that interested people particularly was this Item 5, the summary of results of positive and negative of any non-CIRM funded research or clinical trial. Because I think we - I think there was some sentiment in this committee that this would be an interesting way of effectively - this might be an appropriate way to get kind of a research registry going. So that you didn't have the problem of clinical trials with results banished in the ether or unavailable for further discussion or analysis, etcetera.

Any of this ringing any bells with anybody else here? December teleconference was a long time ago but I think that's what we were talking about. And actually Bernie, David I think you were two of the folks who were interested in that possibility.

David Magnus: Sorry I was just trying to (unintelligible).

Henry Greely: I think in particularly 5 and 6 in this list from the Pro-Choice Alliance summary of results of any non-CIRM funded research or clinical trial, any significant adverse reactions in clinical trial.

David Magnus: Bernie had made a proposal that we investigate (unintelligible) I don't see it in the minutes - that we investigate requiring or considering thinking about requiring being part of the registry of adverse events.

Bernard Lo: (Unintelligible) clinical trial database...NIH (unintelligible)

Man: Yeah.

((Crosstalk))

David Magnus: So Bernie suggested that we might make that a requirement in clinical trials.

Bernard Lo: (Unintelligible) quite as far as (unintelligible) of actually requiring the reporting of all adverse events. All the registry does is before we start the trial to say (unintelligible) getting proposal for the registry. For example some of the major journals say they won't publish an article (unintelligible).

Henry Greely: And did we end up - and we actually did end up requiring that in our guidelines in Section 9A-5 to register the clinical trial with Public Clinical Trials Registry.

David Magnus: Right. I think that's how we resolved that issue, we decided to go ahead. As I go through - I went through the minutes I don't think there was anything outstanding. The other thing that was outstanding was there was one thing about the UC California office of the president issue had to do with a change

of language from changing quote confidentiality donors as protected to privacy of donors protected with confidentiality of patient is maintained.

There was some concern that UCOP had some concern about that change of language and we were going to look into that.

Henry Greely: Does UCOP remember that?

Ellen Auriti: I think that the change that we recommended was really the semantic wording change which is that donor's don't have confidentiality they have privacy rights (unintelligible) protect the confidentiality of your information. It was a (unintelligible)...

Henry Greely: (Unintelligible) the minutes. At what page David?

David Magnus: Page 5.

((Crosstalk))

Ellen Auriti: The confidentiality of the donors is protected the privacy of the donors of semantic for change, so it was - I still think it makes sense, I don't know whether you changed it or not.

Henry Greely: I don't know whether we adopted it or not.

David Magnus: We suggested adopting it pending comments from UCOP during the public session of the teleconference.

Woman: What (unintelligible)?

Henry Greely: I have a nagging feeling that probably it would do - it would be useful for the chair and others to go back over the minutes in more detail and back over what we went through in more detail. But since we're going to have another meeting in November anyway maybe we can - maybe your chair can come better prepared to remember what it was that we didn't decide. Or what we decided last December not to decide.

I'd thought it was mainly this clinical trial disclosure issue but we did in fact deal with that to some extent, not to the whole extent requested through the clinical trials registry. Radhika?

Radhika Rao: Yeah, one point is we were talking about what the informed consent (reporting form) should include and whether it should include information about human adult stem cells and looking at the letters from the Center for Genetics and Society, the Pro-Choice Alliance for Responsible Research, and Senator Ortiz all three of them - that the data and the reporting should include an overview of all human stem cell research being done at the institution. As opposed to simply human embryonic stem cell research.

I just wanted to point that out because currently the form that's been created by the department includes that. But if you change it we may then get adverse comments.

David Magnus: I think - I'd say I would have probably been sympathetic to that before realizing the scope of what is entailed by adult stem cell research and having a better sense of percentage of that versus the kinds of things we can be concerned about. It's voluminous and it's been around for a long time and a lot of it doesn't really raise any particularly interesting or novel issues. It's the kind of research that's been going on for a long time. There's tons of hematopoietic stem cell research for a long time. Very well established. And

increasingly the notion of what counts as the stem cell has been broadening. Almost any cellular research is now being thought of as stem cell research.

And so it's just huge and most of it doesn't really raise anything particularly interesting or troubling or SCRO related.

