

This transcript is the uncertified transcript of the California CDPH Human Stem Cell Research (HSCR) Advisory Committee meeting held on December 5, 2007. This transcript has not been reviewed for accuracy and has not been approved by the CDPH HSCR Advisory Committee.

**STATE OF CA**

**Moderator: Shabbir Ahmad  
December 5, 2007  
10:00 am PST**

Coordinator: Good afternoon and thank you for standing by. All participants will be in a listen-only mode until the question and answer session.

This conference is being recorded. If you have any objections, you may disconnect at this time.

I would like to turn the call over to Dr. Shabbir Ahmad.

Sir, you may begin.

Henry Greely: Operator, you said that all the media telephone participants would be in listen-only.

Dr. Lubin and McLean should be in talk as well. They're members of the committee.

Coordinator: Yes. Thank you, sir.

Henry Greely: So are they - Bert? Margaret, could you hear me and talk?

Bertram Lubin: I'm fine. Can you hear me?

Henry Greely: Yeah. Margaret, how about you? Are you there?

Margaret McLean: I can hear you. Can you hear me?

Henry Greely: Yup.

Bertram Lubin: Yeah.

Margaret McLean: All right.

Henry Greely: Good.

Coordinator: Thank you.

Henry Greely: Okay. I hereby call this meeting to order and thank everybody for being here telephonically or otherwise. It's a beautiful day here in Southern California, and David and I who flew down are happy to be here and visit with our Southern California friends and colleagues.

We really have one important piece of business that comes in two different parts today and that's the discussion and feedback on the proposed reporting forms.

Before we do that, we should probably and in light of Dr. Lubin's time and we want try to do that as expeditiously as possible. But we do need to introduce who's here and approve the minutes. So let's have sort of a roll call for the recording device.

I'm Hank Greely. I'm here.

Gregory Stock: Greg Stock, I'm here.

Henry Greely: Let's go the committee members first and then the staff, and then public members.

David Magnus: David Magnus.

Otoniel Martinez-Maza: Otoniel Martinez-Maza.

Elliot Dorff: Elliot Dorff.

Henry Greely: And then we've got Bert and Margaret both confirm you're there?

Bertram Lubin: Bert Lubin here.

Margaret McLean: Margaret McLean here.

Henry Greely: Okay. Staff?

Shabbir Ahmad: Shabbir Ahmad, here.

Pat Rodriguez: Pat Rodriguez.

Cindy Chambers: Cindy Chambers

Kate Cordell: Kate Cordell

Amber Christiansen: Amber Christiansen

Henry Greely: Okay. There are no public commenters here physically in the room with us. There are two, I believe, on the telephone on listen-only, so we won't ask you to announce your identities at this point, but we know you're here. And when we get to the question items, we will turn your phones on.

And as I've learned from past discussions, there'll be a question and comment section after each numbered item. So we actually now reached the end of one numbered item, the Welcome and Introduction.

So I guess we should turn their phones on. So operator, would you please turn the other phones for us?

Coordinator: One moment please.

Sir, all lines are now open.

Henry Greely: Thank you. So public members, we're at the comment period on the Welcome and Introduction, if you'd like to introduce yourself, that's fine. If there'll be comments on the Welcome and Introduction, now it's time to make them.

Do we have any public commentators on the line?

Emily Galpern: Yeah, this is Emily Galpern, Center for Genetics and Society.

Henry Greely: Okay.

Emily Galpern: I thought that was a fantastic introduction. Thank you.

Henry Greely: Where do I send your check? It's a joke.

Geoffrey Lomax: I'm still here too, Geoff Lomax.

Henry Greely: Okay, Geoff. All right. Approval of the meeting minutes from September 24, 2007. The minutes were sent out electronically and have also been sent out physically. Does any member of the committee have any comments on the minutes?

Sure. There's a motion to approve. Is there a second?

Man: Second.

Henry Greely: All in favor, say "aye".

Man: Aye.

Henry Greely: Opposed? Abstention? The minutes are approved as written. Any public comments on the minutes?

I am beginning to think maybe we should skip numbering some of these items in the future.

Okay. Now, we get to the meat of today's meeting, the discussion and feedback on the proposed reporting forms.

Man: Yeah.

Henry Greely: As I understand this, these are the reporting forms to - that the department has come up with for purposes of SCROs making reports as required by SB 1260.

SB 1260 require SCROs to make several kinds - two different kinds of reports. The department proposed some forms.

Our role as the advisory committee is to give the department advice on these forms. It's not my understanding that we make the ultimate decisions on the forms, its the department's decision, and we give them advice on the form.

There is, I think, an important stage-setting issue to raise at the beginning. The statutes in SB 1260 requires reporting of two different kinds of things - I'm playing around looking for it. Thank you...

((Crosstalk))

Henry Greely: In Section 125119.3 at the Health and Safety Code found at Pages 90 and 91 of the - printed out version that we have at SB 1260, at the bottom of Page 90 and the top of 91, 125119.3(a) says, "Each stem cell research oversight committee that has reviewed human embryonic stem cell research pursued at the Section 125119 shall report to the Department annually on the number of human embryonic stem cell projects that the stem cell research oversight committee has reviewed, and the status and disposition of each of those projects, including the information collected pursuant to Section 125342."

125342 which is over on...

((Crosstalk))

Henry Greely: Yeah. So it's Page 7 - it's on the page numbers at the top, which is over at Page 7 and the page numbers at the top - that provides for the collection of information about programs or projects - the research program or project that involves AOP, artificial, assisted ovarian oocyte procurement?

Man: Assisted oocyte production

Henry Greely: ...assisted oocyte production, or any alternative method of oocyte retrieval, and has a number of very specific requirements there.

So, those get incorporated by reference into the reporting requirements. It's not entirely clear to me from reading the reporting requirement language in 125119.3 exactly what that incorporation by reference of the oocyte production stuff means, whether it means – it says the information collected is to be reported.

But does that mean that the information is to be transmitted to the department or the basic information contained in those records is to be reported to the department. I think it's an interesting ambiguity.

But apart from that, there's a question before us in advising the department whether we take this reporting form should be limited only to what the statute requires. How ever we decide in interpreting it, we - and ultimately I think the department lawyers decide in interpreting it - what the statute actually requires, or whether in addition to things that are specifically required by the statute, we would recommend to the department that the recording forms include other information.

And the comments we've received, particularly, the comments from the three SCROs, there has been at least a tendency to want the reporting restricted to only those things required by the statutes. We could say that, or we could say if it's good reason for other things to be reported that are beyond what the statutes is, we think the department should require that reporting, and then it

would be up to the department lawyers to figure out whether they have the authority to do that, right?

So Dr. Ahmad?

Shabbir Ahmad: If you go to 125119.5-A, it's Page 4 of 1260 copy. "The department shall at least annually review reports from stem cell research oversight committees..."

And based on those, "may revise the guidelines developed pursuant to Section 125118 as it deems necessary." This is one of the intent of getting these reports so that if there is a need to revise the guidelines, that needs can be put forward in front of this committee. And if committee decides to move forward with the recommendation on revising - so those reports becomes handy as initial information or the need to revise the guidelines. So I just want to...

Man: Sure.

Shabbir Ahmad: ...point out that.

Henry Greely: It provides evidence to the department that the department and the committee could use in deciding revised - whether the guidelines needs revision.

Shabbir Ahmad: Right.

David Magnus: And then the department have to report back to legislature.

Shabbir Ahmad: And - yes. And one of the mandates to the department is that department provide biennial review to the legislature on human embryonic stem cell activity. I think that word is very important. It is the part of the 125119.5-B,

“the department shall provide a biennial review to the legislature on human embryonic stem cell research activity.”

And that activity can only be captured by the department through the reporting forms.

Man: Yes, yes.

Henry Greely: So I think that's the general playing field we're in. There are some things the statute requires. We may want to recommend other things the statute doesn't require, what are the purposes for this information that's not the main purpose for the information collection. It's for the department to have information to use in thinking about the guidelines and for - to be able to report to the legislature that kind of information.

So the reporting is for the purpose of collecting information to be used to think about by the department and by the legislature, the regulatory structure which has done some research in California. Dr. Dorff?

Elliot Dorff: At least as I read 119.5-A, that means that it gives us the - at least the authorization to require things that are not specifically in the statute - and in contrast to what the SCROs have said to us. But in any case, or at least to recommend for the legislature, if nothing more.

And I think - and at least as I read the statute again, you know, these things, but not limited to these things. So - and the way they are - so again, I think one of the real issues here is goals, I mean what's the point of having, you know, what kinds of things could be helpful for California in terms of dealing with human embryonic stem cell research in terms of regulating it, in terms of making sure it's safe, in terms of making sure it's effective.

In other words, what are the goals for the reporting it in the first place and what kinds of information are important in order to accomplish those goals?

Henry Greely: There is, of course, also the flip side which the SCROs have pointed out and which is an appropriate consideration what's the cost in time and effort...

Man: Right.

Henry Greely: ...of SCROs of reported it. And it came through in UCSD comments, particularly with respect to the assisted oocyte production - what are the potential confidentiality risks if too much individual information is provided.

So I think you're right, absolutely right, doctor, so I agree with you , Dr. Dorff, on the benefit here, the plus side of this reporting form is producing useful information for making decisions about regulation.

The downside is the cost and efforts of the SCROs in providing the information and the possible confidentiality risks to individuals. It's not necessarily just the subjects. I think some people were concerned, for example, about identifying these PIs of the specific projects...

Man: Uh-huh.

Henry Greely: ...in a public way that might then put them at some risk. Dr. Stock?

Gregory Stock: With the point that you brought earlier making a decision as to whether we want to add additional material or to consider additional material, I think is very, you know, a succinct way - effective ways in devising the problem. I

mean at that point clearly, we need to weigh the risks and benefits, that I think we should consider.

I certainly feel strongly that we should consider additional information because I think we have the responsibility - that we should try and come up with things that are most valuable and least interfering with this effort and make those as recommendations and I would say that we should, at least in our opinion indicate whether - what things are prescribed then or not, and then in an easy way identify those things that are not prescribed.

Henry Greely: Well, the department has I think wisely provided two different forms because the statute does really look in two different directions in terms of the reporting requirements.

So again, to go back to the language of 125119.3-A, each stem cell research oversight committee that has reviewed human embryonic stem cell research blah, blah, 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 those projects.

That part of the sentence is what the department has turned into Form 1260-1. The remainder of the sentence, "including the information collected pursuant to section 125342", which is the collection of information on the assisted oocyte production research, the department has turned into Form 1260-2. That seems to me a useful division.

Man: Uh-huh.

Henry Greely: Many of the SCRO projects - some of the SCROs won't be using assisted oocyte – assisted-produced oocytes at all. In fact, it's been very little research thus far with those throughout the state, so those departments wouldn't even have to fill out that form, or perhaps just turn it and say not applicable or zero. But all of the SCROs - if it reviewed anything will have to turn in the first form.

So let's turn. Unless there are other comments with the committee members on the phone, let's turn to that first form, Form HSCR 1260-1.

There is a cover page, there's a page with the SCRO committee names and the SCRO contact information, the total number of human stem cell project reviewed between January 1 to June 30, January 1 of '07, June 30 of '08, and the total number of hESC projects.

Now, the first one is stem cell project. The second is embryonic stem cell project. Remember the California law requires SCROs to review and not necessarily vote on all stem - human stem cell research with special requirements for human embryonic stem cell research.

Dr. Ahmad?

((Crosstalk))

Henry Greely: ...would you say something about the reason why we've got an 18-month period here? January 1, '07 to June 30, '08.

Shabbir Ahmad: Yes. The – well for the embryonic stem cell lines, I think the statute becomes effective January - first of '07. And we talked that we are going to be required to produce our first reviewed report for the legislatures some time in

November or December 2008 so we can collect the information for the first 18 months to go into that, into the first report.

That's the thinking of the timeline here.

Man: Yes.

Henry Greely: And then it is your intent that thereafter, you'll go from a July 1 to June 30?

Shabbir Ahmad: That is correct, yes.

Henry Greely: So this is a transitional first year only 18-month period, the SCROs still are going to reporting for each year. It's just for the first year they're reporting on 18 months rather than 12 months.

Man: Okay.

Henry Greely: So, comments on - oh, and then the second page of this, there's the Page 3 and 4, I'm sorry. So Page 2 is the SCRO contact information and the total numbers.

Page 3 looks for information of that individual research projects, the research protocol ID, the project title, the project disposition, anticipated duration, most recent protocol review reason, principal investigator information, co-investigator information.

Okay, Question 9, what it involves, what kind of stem cell research. On the following page, we've got a question about oocytes or embryos, a question - two questions about funding, some questions about location, the source of the oocytes, the embryos, and the sources of cell line, lay summary description of

the research project, a brief description of any serious investigator non-compliance issues, and the response of the SCRO committee to these non-compliance issues.

And that's what the form contains. Comments? Dr. Magnus and Dr. Dorff, and then anybody on the phone?

David Magnus: So, I guess that I'm sympathetic to the comment that this form should be aggregate data rather than requiring particular information that's individuated for each of these protocols.

And so I think it should be simplified, to really get a better sense of what is the total number of projects is, how many kinds, I think some of the things that are in Number 9 that - which is on Page 3, this research project involves...

I think it might be useful to individuate a little bit of the aggregate data that gets collected. Then people can say - specify - about what kind of research they do, that can be useful for the information for the report for legislature, about how much SCNT is taking place versus how much derivation, and trying to get a little bit of information about what sort of categories of research are being done along with an explanation of the unanticipated, unforeseen problems or non-compliance issues.

But I think it should all be - it should be a fairly simple form that lays out so that aggregate data that could then be used for reporting requirements by the department.

Henry Greely: Dr. Dorff?

Elliot Dorff: I agree with that. But I think one thing that I would add to this form is the statement of the progress. I mean, as I read the word “disposition” of each of these project, at least from a lay perspective, I mean from the legislature, I would be interested in knowing what result occur, I mean was there anything important that was discovered, and what are promising things, and what turned out to be not so promising things so that we get a sense of the status of the research.

David Magnus: I think that would be prohibitively difficult and require a tremendous amount of information for every single research project to then be turned over, and I think that's...

It's not - I think it's not feasible. I don't think it was meant in those statutes, and I don't think that it's really feasible.

Elliot Dorff: If I were a legislator, I would want to know what kinds of stuff are - I mean, what's the purpose of this research and is it happening? Is this just a bust or is this something that, you know, where you have the where there is something seriously going on that has some potential.

And I don't think it takes a lot of time. I think it takes two sentences to describe in lay terms what the purposes of the research was, the particular concept was.

((Crosstalk))

David Magnus: Of every research project that takes place?

Elliot Dorff: Or even if you're doing this as a composite, the - let's say, the 60 research projects that we're doing, have the following kinds of goals, and these are kinds of things we discovered to be fruitful, and these not. I mean how much does that take? It takes a paragraph or two.

David Magnus: It's impossible to know at any given time...

Elliot Dorff: And you'll say these things are still in progress, we don't know. This is what you do. In order to be able to inform the legislature - actually, the point of the form is to inform the legislature as to whether there needs to be any further kind of either support, financial support or laws and regulations or whatever in terms of future human embryonic stem cell research.

So, you need to tell a non-scientist, presumably, right, who are primarily the legislators, what kind - what's the status of this? And you can - and it seems to me that every - if you did this from, you know, the major institutions are involved in this. You have four or five reports whatever number it is, 10 maybe, in the whole state.

((Crosstalk))

Man: That's just not....

Gregory Stock: It seems to me that that's not a bad idea, but it would bare a lot of thinking as to what - how you would actually categorize things that are really - for instance the forms - and the reports would arrive at various times that were, you know, ongoing research - much of it basic research.

It's not clear to me what you'd end up with and how valuable it would be - after a short period of time, or even at the time it was produced. It would be

kind of a series of - I think the natural result of this would be that there will be a little puff piece basically about, you know, we have interesting things going on in these various diseases. Maybe that is desirable to create a form that could document – justifying – a couple sentences justifying the research that is being produced.

I think that we need to think about what - if it's really for a hard assessment for the legislation - so there is this much progress being made, or whatever, I think is not going to be achievable without a great amount of effort, and it would be very hard to regulate or police and simply say here are the areas where investigation is going on. Some categorization of those and...

((Crosstalk))

David Magnus: ...captured by the categories that we had in mi - so much SCNT research, so much other research.

So I think what you have in mind is at least seeing here – here's what's working, these experiments at this stage - these experiments going this way that is not feasible, which is not...

Henry Greely: Dr. Martinez-Maza has a comment about that.

Otoniel Martinez-Maza: Plus the state will get a lot of information from CIRM – which is funding at least the state-supported stem cell research, in terms of research progress - and that information will be much more detailed.

Henry Greely: Doctors Lubin and McLean, do you have anything to add on this particular point?

Bertram Lubin: Well, I want to add - can you hear me?

Henry Greely: Yes, very well.

Bertram Lubin: Okay. So I wanted to ask if CIRM doesn't collect the same information for CIRM related things? So that was one question.

And the second is, what about complications or adverse reactions or adverse events, are we - is this in the form as well?

Henry Greely: Yes. This form does require a brief description of any serious adverse reactions. Well, actually, this is investigator non-compliance.

((Crosstalk))

Henry Greely: And then specifically - so we're in the first form, the form we're currently dealing with - the rest is stem cell research overall leaving aside the oocyte. It does require - and the statute requires I think - or doesn't require.

Man: The next section...

Man: All right.

((Crosstalk))

Henry Greely: So in 125119.3 sub B, "each stem cell research oversight committee shall also report to the department regarding unanticipated problems, unforeseen issues or serious continuing investigator noncompliance with the requirements or the determination of the SCRO committee with respect to the review of human

embryonic stem cell research projects, and the actions taken to respond to these situations.” So that's a specific statutory requirement.

This reporting form includes that down on 17 and 18, although having said that, the form talks about serious investigator noncompliance issues. And the statute actually is a little broader than that. It talks about unanticipated problems, unforeseen issues or serious continuing investigator compliance problems. And that's maybe something that we'll need to deal with.

Dr. Ahmad?

Shabbir Ahmad: That's just the correction we'll make in that question. But I have one comment just to clarify on the aggregate...

Henry Greely: Uh-huh.

Shabbir Ahmad: ...information. The statute says that “the status and the disposition of each of those projects”, so it's the word “each” is there - yeah. And the second comment I have is regarding - just to clarify - because this form would not be filled by the researcher, this form would be filled out by the SCRO.

Man: Right.

Shabbir Ahmad: This would be filled by the SCRO, and SCROs have already - you will see in your comments to which you receive, they have raised a very huge concern about the burden of filling these forms.

So look at the - how the information would flow. From each of the researcher, it would come to SCRO. SCRO would fill for each project, so that's just a

clarification. Whatever the recommendation comes from the committee - I will respect that.

David Magnus: From when I was reading this...I thought...

((Crosstalk))

David Magnus: I thought that the status and disposition of each of these projects - I thought could be captured in either individual or aggregate form.

So if somebody says we have 15 protocols, three of them were this, four of them were like this, two of them were like this, what happens to each of them, and reported that in an aggregate format, but that would constitute giving this information about which the statute requires.

Is that incorrect? Is it that each require individual information about each protocol or is that information can be captured in an aggregate fashion?

Elliot Dorff: It's a more creative interpretation of the language.

Henry Greely: But it's not necessarily an impossible interpretation of the language.

((Crosstalk))

Henry Greely: So I think you've accurately identified - I think that this is interpretation differences between you and Dr. Ahmad - it has accurately identified an ambiguity in the statutory language. Statutory language typically has ambiguity for the rate of at least 2 or 3 per sentence if you really start looking at it hard enough.

I think you could read that either way, Shabbir's way is a little more intuitively plausible, but your way isn't implausible.

David Magnus: And in terms of the goals of the statute, I mean my interpretation, not only makes life easier for the SCROs and ultimately for the department – because it gives them the kind of information they need for putting together the reporting that they need to do - whereas giving them very fine details of the information about each individual protocol - means essentially the department will have to then aggregate it and then get back to the state legislature.

Henry Greely: And then in terms of this information about disposition of the protocols, how useful is that information going to be to the legislature if disposition's protocol is completed, and in this protocol, was renewed protocol still in progress?

Would the legislature find the disposition of individual projects of any value?

Man: Right.

Gregory Stock: Yes, I would say something. If you aggregate the information, does the individual information - essentially, would it have to be collected? And is there a way of going back from the aggregate information, you know, this would raise some question. You know, there are several projects in this particular area, we'd like to know more about those. Is that possible?

And if it is, in fact, the individual information that's captured, then does reporting in an aggregate actually just increases the time that it takes to actually now aggregated it further for the report.

David Magnus: We heard that clearly from the SCROs that they would prefer that the statute be done aggregately. I think if the reporting was aggregate to the department, but they would have all the individual information. So they - the SCROs...

Gregory Stock: Is it just that they wouldn't have individual reporting forms to fill out?

David Magnus: Correct.

Gregory Stock: They would aggregate the information?

David Magnus: Correct.

Henry Greely: Other comments on this general topic? I was going to suggest that we start going page by page through the form.

Hearing no objection, let's take a look at the first page of this form 1260-1. The cover page - I don't think there's anything we need to spend time on the cover page. And the next page is just the SCRO committee name, the contact information for the SCRO.

I don't see anything particularly troubling there, although - if somebody does, let me know. A lot of address lines, but some universities have long addresses.