Henry Greely: Any more comments from the committee? We can of course - we have the luxury of coming back to this in November if we conclude that we need further discussion. We probably should put it on the agenda for November anyway just to make sure that in an official meeting we can discuss it. I expect we may have some public comment on this since some of the groups that did write the letters are here so I see no more committee comments. Is there public comments on Agenda Item 6, remaining issues from December?

I see nobody in the room jumping up. Anybody on the phone jumping up and down?

Coordinator: I do not have anyone on the phone.

Henry Greely: Well that answers that. And Operator you don't have any comments?

Coordinator: No.

Henry Greely: Clinical trials we don't have anybody to give a clinical trial update. The last I heard Geron is once again for about the fourth consecutive year they're going to start clinical trials next summer. The next summer...

David Magnus: Seek FDA approval.

Henry Greely: Right. Which seems to be a perennially shifting timeframe for them. But one of these days sooner or later it will probably happen. It does mean though that we've got some more time before we have to consider - we have some more time to consider our clinical trials aspect. If we want to change any of it. This is the part that is clearly the most innovative thing in our guidelines because CIRM understandably thinking of what's the best in some clinical trials doesn't have any clinical trials section in its standards. I think this is the most groundbreaking thing we did. And we may try to get a clinical trials report from somebody about what's the actual plausible status is of these clinical trials for our next meeting.

Well, anything – so there is no update on clinical trials.

David Magnus: I just wanted to say that Geron clinical trials haven't happened yet under our recommended guidelines. It also does include certain kinds of - certain classes of adult stem cell trials where normal stem cells are placed in central nervous system. And some of those trials have actually taken place. So there actually are clinical trials that would fall under our guidelines that have taken place.

Henry Greely: Anything other than the Batten's trial in Oregon?

David Magnus: I believe that San Diego is going to be having clinical trials. I don't know what the status of that is for a similar childhood disorder.

Henry Greely: Other comments from the committee on this or any other issue? New business I guess I'm asking for. Any comments from the public on this or any other issue?

Ellen Auriti: I want to ask for clarification on what you anticipate the timing will be for requiring reports from SCRO committees. Just to clarify, there are not reports

required currently because the guidelines haven't been developed yet for what gets reported, is that correct?

Shabbir Ahmad: What we are expecting once these forms are finalized through this committee and approved then by the department we would be distributing them to SCROs probably next year. And would be asking for report in the summer 2008. We are due for a legislative report by the end of the year...

Ellen Auriti: And before that happens though there will be a formal process of formally posting the revised forms maybe based on this with an opportunity to comment.

Shabbir Ahmad: That is correct.

Henry Greely: For our next meeting because at our next meeting we will more officially consider - we will officially consider the proposed forms. And either approve them or suggest further changes to them.

I thought I heard somebody on the phone try to say something.

Fred Gage: That was me, I was talking to somebody else. Sorry to disturb the meeting.

Henry Greely: Okay. In that case any other public comments? Well we have to - we'll schedule another meeting. You know, we've been promising from the beginning that our Southern California brethren would no longer necessarily have to have the pleasure of coming to the best part of California for the meeting...

Man: Undisputed.

Henry Greely: So I think we really do owe them a Southern California meeting. This is about our forth, third or fourth. And even though I grew up in Southern California I don't view that with great joy but I think we will try to schedule our November meeting for Southern California. We'll be in touch via email. We'll try to do the scheduling and we will make sure that all the appropriate postings are made so that we can have a more official meeting next time.

Dr. Ahmad, last comment?

Shabbir Ahmad: By the end of the week or early next week you will be receiving the - an email for the next meeting (unintelligible). I thank you very much for this meeting that give us some guidelines of how to write these forms, modify these forms, so that we can put this in front of the committee next time. And behalf of the department thank you very much. I also want to thank Dr. Lubin and his team over here for arranging, hosting, this meeting.

Henry Greely: You Southern Californians will have to come up with a venue at least as nice...

Man: Oh yeah.

Henry Greely: As the Hospital Research Institute.

Bernard Lo: Can I make a comment? The last two meetings in Los Angeles I went to I had a terrible time getting back (unintelligible) as much as I hate airports (unintelligible)...

((Crosstalk))

Henry Greely: Okay, I think that is certainly something to take into consideration. But you Angelenians I think the department I hope will consult with our Southern California members on the possible location.

Well I'm going to thank you all for coming. And drive home safe.

END