The total number of human stem cell projects reviewed and the total number of hESC projects reviewed. I don't see anything objectionable about either of those. Anybody have any problems with that first page?

Turn to the second page. This is the page that would be individual reporting on each project, this and the next page.

David Magnus: I recommend replacing these two pages with something that basically gives aggregate information on - say more along the line of proposal that the Steve Peckmen provided in his comments that gives - that lays out the disposition of the project, whether there are unanticipated/unforeseen problems or there were serious continuing and non-compliance issues and how those were addressed.

And then I would - but I would add to that in addition to just the information on how many projects and what were their disposition, but that we break it down a little to see what kinds of research projects that were approved of the type that's better restated in Number 9 on Page 3 of this form, you know, it's what - it's actually in vitro, in vivo, how much creation are derivation, somatic cell nuclear transfer, basically these types of things.

I think that information would be actually easy pretty much to put together.

I would add to this how much was - maybe something about placing of embryos into non human animals.

((Crosstalk))

Henry Greely: Placement of embryonic stem cell...

((Crosstalk))

Henry Greely: ...and not embryo.

David Magnus: Sorry.

((Crosstalk))

Gregory Stock: And possible additions, I like the suggestion, but I was wondering whether the Number 1 through 6, for example, could be reported individually? So essentially, there's a little table that lists all of the projects and basically - so there's - we have, you know, a list of all the projects, and not who the principal investigators are, all of the details about that.

And then an aggregate presentation of all the other kinds of information. I think it would reduce the burden I mean, of reporting individually and then it doesn't allow easy access to inspection or - into the project, but it's clear, that does provide some additional information as well.

David Magnus: It does seem give you some sense of the kind of research going on.

Gregory Stock: It would be very easy they have got all that information that we have to go through anyway. So I would - if you would, report the information in that way.

((Crosstalk))

David Magnus: I would - it would be interesting to see what the SCROs say about it...

Henry Greely: I would - make a note on that particular point. This may be an issue where we wanted - make it a - would want to ask the department to make a distinction between human embryonic stem cell research and human stem cell research.

As our SCRO has had many protocols that it has had to review administratively from non-embryonic stem cell research. That's not the area that the state is particularly interested in. It's interested enough, that for historical reasons, it's requiring some SCRO review, but it's not requiring a vote, it's not requiring - it's not a - not the same level of interest.

But if we wanted to keep something like 1 through 6 and 9 from this form, on an individual basis, 1 through 6 on an individual basis, David, I guess your proposal is 9 on an aggregate basis?

I would think we'd really want to do that in a human embryonic stem cell research and not the non-embryonic stem cell research.

Man: Right.

Henry Greely: ...not the bone marrow research.

Otoniel Martinez-Maza: What about new methods of generating pluripotent stem cell that is still evolving...

Henry Greely: You know, I actually have on the agenda suggested in - we put on the agenda as Items 4 and 5, discussions about the guidelines and discussions about future topics. And I think that's one of the future topics or guidelines that I think we should talk about. How do these new methods - how should we view these new methods?

Currently, our guidelines deal with pluripotent cells so they would apply to that these, but we might want to reconsider it at our next meeting, whether that's the case.

But let me suggest we cover that question, but we'll cover it deeper in the agenda. Dr. Dorff?

Elliot Dorff: All I would do as he suggested is just add one more thing, just simply the goal of the project, in a one sentence, what's the goal of doing it, whether it's a

certain kind of basic research and certain - whatever it is, just simply - ask somebody...

David Magnus: That's a lot of work to be able to pull this information, that's great if it's actually articulated.

Elliot Dorff: For every research project, the principal investigator must have at least some goal in mind.

Gregory Stock: I would say that...

Elliot Dorff: Right.

Gregory Stock: ...it would occur that you could get that information specifically from the title.

((Crosstalk))

Elliot Dorff: The question is the title - I'm thinking of legislators, right, the goal of all of these reporting is to go to the legislature. Legislators are not scientists, and the title is likely to be in scientific terms. I was simply looking for one sentence, a one phrase thing, statement of the goal by the principal investigator as to what's the point of this project.

David Magnus: The legislature is just not going to get a list of all the titles.

Elliot Dorff: If they want them, they can get a sense of what's going on.

David Magnus: That would not be helpful and the reality is if you had investigators saying here's what my goal is, the ability of the legislators to understand is slim. I

have spent a lot of time trying to reword the forms so that it would be understandable. I think that's unlikely to happen.

What this would do is give more information - the titles would give information for the department so they have a better sense of what the research that's going on is - to then communicate with the legislature the sort of scope of what the nature of the activity is -

But having a legislature be involved in that level of detail of being on top of what all of the research is- every individual protocol in the State of California for stem cell research, I think is neither reasonable nor desirable...

Elliot Dorff: I disagree, I will just leave it at that.

Henry Greely: Let's - and, you know, we're not resolving this right now one way or the other. And maybe if we don't resolve, the committee doesn't necessarily have to vote and bless one or two - one of these two different recommendations, the staff is here for the department, the staff is hearing what's being said and this is advised to them. And the advice might be - some people think this, some people think that, something I think we may be able to agree on is number 7-8.

You know, I'm in the - let's find some progress to make mode here. Question 7 and 8, all the details - the principal investigator and co-investigators, I'd felt - why do we need those and would we suggest that we eliminate them?

Elliot Dorff: Right, especially for the confidentiality issue that would be great, yeah.

Henry Greely: Any objections? Any disagreement with that?

Man: No.

Gregory Stock: I would agree.

Henry Greely: Okay. And that I do think it's a ... a question that I am not on rest on is this question 9, this research project involves the various sorts of things.

David is suggesting that the form report that in the aggregate so you know that three of them involve this, six of them involve that, nine of this involve - nine of them involve this. And, you know, David, one of the other complications there is some projects involve more than one.

David Magnus: Right.

Henry Greely: So you'll have an adding up to greater than 100% versus having for each of the individual projects identify 1 through 6, check marks in these boxes. Those strike me as the two big alternatives there.

Obviously, there is some increased work for SCROs doing them individually. I don't know that I think it's that much. Is there some increased information. There is - I'm not sure that there's that much, although if we read this in conjunction with 17 and 18 which are the questions about where there unanticipated problems, unforeseen issues, investigator problems?

And one could argue that if you've seen more problems with a certain kind of research, that's a helpful piece of information. So what people think about the aggregates versus the individual on Question 9? Dr. Stock?

Gregory Stock: I feel that it's actually less useful individually than aggregate because anybody who is reading through the individual information would actually be...

((Crosstalk))

Gregory Stock: ...aggregating to get the aggregate information.

And I think just the points that you've made about adding up more than 100% would not be an issue if these were simply - if you were checking it off, and you'd get them numbers of projects that involve each of these categories then...

Man: Right.

Gregory Stock: ...it doesn't matter whether if one has - if we could be interested in these levels of activities. So I think that number 9 should definitely be on the aggregate.

Much more valuable. And as I look at the items 1 through 6, I'm thinking that really as items 1 through 4 just need to be reported individually and probably for the purposes of legislatures 5 and 6 are not useful, and there are a lot of work to put in the - or very quickly out of date.

Man: Yeah.

Henry Greely: And Dr. Ahmad, can you give us your thoughts on questions 5 and 6, the protocol dates and the reason for the most recent review, what does the department find useful in asking those questions? Do you recall?

Shabbir Ahmad: This was like - to basically identify each project because there is going to be yearly reports and the project usually did not enter within the year, so there may be a project that should be - that's being reported for multiple years. So these are - some of these information identify the projects.

And that also this would give some information about the activity related with that non-compliance like the project started in 2005, and the non-compliance was reported from that project in 2008. So it would relate the information to the project.

Henry Greely: Dr. Dorff?

Elliot Dorff: If this is an aggregate and those kinds of things would be by SCRO. It would say the number of projects, the number of new projects, the number of projects that are on going, the number of projects that have been completed, and that was...

Henry Greely: I think 5 and 6 – currently we don't intend to be aggregate. That's individual, right?

Shabbir Ahmad: That is my - that was the basis of my question.

Henry Greely: So 1 through 6 would still be individual project based.

((Crosstalk))

Henry Greely: Nine would be aggregate.

David Magnus: Let's make a version that 5 and 6 that are aggregate - and keep 1 through 4 individual.

Man: Yes.

Man: Right.

Man: Right.

Gregory Stock: Or individual - you got everything individual, you would like that information captured individually if you're going to be some of it in aggregate, then I would think that the intent is really to have aggregate information about that type of decision that have been made. I mean in terms of the adverse events versus or the number of the renewals, the number of new applications...

Man: Yeah.

David Magnus: You want to capture the activity of the SCRO.

Man: That's right.

Otoniel Martinez-Maza: We see a lot of modifications adding in a person to the protocol, and so thinking what we would get, we have a lot of these modifications which really tell you very little about how old the project was or other things that occur.

Man: Uh-huh.

Henry Greely: So you are arguing that six is likely to be not very useful - individually or aggregate.

Man: It might be good to know how long the project has existed, but whether the last protocol was reviewed for simply modification and renewal would be confusing.

Man: Dr. Ahmad?

Shabbir Ahmad: We, the department does not have a strong feeling about 5.3 – the expiration date. Based on comments received...

Man: Yeah.

Shabbir Ahmad: ...from ESCROs and also having some experience with the research, you don't have a particular end date for a given project. I think that is the – in front of the committee here - if you want to recommend that we remove the expiration date 5.3, that is okay.

But whatever is your recommendation on the initial review or most recent review, I think that's up to the committee, yeah.

Henry Greely: Okay. What does - department have any particular interest and a reason for arguing strongly for Question 6. I thought Otto's comment on Question 6 is a very powerful one that most of what you see are modifications or renewals. It's not going to be a very useful question.

Shabbir Ahmad: I think there is some information there. Although there may be majority of the projects that would be marked as modification, but there would be some percentage of projects which would be like a new project or a renewal. And it's also captured - that this project, if the individual information is coming from each project, then this project has in a non-compliance issue.

The information is there, then this is Number 6.

Henry Greely: Although non-compliance would be picked up in 17 and 18.

Shabbir Ahmad: Right. But if the committee is feeling that information would come in aggregate, then that would be lost in terms of identifying the problems.

Henry Greely: So I think you're hearing from various members of the committee, a variety of different questions about 5 and 6, one is aggregates versus individual, one is are they useful at all in either aggregate or individually?

The expiration date, I think you've accurately identified is the one thing here that seems to have the least value.

Personally, I'm not sure that Question 6 has significant value particularly in light of Otto's comments, but even more generally, I'm not sure why you would care what the reason for the most recent review was.

With 5, 5-1 and 5-2, I can see arguments for that, and I actually - I don't think this is universally shared. I think you could - I think it'll be somewhat useful to have that on an individual basis rather than an aggregate basis so you know for each thing when it's started - basically how long it's been going and when it was last reviewed.

That often has - should add a little bit of the enforcement assistance and that they're supposed to - these things were supposed to last only for a year. And so as a reminder to the SCROs, when you put them, first renewed in January 2007, next renewed in March 2008, what hopes that probably say, "Oh darn."

Man: Yeah.

((Crosstalk))

Man: Or something perhaps little more colorful...

Man: Right.

Henry Greely: ...on the part of the SCROs. So I kind of like 5-1 and 5-2. I don't care much about 6. I don't think it's a big deal, but I don't really see any value to it.

Man: Okay.

Gregory Stock: If you make the non-compliance issue, I think that that should be a single presentation, but should refer to any - it should be focused on particular project...

((Crosstalk))

Henry Greely: Right, right, right.

((Crosstalk))

Gregory Stock: If we make 17 and 18, individual...

((Crosstalk))

Henry Greely: Yes, yes.

Man: Right.

Gregory Stock: Then I think we have no need for 6...

((Crosstalk))

Henry Greely: But I think even Steve Peckman in his very summary form had individualized answers to those.

((Crosstalk))

Gregory Stock: And then 6 would not be relevant. And I agree with you about your initial review data and your most recent review. It sort of makes a nice little table for all of these.

Man: Yes, I agree.

Elliot Dorff: Right. But I'm on 17 and 18, are you going to include what's in the statute of unanticipated problems, unforeseen issues, or serious continuing noncompliance?

Shabbir Ahmad: Yes.

((Crosstalk))

Shabbir Ahmad: That is the correction that we want to make.

Man: Okay.

Henry Greely: That's a good segue. Can we turn the page?

Man: Okay.

Henry Greely: Yeah. I think that helps. I think we finished with the previous page, so now we're on the fourth and last page of this form. We've had some reference to 17 and 18 at the bottom of this, and in fact, that they will be expanded to include the entire statutory language therein.

But now we've got six other questions on this page. The first deals with - if human oocytes or embryos were used in this project, please specify if the women from whom - from which...

Elliot Dorff: From whom.

Henry Greely: From whom, right.

...materials were procured, were they IVF patients or did they donate specifically for research, for each of those, how many?

And then list unique clinic and patients identifiers, then Form 1260-2 has to have been completed for all the subjects listed above. So this in a way ties together the two forms, it's not something that appears in that first part of 125119-3.

David Magnus: I'm not sure why we have overlap between subjects in this form and the other form which oocytes procurement. We have another form HSCR1260-2 for that. I'm not sure why we also need to have something about oocyte procurement in this form.

Shabbir Ahmad: The - if the project involves only IVF, so then there is even no need to go to the other form in that case.

Man: That was one of the questions I had, is that right?

Woman: Uh-huh.

David Magnus: So, for oocyte retrieval only in cases where its non IVF cases- that's where the problem with the CIRM regulations is they don't make a distinction between oocyte procurement was done incidentally for IVF or for some other sort of reasons.

But does 1260 does not make the distinction?

Shabbir Ahmad: 1260 always says AOP for research.

David Magnus: Okay. Yeah, yeah.

Shabbir Ahmad: So I think that's a quite clear distinction of 1260.

David Magnus: Okay.

Shabbir Ahmad: So that's the basic reason of including over here that's - what the source of the embryos whether it is IVF or it is donated specifically for research.

David Magnus: I guess.

((Crosstalk))

Henry Greely: ...or the development of medical therapy.

David Magnus: I guess that's the question whether this should be aggregate data or individual data.

Man: Right.

David Magnus: About whether it would be better to have just information about how many of our protocols involve, you know, procurement or access to these things taken from IVF. We have this much from this because it's so much whether or not aggregate is better than...

Gregory Stock: Okay. Just a question to clarify, whoever is filling out Item 10 on this Form Number 1, 1260-1, they will be filling out form 1260-2, right?

David Magnus: But not everybody is going to have to do 1260-2 at all.

Gregory Stock: Right. But anybody is answering in affirmative here which is the ones in whom we are most interested...

David Magnus: No. No. So some people can be answering yes on this question, but not have to do form 2. Say - and again, if it's from IVF. They might not do any oocyte procurement and they don't have to fill out the form 2.

Elliot Dorff: So that's why you need to have this.

Gregory Stock: Or - I was thinking individually, what you really want to - perhaps do is identify in this initial information - you want to have a check mark if that particular project involved donors. So - but then, you need to go through and see that list, and it's very easy to see which ones you needed to have...

Man: Uh-huh.

Gregory Stock: ... this other form. And then it would be useful information whereas this information here may not be useful individually.

David Magnus: Yeah. And so I am still not sure why we have this when we've got essentially the kinds of research being captured by Number 9? Why? What's the point of Number - what's the point of Number 10?

Shabbir Ahmad: I think it's - it relates to provenance of the embryo or oocyte.

David Magnus: There's nothing in here that really establish that or not.

Shabbir Ahmad: If that would establish whether the embryo or oocyte is coming from IVF, then they call it as donated by an individual for research purposes. I think the...

Elliot Dorff: You know, 9 is really the kinds of research whereas 10 is the sources of the material that are - so they really are separate.

David Magnus: So I guess - anybody who does research where they are deriving it from a research donor has to fill out the second form. We essentially already have that information because if they fill out this form and not this one, so we know that they got this from IVF.

Shabbir Ahmad: This is a good point so that would - this would link form 1 and 2, yeah.

David Magnus: That, you know, is redundant. You already have that information, so everybody who has filled out this form and not this one, you know that that - and have indicated on question 9 about the kind of research they've got. You know the source from that.

Shabbir Ahmad: Except IVF information would not be captured, but then the...

David Magnus: So you know that they had to have gotten from IVF and that's the only possibility that you saw Number 2, then they had to have gotten the them from IVF, right? There aren't any other source of embryos other than research donors or...

Shabbir Ahmad: We did give the possibility 10.3 "neither". It could be anything, I don't know.

((Crosstalk))

Gregory Stock: So the question is, is it useful to have the ratio of the women or the number of oocytes from IVF patients as opposed to one, specifically for research, and that's the only thing captured here, that would be important.

David Magnus: I'm just thinking about how hard it's going to be to get this information especially the reality with what a lot of these protocols are looking like is that they're mixed, right, so they are using a combination of - failure-to-fertilize oocytes with - along at least for CIRM funded research - along with trying to get research donors.

I could imagine that these questions could be very hard to answer. The SCROs won't be able to guess from the - based on the information that I've seen being on the SCRO and looking at these kinds of protocols...

Man: Right.

David Magnus: ...I couldn't answer this question, and that means I'm going to have to get back to the researchers and ask the questions that I'm not sure if they're going

to be able to figure out, which just means that the SCROs are going to start squawking...

Henry Greely: And what useful information do we - would we get as the result?

((Crosstalk))

Henry Greely: We get information about the ratio of IVF derived oocytes versus research donor derived oocytes?

David Magnus: Which we won't even know, I mean at the time that the protocols are approved...

Henry Greely: Right, right. That is what's being asked. If everything worked perfectly and you got all the information that is being asked – that is the piece of information that you have gotten, - how much is that worth?

David Magnus: Well, what I am saying, at the time that the protocols are approved you don't have that information.

((Crosstalk))

Gregory Stock: If you had that information, would it even be of value, anyway. Okay. So then you could create the linkage if you just had a single box to check where there research donors involved...

((Crosstalk))

Gregory Stock: ...we didn't have to say if so, and then anybody, the ones who wants to look through could make sure that all of those forms were present, you know, if

you wanted to have that linkage, but all these information is somewhat redundant, and not very useful.

David Magnus: And again, I say, even more that, I don't think it can be filled out. At the time that protocols are approved, I don't think we can answer these – in practice SCROs can't answer these.

((Crosstalk))

Henry Greely: That is true, you can say that we expect to use 20 eggs, and we expect to get them from IVF. But at the time the SCRO approves it, you don't know how many eggs did they actually use and where they came from.

David Magnus: And you might say, that we are going to look at two different sources we are going to get as many as we can up to the 50 that we are going to use, and we are hoping to get some of these and some of these...

((Crosstalk))

Henry Greely: You would know how many that they used up to the point of the renewal.

((Crosstalk))

Elliot Dorff: And the one thing that you might find out from this is whether the timelines that we have that require no payments for donors for research are effectively meaning that they're getting no donors.

((Crosstalk))

David Magnus: We will know that if nobody fills out form 2.

Gregory Stock : You'll know because you will know how many actual donors there were.

((Crosstalk))

Gregory Stock: In fact, you could get that ratio if instead this is, except for the renewals, it's filled out in advance, so it's probably easy to see the number or eggs that are targeted or something like that in the research ...

((Crosstalk))

David Magnus: The problem is you - the protocols target the number of oocytes, and they will specify a source. They might not give you a break down of how many oocytes you are going to get from IVF versus from research donors.

Because you don't - it's impossible to know at this point...

((Crosstalk))

Henry Greely: I think we're getting significant question to department and that's the value of question 10. You need to think hard about whether that's a question that has any significant value.

David Magnus: Or if it can even be filled out.

Henry Greely: Or when it could be filled out or how. I also don't understand why you would you want to list the unique clinic patient identifiers on this form?

Elliot Dorff: Especially, if it is going to be in aggregate form to begin with.

Henry Greely: The questions 11 and 12 are funding question.

Margaret McLean: Hi.

Henry Greely: Yeah.

Margaret McLean: This is Margaret...

Henry Greely: Hi, Margaret.

Margaret McLean: ...and I'm going to have to go unfortunately.

Henry Greely: Oh okay.

Margaret McLean: My only comment on this where you're going now is the necessity of Question 11. Since the 100%-funded CIRM research is not required to fill out this form according to Page 1. So I'm not sure that question needs to be...

Henry Greely: Right.

Margaret McLean: But I have a case consult that I need to attend, and I'm going to sign off now.

Henry Greely: Okay.

Margaret McLean: I'm sorry.

Henry Greely: No, no, I understand. I guess this raises the question of whether the committee is actually going to vote on any of these things. If we no longer have a quorum, we can't take any official action is my understanding.

We could probably - I don't know that we couldn't continue the talk and provide our inputs to the department.

((Crosstalk))

Henry Greely: We could do it through a motion if you want to. I'm not sure that we need to, but we could.

Margaret, are you still there?

Margaret McLean: I'm still here.

Henry Greely: For another minute. And Bert, are you there?

Bert, with your confession and apology may turn out to be moot, Bert?

Margaret McLean: Hi.

Henry Greely: Calling Bert.

And Bert was going to be in a cab, and he may - we may have already been without - it sounds like we don't have a quorum right now.

((Crosstalk))

David Magnus: So we can't vote.

Man: Okay.

Henry Greely: But, you know, that the staff is hearing our advice.

David Magnus: Right.

Henry Greely: So Margaret, thank you for coming while you were here.

Margaret McLean: Yes, you're welcome. Sorry about this.

((Crosstalk))

Margaret McLean: See you next time.

Henry Greely: Well, now that Margaret is gone and then there are like five of us here.

So, this now becomes truly the committee and the public commenters giving advice, giving our thoughts and comments without any official vote on it or any committee action. I think that still - and I think they've gotten a lot from what we said so far without they're being any committee action on it.

There is my view that it's worthwhile for us to continue going through these...

Man: Uh-huh.

Henry Greely: ...especially some points until 3 o'clock. Other thoughts on that?

Man: None.

Henry Greely: Okay. So 11 and 12, others have some comments on 11 and 12?

David Magnus: I think Margaret is right, 11 is mostly not relevant.

Henry Greely: You don't have to fill us out. But...You know, actually, it's not clear to me that you don't have to fill this out. This is - yeah, supposed it's right...

((Crosstalk))

Henry Greely: ...and you need the CIRM funded one is...this is not – the CIRM is not subject for 125119.3. On the other hand, we're asking SCROs. SCROs might be subject to - well, forget about the legal argument which I think could be a - I could imagine getting convoluted in complicated ways.

Is there - if we're interested in getting information, is there an advantage, is there any value in getting aggregate information, not from each SCRO, not individual project information, I don't see any good reason for 11 and 12 as individual project information.

But aggregate information about who's doing the funding for the stem cell, for the human embryonic stem cell research that's going on in the institution.

Elliot Dorff: Right. In which case, what you'll be getting is how many of the SCRO projects were 100% funded by CIRM and how many were funded in part by CIRM which is in - which is 12, as well as other funds - sources of funding. And the question is - I mean I think on an aggregate basis, that might be interesting information.

I don't know whether it's necessarily useful. I mean...

((Crosstalk))

David Magnus : And SCROs don't often have that information, do they?

Henry Greely: We ask for funding source, although, you know, I don't know if that would require somebody to amend or modify their protocol if they got an extra funding source...or lost a funding source they expected.

Otoniel Martinez-Maza: Many times its stated as applying to multiple funding sources.

Man: Yeah.

Henry Greely: So we may not be able to answer it.

Man: Right.

Henry Greely: Okay. Benefit is marginal. Benefit is limited; cost or ability to do it is a non trivial issue.

((Crosstalk))

Henry Greely: Well, and just because you won't know at the time you approve it. So the SCRO might have go back and ask the investigators, so did you end up getting that grant you're hoping to get?

Man: Yeah, right.

((Crosstalk))

Gregory Stock: So it seems to me that the accuracy of the information would be somewhat questionable, but none-the-less the aggregate information might be useful.

Man: Right.

David Magnus: We can't ask SCROs to give official information to the Department of Health if it's not accurate. So what it means is in practice to fill this out and turn this in, it means they're going to have to track down researchers to specify funding - I think there is a problem.

Otoniel Martinez-Maza: It would require contact with the PIs on a regular basis.

David Magnus: On a regular basis.

Henry Greely: At least at the time you're doing the report.

Otoniel Martinez-Maza: With us, since many people begin a project with unrestricted funds and then seek funding, it becomes funded some time after being approved, and the SCRO doesn't necessarily know that.

((Crosstalk))

Gregory Stock: You could modify this then, it could be the funding sources anticipated at the time of the original provision or something like that.

Elliot Dorff: And some question is...

Henry Greely: How useful.

Elliot Dorff: ...how useful is that? Yes, that's right.

Man: As we're going to fund, it's...

Elliot Dorff: And I can imagine the legislature wanting to know the percentage of funding that's coming from the state project itself as opposed to the percentage of funding that's coming from other sources.

But I think - but given, you know, the fact that SCROs don't know that, I don't know that SCROs can provide that information. We would question ...

David Magnus: And it would not be telling you the amount anyway. All this would tell you is...

Elliot Dorff: Right. The sources. Right.

Henry Greely: And there's sort of another deep point that hadn't really occurred to me until this discussion, let's say the legislature, or the committee shares with the legislature, gets interest in this question, how much of the research funding is from where - or the department, for some reason, gets interested in the question.

There is nothing in the law that prohibits the department from asking SCROs, would you please tell us, give us this information because the chair of the Senate Health Committee has asked us for this information? And I could be wrong, but I think SCROs will typically be eager to respond to reasonable requests from the department.

So if you wanted the information for some specific useful purpose, you can ask for - separately from this reporting form. From the department's perspective, the reporting form just makes it easier. You don't have to go out and ask separately.

From the SCROs perspective, it means you've got to keep churning out the data whether it turns out to be used or not.

Elliot Dorff: Right. So you might want to just eliminated from the form and just - and then if the legislature ask for it, so then you'll find it.

Henry Greely: What about 13, 14, and 15, the locale of co-investigators and collaborators, first of oocytes and embryos source in this contact a geographical source and source of cells and cell line again geographical source?

David Magnus: Again, I think that shouldn't be individualized. And I said, again I...

((Crosstalk))

Henry Greely: Although, to be fair, we do know - we do find out what cell lines they're using if they are using outside cell lines

((Crosstalk))

Henry Greely: But oocytes - that would only be 15.

Gregory Stock: Yeah, 14 is in - 13 is relatively - right...

David Magnus: and even 15, I mean the reality is there's active research engaged in, I think that researchers are engaged in to determine whose cell lines are mostly used - the question of cell lines, and then you've got some research project on (unintelligible) to which the white cells versus the Harvard cell lines are being used by researchers and how many people have.

So, I think that information is actually available in the literature, so...

Henry Greely: So you're in for cutting 13, 14, and 15?

David Magnus: Right.

Henry Greely: On both the individual and aggregate.

David Magnus: Right.

Gregory Stock: I would say the aggregate, the 13 might be of use, they usually know this, why would it be difficult?

David Magnus: Why would it be helpful. It could change.

((Crosstalk))

Gregory Stock: Are all these thing being put in place there is an attempt to get some sort of information about value of the program of - and they're trying to grapple to get a feel from where the research is simulated in California, maybe it's leaving the same...

((Crosstalk))

Gregory Stock: Is there anything that we could get that would give communicate something of that flavor that's valuable that would be meaningfully used, or is it just, you know...

Henry Greely: Another way to read 119125 - 125119-3 is that it tells you the number, the amount and it tells you whether there are any problems. If you could say it's really aimed at getting information about problems, safety and other problems

rather than necessarily getting a deep amount of information about the status of the research in California. You could say the other one as well.

Man: Right.

Henry Greely: Reading legislators' minds is usually a challenging and not necessarily deeply rewarding project.

Man: That's right.

Gregory Stock: And I think the comment too that if we're really trying to get information where some social research can be done without - because that probably could be meaningful, someone who does that would have to go around and get more detailed information.

Man: Right.

Gregory Stock: So all it would encourage would be that there would be rather loose statements that really probably aren't very grounded in reality.

Man: Right.

Gregory Stock: It could be derived from very easy to access information. So maybe it's better that we don't collect the information.

Henry Greely: Yeah. So Dr. Ahmad, you and I would talk about the department theory behind 13, 14, and 15?

Shabbir Ahmad: The 14 and 15, it's mainly related to provenance. And then also if you look at the SB 1260 last page, which is the Page 8, 125346, although this is not a

requirement for collection of the information, but it did say that any procedures for procuring the oocytes in this state for research or the development of medical therapies shall meet all the standards for subject included in this chapter.

All oocytes procured outside of this state for research taking place in this state shall meet these same standards.

So, and these are a couple...

David Magnus: There is a difference between a requirement substantively of what the SCROs have to do and from a reporting requirement.

Man: Right.

Shabbir Ahmad: Right, right. Yeah. This is not requirement for reporting...

((Crosstalk))

Henry Greely: Yeah. Right. But one can argue that if the state knows that a SCRO - that the UCLA's SCRO is using or plans to use approved projects that plans to use non-California oocytes and they were interested in investigating compliance with that section they would know to go to UCLA. Although, of course, the question on oocyte or embryos or just oocytes? Does this question just deal with oocytes?

Man: Yeah.

Man: Yes.

David Magnus: And realistically, oocytes are much more limited in where you can get them from because they go south very quickly. So embryos you can actually get them from out of state, but oocytes probably not.

David Magnus: Realistically, we don't have any - we don't know how much if any oocyte research is actually going on so far or will go on in the future depending on how science develops.

Man: Okay.

Gregory Stock: Just to make sure, are we going to capture what – we are going to not vote on it, but is the goal at this point to come up with a recommendation that we are going to bookmark so at the next time the whole committee gets together then we can say that as this working group, we came up with the following suggestions, it is unlikely - would be very likely to be not revisited...

Shabbir Ahmad: Well, we can put that information together for the committee from the...

Gregory Stock: So the next time we will have the...

((Crosstalk))

Henry Greely: Well, although you guys want to get these forms ready before long - right?

((Crosstalk))

Man: Can we do it by mail?

Henry Greely: Well, the alternative is, do we need to have a committee recommendation as opposed to the comments made here and recorded and transcribed of

committee members who have observed it which then providing input to the department.

Man: Did you find it helpful to have a formal vote and do you think the discussion is sufficient for you?

((Crosstalk))

Shabbir Ahmad: I'll leave this to the chair of the committee.

((Crosstalk))

Henry Greely: A formal vote requires another meeting.

((Crosstalk))

Gregory Stock: Can we do it by email?

((Crosstalk))

Henry Greely: I think that maybe difficult. Phone conference, we could, but to vote without a meeting where there's - because the public transparency and public comment provisions, I don't think we can just circulate the resolution by email and say, "Who's in favor?"

Shabbir Ahmad: No, no. No what I mean was in the future meeting...

Man: No, no, no.

Man: Yes, I understand, yes.

Henry Greely: I think what Greg was suggesting is do we actually need another meeting? I think the answer because of the open meeting's law is that we do. So that is not an area...

Gregory Stock: So I would suggest that we could accomplish this. And that what we could do is we could make, you know, in the discussion. We could come to a little resolution where we as a group decide which will provide you a direction. And then at the next meeting whenever that is, we could get...

((Crosstalk))

Gregory Stock: ...see if there is either formally adopted or see if there is any further comments about it.

Henry Greely: Although - yeah, I mean we could do that. I'm not sure that we are effectively doing that in our discussion because we've gone over each question and there are only - there are not very many questions where we ended up with some disagreement.

Man: Right.

Henry Greely: A few but not very many.

((Crosstalk))

Henry Greely: I think the preference - my preference would be if we had a full meeting with the quorum and the ability to vote. And it looks like we did have something close to a consensus.

My preference would be for a formal committee motion but rather it's worth having another meeting in a relatively short timeframe in order to do that is that – a tough question.

Elliot Dorff: Especially because - as I understand it, we are the advisory committee to you, right? So that doesn't mean - and you can completely ignore our advise, right? I mean you probably won't but I understand that. But I mean is this, so that - I mean - is it - I mean - and Hank, you're the only that knows a lot here. I mean we don't have to - so the department can do whatever it wants with these forms, right? Regardless of what we say.

Henry Greely: The department can do whatever they want regardless of what we say. It has to follow the statute of course...

Elliot Dorff: Yes, that's correct. So it seems to me that - you know, that having a formal vote on this doesn't really add very much

Henry Greely: Add very much.

Man: Yeah.

Man: Right.

((Crosstalk))

Man: Do you want to...

Pat Rodriguez: Yes. I agree with that and the department...

Man: Uh-huh.

Pat Rodriguez: Statutory compliance is required.

Man: Yes, it is.

Pat Rodriguez: And I just wanted to point out, there's something that the department might want - is the language of the statute. And this is in regards to our individual discussions...

Man: Yeah.

Pat Rodriguez: ...individual discussions. And that is that we will comply with the status and disposition of each of those projects must be reported

Man: Right.

Pat Rodriguez: There is a concern that if you look at 125119-A - that there would have to be some individuality - at least with respect to those items, status...

Henry Greely: Status and disposition.

Pat Rodriguez: And then - I'm so sorry -- in terms of aggregate, the final part then was -- including the information pursuant to Section 125342. So those three are - there is an indication certainly and possibly - that those have some of individual requirement.

To satisfy the statute.

Man: That is on (10).

Henry Greely: Well, it depends on where you decide to include the information to and where you attach that to the clause that has “each” or not.

Pat Rodriguez: I’m just saying we had to consider...

Henry Greely: Yeah, that’s certainly fair.

Pat Rodriguez: And we are considering our...

Henry Greely: But I would note that many of the things we’ve talked about on the first form, the status and disposition are the only things to which the “each” apply and things like Question 9 where we recommended aggregate information on neither status nor disposition.

Pat Rodriguez: That’s how I’m thinking.

Man: Okay.

Pat Rodriguez: And I will also add though that in the 125342, there is the requirement that the department shall take this information and which shall aggregate this data. And they are - the legislation were clear about this point...

Henry Greely: That’s for the oocyte information which I completely agree have to be - probably would have to be...

Pat Rodriguez: I’m just pointing out that if the legislation had meant to be clear on this part they could have used the term aggregate.

Man: Right.

((Crosstalk))

Henry Greely: But what you're reading is, I think closer than the one that we've been using.

((Crosstalk))

Gregory Stock: That one that comes from this information seems to be that we are satisfying on capturing the individual information, the initial 1, 2, 3, 4 & 5.

Man: Four, five...

Gregory Stock: ...4 and 5 that really captures individual information. We have then decided that we would get rid - the 7 and 8 could not be reported, and 9 would be reported in aggregate. I believe that we've said that 10 was redundant and we thought it was not...

((Crosstalk))

Gregory Stock: We thought that 11 and - 11 through 15 were not useful. And we haven't discussed 16 and we were going to do 17 and 18 by the individual...

Man: Right.

Henry Greely: So the question is if we made that decision, would not that be fully in compliance with legislation?

Pat Rodriguez: Well, I agree that your discussion along those lines..

The only point I wanted to make is this, there should some individual information involved.

Henry Greely: In which we're going to be getting from 1 to 4 and from 17 and 18.

Pat Rodriguez: Correct.

Man: Okay. I think 16, 17 and 18.

Pat Rodriguez: But the only part that I didn't see this quite covered was the information including the information pursuant to 125342 the oocyte information...

((Crosstalk))

David Magnus: That's the other form though...

Man: That's the only thing to...

Pat Rodriguez: But that is part of the statute that says that the SCRO shall report back...

Man: Right, yeah.

((Crosstalk))

Man: There are two reporting forms. Each from SCRO...

Man: Right.

((Crosstalk))

Henry Greely: And I think we agreed that that needs to be individualized - at least that is my current recollection.

Man: Right.

Woman: Yeah.

((Crosstalk))

Man: Okay.

Henry Greely: Your point is noted

((Crosstalk))

Pat Rodriguez: And the one authority I would also suggest is there. I'm not saying which way the department is going to go on it . That's in relation to your question about 13, 14 and 15. And they want it by 125342 they say they are asking about every oocyte...

Man: Right, right. That's - but that's the other form?

Pat Rodriguez: Correct.

((Crosstalk))

Henry Greely: But speaking of the other form, in my - in the interest of forward momentum, we are almost to the other form but not quite. I think we have discussed 1 thru 15 on this form, 17 and 18, the department will amend.

Well, our advice, which the department seems to accept is that they will amend it to include this to the broader statutory language of what's required to be reported and we all agree there has to be individually reported, right?

Man: Right.

Henry Greely: So we're left with Question 16, lay person summary or description of research project limit of 500 characters.

David Magnus: Again, I think that's asking too much to ask the SCROs to do.

((Crosstalk))

Elliot Dorff: I don't. I mean I think this will come directly from the principal investigator and that we just simply be - as would the things at the beginning of this document.

And it's - I think that's the point. The point is...

Man: If we asked for something, would it be in the submission? Would there be no blurb...

((Crosstalk))

Man: Actually our form at Stanford does call for that now.

David Magnus: But that is not understandable by a lay person, but by SCROs - so if somebody has sufficient expertise to be able to serve on SCRO, a lot of experience and knowledge in the science, it would be very easy to look something up of this

that could be understood by a scientist. And that would not be understandable by a lay person.

((Crosstalk))

Elliot Dorff: So what we're asking from a principal investigator is two sentences, 500 characters, right, to...

Elliot Dorff: Yeah, it's not 500 words, it's 500 characters.

David Magnus: Characters, that's right.

Elliot Dorff: That's not much.

Elliot Dorff: That's not much. That is really not.

((Crosstalk))

Elliot Dorff: Well, but I think and it's a really important challenge. And if there's - there some investigators cannot say in one or two sentences, "What's the point of this?" And, you know...

Gregory Stock: So wait, because I think the point that you make is the principal investigator is the only person that can do that.

Man: That's correct.

Gregory Stock: I think that's going to be required in the submission form to the SCRO and that's a different story and I don't think it's burdensome.

Man: That's right.

Gregory Stock: SCRO can just copy it and...

Man: Exactly right.

Gregory Stock: And if it's not, then I think it could be burdensome. And so that...

David Magnus: So right now, this is not the information the SCROs have. It also means that there is an immediate report requirement, It means that SCROs will have to go back to all the investigators that they have approved and ask them to do something that they have not done yet.

Henry Greely: David, I...

((Crosstalk))

Henry Greely: I don't disagree with your principles. On the other hand, our SCRO could easily write a two-sentence description of the research project for all of the protocols we will do.

This research project is going to try to differentiate human embryonic stem cells into neural progenitor cells and see what happens when we put them in rodents.

Man: Very well.

David Magnus: I think that - I think it's harder than you're suggesting for some of the protocols. We both have experienced claims that articulate that in our SCRO review. I think it's much harder than you think and then explaining in a way it's going to be meaningful to legislature. I'm not sure but...

((Crosstalk))

Man: I'm not a scientist.

Henry Greely: The other extreme is that the SCROs will say "The purpose of our research is to improve human health."

David Magnus: I think that is what you will get a lot. It will be so vague that it will be meaningless.

((Crosstalk))

Henry Greely: Right, to understand better human biology and improvement...

((Crosstalk))

Gregory Stock: So then here's the question, if you really have 500 characters and there's a serious disagreement here, then the issue is, will it be of value? If it's not a value and that simply is to improve human health. The less valuable it is, the less burdensome it is.

Man: Right.

((Crosstalk))

David Magnus: It's could either be – something that would be burdensome or it will be...

Elliot Dorff: Now, there is the middle ground. We don't live – there is a middle ground. Most of life lies in the middle or somewhere. And that I think people can -

right, again, they got a doctorate in science, they should be able to write two English sentences in which they describe in, you know, more - I mean not just "for the good of humanity". I mean nothing like that, right? And that is...

David Magnus: So I will make one last argument against this. Although, I think that in principle that I agree that we should think about things beyond what the statute requires, but this is asking something like this is burdensome and that it is not in statute.

Elliot Dorff: I think that's what the disposition means. I think that what the disposition means.

((Crosstalk))

Gregory Stock: In practice, will not the SCROs go through and write there and will not agonize about it...

Man: Those organizations...

((Crosstalk))

Otoniel Martinez-Maza: They will ask the investigators to write it, and in our IRB, we have to write currently lay summaries and I think it's only 500 characters. I don't think we have asked for that on our SCRO form so it would require adding that to...

Gregory Stock: So that's probably the impact then would be add that to the existing form.

Otoniel Martinez-Maza: Yes. Now that the - the immediate impact would be the X-number of approved projects and going back and abstracting that. And I don't think it would be that easy.

A lot of things are pretty archaic, I think, looking at some weird transcription factors that maybe involved and shifting it down some neural pathway versus a hematopoietic pathway. I mean how do you get that into a lay abstract in 500 characters? That is pretty hard.

Gregory Stock: If you didn't have to go back, would it be useful for just something like this that is prospective for research project or new applications only or something of that sort?

Otoniel Martinez-Maza: I don't think it would be very hard to do that.

((Crosstalk))

Gregory Stock: ...for new applications or renewals that automatically come in.

((Crosstalk))

Henry Greely: So I'm hearing here, David is concerned about burdens. Otto is concern about burden at least post-hoc, but maybe not so much prospectively. Elliot thinks not so much of a burden and might be helpful. Greg, are you still roughly on Elliot's side?

Gregory Stock: To make the provision that you did not have to go back...

Elliot Dorff: Yeah. I would be happy with that.

Gregory Stock: And so if there was a push that that was included in the original application so it's falls upon the principal investigator which isn't that hard.

Man: That's right.

((Crosstalk))

David Magnus: I'll just note again that the SCROs have all come out very strongly against this.

Gregory Stock: Because they're going to have to go back and we do...

David Magnus: Not just that. I think they think this is burdensome and unsupported by immediate justification within statute.

Otoniel Martinez-Maza: I think I would be - I agree. I think - I do know for sure that our SCRO want to stay as close to what is required.

Henry Greeley: They want to do as little as possible.

Otoniel Martinez-Maza: And you know, as an investigator, I spend a remarkable fraction of my time doing the IRB, Radiation Safety, Biosafety, SCRO and all these other things. And adding more is not appreciated but...

Elliot Dorff: But two sentences?

David Magnus: That is a hard thing for somebody to do...

((Crosstalk))

Elliot Dorff: If you can't say in two sentences, what you're ...

((Crosstalk))

Henry Greely: Dr. Ahmad.

Shabbir Ahmad: Yeah. Just to point out, the intent of the legislature is that they want to know the human embryonic stem cell research activity and that the activity probably, this would be one of the main sources from where we can capture some information -- general information about the project - for the activity.

David Magnus: And titles give them some information that they can understand.

Shabbir Ahmad: Yeah. But the title is...

((Crosstalk))

David Magnus: The aggregate information to give them some big picture...

Shabbir Ahmad: And the - title is 50 characters only, yeah.

David Magnus: Yeah. There are no questions. They are very technical and most of them will not understand.

Henry Greely: Okay. I'm not sure we're going to make any more progress on this. I think we've got split advice from the committee with two people expressing substantial concern of SCRO requirement especially it's retroactive.

Otto if its perspective, are you...?

Otoniel Martinez-Maza: If it is prospective, especially if the information is collected electronically, it would be pretty easy to cut and paste

Henry Greely: Okay. And we've got Dr. Stock in favor of it and I think...

((Crosstalk))

Henry Greely: And I think I've joined that position. So David, I think you're alone. But you are a set of views and advice that department hears and should consider.

((Crosstalk))

Henry Greely: Okay. I think we should actually open to our listeners, if we still have any listeners. If anybody has been patient enough and awoken up to have gone through this rather than waiting till we go through the next form as well - before people ask that the catatonic state on the end of the phone lines, we should let them comment on this first form. So do we have - operator, are you still on there?

Coordinator: Yes, sir.

Henry Greely: Okay. Are they nonmember lines now available for them to talk?

Coordinator: They are.

Henry Greely: Okay. Commenters, any comment?

Christine Hui: Go ahead, I don't have any comments.

Henry Greely: Okay.

Geoffrey Lomax: Good discussion by the way. It's very actually very useful for my end.

Henry Greely: Thank you for your comment, Geoff.

Geoffrey Lomax: Just one - just to respond to actually a question Dr. Lubin raised, I don't know if it's even relevant at this point but it was a question about how do we - what sort of reporting do we provide on the research end, you know, what we put together is a compilation of awards and the abstracts approved for funding and then we tried to summarize to some degree categorically but not - you wouldn't be able to - it doesn't pull the exact categorization that would be made thru the reporting form at least to that point of discussion.

Man: So you have...

Geoffrey Lomax: There is a compilation of what's funded and...

Henry Greely: All right, Geoff, do you have a lay language summary requirement or - in what you produce? The abstract.

Geoffrey Lomax: I think it's - I don't know if we...

((Crosstalk))

Geoffrey Lomax: ...as a lay but it's a very - it's a very short summary and then the staff here does then sort of modify that for public purposes on the Web. I'd say it's "layesque."

I mean it is - the intent is to give the interested public and non-technical audiences a flavor of what we're funding, you know, to abstract the research in a sort of public way. But it's certainly not down to a kind of two-sentenced level. It's an abstract. It's kind of more on the 500-word level, that sort of thing.

Henry Greely: I think the term is “layish.”

Geoffrey Lomax: Oh, I hope that’s helpful.

Henry Greely: Okay, thanks. Any other comments from those of you on the telephone?

All right. We finished Form 1.

Gregory Stock: No. Can I just – is in this view - what I hear was that we would have 1 through 5 minus 5.3 -- not including the 5.3 plus 16, the individuals...

Henry Greely: And 17 and 18.

Gregory Stock: Sixteen would not be retroactive and then 17 and 18 but that’s kind of - it individualizes but summary data.

Henry Greely: Right. And probably not very common.

Gregory Stock: Yeah. And then we would have Number 9, the summary data that would be aggregate data and followed by 17 and 18 which would refer to the individual data.

Henry Greely: Yeah. I’m not sure that we’ve got a recommendation of the order would...

((Crosstalk))

Henry Greely: That I believe is an accurate lay summary of what we’ve talked about with the one notable point of disagreement over point - over Question 16.

Man: Okay.

Gregory Stock: ...relatively minor disagreement is if it's not made retroactive?

David Magnus: I am opposed to it.

Gregory Stock: You are strongly opposed to it.

Henry Greely: The people or the majority characterizes this disagreement is minor...

((Crosstalk))

Gregory Stock: I have to say at least there would be more general consensus of...

Henry Greely: Yeah, I think that's an excellent idea. We don't want to make this meeting go on past the 1:00 schedule to endpoint but a very short break would be appreciated, I'm sure, by the people (at this table).

David Magnus: We've got a lot of work to do.

Henry Greely: Yeah, I know. So let's take a five minute - only five minutes to take this to 12:13 and then we'll have to concentrate hard on the second form.

((Crosstalk))

Henry Greely: Now, we have several agenda items left. The most important of which is the discussion of the second form, HSCR 1260-2. This is the form dealing with reporting on some aspects of oocyte research. And let's turn to that specifically.

Now, this is the form that reflects the mandates of the statute Section 125342, all the information that is required to be collected under that. We once again have a four pages worth of form although the pages aren't numbered 1 through 4.

And again, we've got a cover sheet that I think seems relatively uncontroversial unless I hear controversy about the cover sheet.

We turn to the next page, facility information and IRB information, just the name, contact information, et cetera with respect to the facility and the IRB. The facility here is referring to the facility at which the oocytes were procured, at which the activity was done. The IRB will review - is referring to presumably the IRB that approved that, approved the procurement. Any comments or questions on those?

David Magnus: Around this one?

Henry Greely: We're on the second page of the packet on...

Man: Facility information and IRB...

Henry Greely: Right, and the IRB information. And if suppose one might question how much detail we need about - we need the SCRO to tell the state the IRB, but I don't see that it hurts.

Dr. Ahmad?

Shabbir Ahmad: I have one clarification.

Henry Greely: Yeah.

Shabbir Ahmad: This form would not be filled by SCRO. This form should be filled by the researcher of the research project, one of the same thing, yeah. So that's the 1260 going back to...

Henry Greely: ...125342.

Shabbir Ahmad: Yeah, that's correct, yeah.

Henry Greely: So to refer back Page 7 of our statute's copy, 125342-A, "a research program or project that involves AOP or any alternative method of oocyte retrieval shall ensure that a written record is established and maintained to include but not be limited to" all the following components. B-the information included in this record pursuant shall not be disclosed. This information shall be reported to the state department of health services.

So this is actually not just required to be reported thru 125119.3-A which is where we were having our discussion about the placement of that last dangling clause but it has an independent reporting requirement within 125342 which I didn't notice until just now. So given that, we don't have to argue so much about individual or aggregative that applies with respect to 125119.3.

David Magnus: I am sorry, but I am not seeing in 342, where it says that the investigators does this.

Henry Greely: It says project does it so - well...

David Magnus: No it says a research program or project shall ensure that a written record established and maintained and...

((Crosstalk))

David Magnus: The other section, it says that the SCRO is responsible for ensuring that that information is communicated to the state.

Henry Greely: Okay. But if you look at - you stay with 125342B, David, and the fourth line or so, this information shall be reported to the state department of health services and that's a nice use of the passive voice. It doesn't say, who shall report it, you are right under - it's more complicated under 125119.3. That says the SCRO shall report it.

David Magnus: Yeah.

Henry Greely: So it's not for the individual investigator to report to the state. The individual investigators have to keep a record of it. But apparently, if the record somebody has to report that information to the state under 125342-B and under 125119.3-A, it's the SCRO that has to report that. So you think we've put that puzzle together properly?

((Crosstalk))

Henry Greely: So then the program has to compile, somebody has to report it under 1 - under 342 and it turns out if you look at 119 and SCRO had to report it. We could have both reported if you want but I doubt that any university is going to want to do that.

Elliot Dorff: That's for sure.

((Crosstalk))

Gregory Stock: The passive voice is a difficult one to use when we're talking about reporting.

Elliot Dorff: Right, that's right. Somebody would have to come down - dropdown and report this.

Man: Right.

((Crosstalk))

Henry Greely: It's just in fairness to the legislature. It's awfully easy in retrospect to - when you are actually applying something to find ambiguities that are harder to spot in advance, but I am reminded that the great scene and wonderful funny movie, "Galaxy Quest" where Sigourney Weaver says, "That episode was poorly written." (Unintelligible).

Elliot Dorff: Yeah, that's right, yes.

Henry Greely: So I think, you know, as I read through this, it does sound like the SCRO has to record the information that's collected by the program.

Man: So actually...

Pat Rodriguez: Well, and I agree that it could have been clearer about the relationship between these sections, but sometimes the legislature deliberately leaves ambiguity in case they don't know actually how these things will be implemented.

Henry Greely: Passive voice is sometimes a good deliverance tactic.

David Magnus: I recommend the reporting actually not be done directly by the investigator by the SCRO. If you take the SCRO out of it and make this all investigators in

California should do this, you will have a very low compliance rate. Because unlike CIRM, where they don't get the money until they comply, there is really nothing is going to make the investigators to be aware of this. If the SCRO has nothing to do with it, fine but you won't get any of the information.

Gregory Stock: Can the SCRO get the information so that they are simply transmitting the information as opposed to...

David Magnus: Could be done, yes. I suspect that some of this will have to be - but it will be - but if you don't have the SCRO get to be responsible for actually transmitting it so that there're some mechanisms to force the investigators actually do this information then you're going end up very very low compliance.

Gregory Stock: The reason that I was asking was, if there was a kind of issue - the issue is previously was they're going to have to write and that is a big burden so with this - all of this data, if this is actually compiled by the investigator then just transmitted, then the level of burden is - the consideration of burden is quite different then if...

David Magnus: Either way...

((Crosstalk))

David Magnus: And there's no question that we might get a lot of - about this but the state legislature required it so.

Henry Greely: Actually as I see this, it is beginning to actually look simpler to me and that is an unusual experience, I'm sure I'm wrong, but now as I read this, it looks like the research has to collect under 342A a bunch of information.

That information that needs to be forwarded by the SCROs to the state, the state then needs to make some of that public. I do now think from reading this that that information has to be individual.

And previously, I was wondering playing around this the language in 125119.3 whether it truly needed to be individual or not and going off on - along with Pat the implications to the word "each" but the - I think it does have to be individual and let's take a look at the third page.

David Magnus: I think we have to get rid of height and weight.

Henry Greely: Well, so let's take a look at the third page. I do wonder why - the first question on the third page is Question 2. Now, let's just point there. There doesn't appear to be a question 1 anywhere.

And in fact, in the previous page, it goes through Question 6. So I would suggest we just start with Question 7 or Question 1. Maybe Question 1 because it's a written record of the subject.

Then unique identify number - I think it makes sense. Then we've got the statute requiring the demographics of the subjects including but not limited to. So there is an expressed "but not limited to" there.

Their age, race, primary language, ethnicity, income record, education level and the first three digits of the zip code of current resident.

Man: What is Parity?

Henry Greely: Number of babies or was it number of pregnancies.

Shabbir Ahmad: Number of live births.

Henry Greely: Number of live births, okay. And it's actually number of times you've given - the twin only counts as one, right?

((Crosstalk))

Henry Greely: Yeah, presumably somebody on the SCRO will know this...

David Magnus: Now, I think if you add height and weight with all these other things, I think it violates the perusal of the statutes of not being able to identify these women.

Henry Greely: What is useful about height and weight? Are we worried about short women being exploited or a fat woman being exploited.

Cindy Chambers: It is to calculate BMI, because there are risks both with very small or very large women with AOP and donation.

Henry Greely: That was right. Okay, so there is a real reason here.

David Magnus: In talking about collection of data, there is literature written about how easy it is to identify individuals from this type of data, and it turns out that it is much easier than you realize to individuate and get people, and I am not sure if taking out even that if it would be sufficient, and I am very confident that either of these things will get you individual information and violate the statute.

Shabbir Ahmad: And the department does not have a strong feeling about to include it if the committee will go forward the recommended that they should be excluded, it will be considered.

Gregory Stock: I would suggest that if you really want BMI that using that equation is not very good, that you use BMI itself.

((Crosstalk))

David Magnus: You need to look very carefully at these data sets to make sure that you can't individuate based on whatever is included.

Henry Greely: Although this report, the SCRO will compile. The SCRO will give it to the state. They report the state itself is supposed to aggregate so this won't be a public document. It's my understanding.

And it says under B that the information included in the written record pursuant to the subdivision A shall not disclose personally identifiable information about the subject and shall be confidential and is deemed protected by subject privacy provision to the law. This information shall be reported to the state which shall aggregate and make it publicly available in a manner that does not reveal personally identifiable information. So I think that may not be a problem, David.

David Magnus: Okay.

Henry Greely: But certainly, I mean, I'm with you entirely on this. It's somewhat shocking evidence of that re-identify ability and how easy it is. I'm thinking about zip codes, the 943 is the zip code is Palo Alto and Stanford. There are about 60,000 people who live there. That's a pretty big number.

Thirty thousand of those are going to be women, roughly only 8,000 of those are going to be women of an age and might probably fewer than that, that might be donors - probably 4,000. Four thousand is a pretty high number but you start looking at race and ethnicity, age. And age, you can get from things like driver's license records.

So find, you know, how many Hispanic, 27-year-old women are there in the 943 district. And if there are seven and the person has highest level of education that is MD, then maybe there is only one.

So there is - re-identify ability is a concern and a lot of these three-number zip code areas, I think, are going to be smaller than Palo Alto.

Gregory Stock I the ultimate example of that is (unintelligible).

And that's the same thing. If you put specific and you break it into categories with age for example of 20, 30, 40, they're not specific then it becomes much, much larger.

So things like height and weight are very easily – because they are precise – so just height alone may be enough.

Henry Greely: Assuming people tell the truth about this.

Henry Greely: Yes, Dr. Ahmad.

Shabbir Ahmad: In public health in general - there is a general rule that if you have less than five cases in each - in a particular area then you don't report that. So that

would be considered - let's say we don't think that we will be getting a lot of information - a lot of forms like form 2.

Let's say there is - there are only four forms submitted in a year so the department would consider rather that information should be released a lot based on that general principle.

I don't see that the department will not release, but the department will consider not releasing it.

Gregory Stock: But wasn't there a requirement in the code that you just read that the information communicated could not be personally identifiable.

((Crosstalk))

Henry Greely: In a manner that does not reveal personally identifiable information.

Gregory Stock: But that was for the public communication, then also from the transmission to the state, wasn't it?

Shabbir Ahmad: No, the state would get it even if it was once case – the state would receive the form 2.

Gregory Stock: What I'm saying wasn't the requirement that you can't communicate personal information to the state as well and not personally information that is identifiable information to the state.

((Crosstalk))

David Magnus: I understand that he thinks we can, as long as the department won't then...

((Crosstalk))

Henry Greely: There is another ambiguity. The information included in the written record shall not disclose personally identifiable information about the subject and shall be confidential and is deemed protected by...

((Crosstalk))

Otoniel Martinez-Maza: So the information that this is referring to, is that the report to the legislation or ...?

Henry Greely: No. No, this is - the program has to make them - first, the program has to make a written record of all this data that could be this form but not necessarily this form.

Then the SCRO has to report what the written data - what - I guess it is this form- what's the information in the written record to the state and the state then has to make it publicly available in a way that is confidential.

((Crosstalk))

Henry Greely: Well, height and weight are not required by the statute. Born in the United States was not required by the statute. We had one comment from Emily Galpern and the center - suggesting that's this be dropped.

You know, I actually could imagine you might be concerned about whether non-US born people are being excessively used or exploited in this context. On the other hand, US-born is not the same as - all US -born people are citizens but not all citizens are US-born.

If you worry about that citizen is being exploited, you know, I don't have a strong feeling about it. My thoughts are that the comment had merit to it. I'm not sure how much you add by asking US-born.

((Crosstalk))

Man: Right, that's right.

Man: One of the commentators recommended that we involved the statute in feeding this income bracket rather than income.

Man: Yeah. And I think that's - I was going to say, on the number days, you might want to be a little clear so income brackets, I think, are much better than \$74,692.17.

Kate Cordell: There is a drop-down for income bracket.

Man: Okay, thanks.

Did you drop down with race/ethnicity?

Kate Cordell: Yes. We can pull a form up and show you.

Henry Greely: Yeah, actually, that's - it would be interesting to see the dropdown. I know you had these macros when you send it to me and my computer doesn't like the macros.

Okay. I think 75,000 might be the right place to go and determine.

((Crosstalk))

Henry Greely: And I think for a lot of the country, I would wonder about that. California I think we do tend to have higher incomes than the rest of the country.

Okay. Those are the census ethnicities?

((Crosstalk))

Gregory Stock: I think it's relevant because what they're really trying to do is consider the poor, so....

((Crosstalk))

Amber Christiansen: these are the brackets that are collected on the US census.

((Crosstalk))

Henry Greely: Let's go back to primary language for a second... Indic is from the Indian subcontinent, is that the theory? Okay. That's at least three different major language families they spoke in there.

Man: Right, exactly.

Man: What is the thinking behind including that first three digit...

Henry Greely: But I do think the idea was that three digits were not that identifying – did not give that much information.

((Crosstalk))

Henry Greely: Before this was being passed, as this was being discussion in the legislature, there were comments and I think Margaret Cho from Stanford that pushed for it with some of the people from Senator Ortiz' staff. We have to be careful about not giving too much of identifiable information. So I think that the first three digits was the result of that comment. But even first three digits, depending on your location, first three digits might be a relatively small number of people. It would never be tens but it might be thousands.

((Crosstalk))

Otoniel Martinez-Maza: But I think you get to the point where it's so useful in identifying individuals but not very useful for policy purposes.

David Magnus: Yeah. Yeah, it probably should not have been included in statute - I mean we were surprised and talked to Ortiz's office and with Mildred, and there was an intent to take this out, but it never happened. (unintelligible).

Henry Greely: So other comments on Question 3?

Gregory Stock: You know, what was the - to summarize, was there any issues about doing other than removing height and weight?

Henry Greely: And born in the United States.

((Crosstalk))

David Magnus: and stratification...

Henry Greely: Yeah, the dropdown, solved several problems with that.

Man: Okay.

Henry Greely: Now, the rest of the form, I think just about everything else on the rest - well, the statute requires information regarding every oocyte that's been donated and used, sufficiently, in terms of provenance and disposition of the materials and a record of adverse health outcomes including, but not limited to, incidences and degrees of severity, result from AOP and any alternative methods of oocytes retrieval. That's what the statutes requires.

All of this section is included, but not be limited to, the section itself expressly includes the opportunity of going beyond what is requires.

The consent process Section 4, 5 and - 4, 5, 6 and 7 does not look to me like it's - well, it fits within the statutory requirements only to the extent that it's evidence about the provenance of the eggs. Right?

This record should be sufficient to determine the provenance and disposition of those materials. Now, provenance could mean where it came from or it could mean whether it was ethically derived, and the consent questions go to in part whether it was ethically inappropriate or derived.

These are things that are required - I believe 4, 5, 6 and 7 are all required by the statutes.

David Magnus: And some other parts as well. So I think they all need to be done. I'm trying to say, you know, I think, you know, a lot of the things are going to be required. I'm just thinking about what is going to happen, - I mean - you think - we add these, you know, to forms that were already need to fill out. And now we're

going to add another set of forms that the investigators have to do. I was just saying it's going to be not fun.

Henry Greely: But 4, 5, 6 and 7 are required by the statutes.

David Magnus: Yeah, so it just means saying, yes, yes, yes for each one – and with a code, may not set up for each individual and putting all this information to each of this is adding just another set of hoops to jump through, and I understand that some of these fields are required, but I'm just - the SCRO already require this information, because we're required to do this, so we make them give us a lot of information on the SCRO as part of the approval process.

And now, we have a form that makes them duplicate a lot of that. They duplicate a lot of that to say, yes, we did do those things that we say we're going to do. When we said we're going to do this with each individual, our protocol and you approved it, that meant, "Yes, we did it for this person. Yes, we did it for this person. Yes, we did it for this person."

We are basically asking them to say "yes" to things that are required at the protocol level at the individual level.

Gregory Stock: But they're also required and all sort of other different levels as well. I mean they're going to be - is there any know that they are going to be checked...

((Crosstalk))

Henry Greely: But this is, again, serves as regulatory reminder function that's saying – gosh, did we remember that we actually - did she finally sign that or not? I don't remember.

((Crosstalk))

Henry Greely: We better know because we're pulling out this form. I presume the form gets filled out for each patient, for each subject, for each whatever the appropriate noun is for woman who is donating oocytes...

Man: Research donor.

Man: ...okay?

Man: They can't even do the procedure.

David Magnus: Yeah, that's correct. Its already required by...

Henry Greely: So they are filling out the form anyway. So how much harder is it to check these boxes?

David Magnus: I'm just, I am -

Henry Greely: Yeah, we'll get the pushback.

David Magnus: And I - and legitimately so.

Otoniel Martinez-Maza: Is written consent required for the statutes? Because we have reviewed stuff in our SCRO on lines developed abroad, and written consent was not obtained.

David Magnus: Did they do oocyte procurement?

((Crosstalk))

Henry Greely: So the oocytes are different stories.

David Magnus: Oocyte procurement, well that is the most sensitive stuff there is. That's why...

Henry Greely: So this would not apply to a cell line that you would want to use. It only applied to oocytes that are being used in research.

David Magnus: With the woman is a research donor. So...

((Crosstalk))

Henry Greely: Then if you get any oocytes Sweden, then you wouldn't bring the oocytes in, well, I guess you could freeze them, but...

Otoniel Martinez-Maza: That is what I'm thinking of. And the work would be done by a collaborator.

Henry Greely: But the statute says right clearly, any oocytes brought in from out of state had to have been done by state, have to have met California State standards.

David Magnus: The technology is not there to bring in oocytes.

Shabbir Ahmad: And then in that case, just IVF - maybe the state because of the initial donation was for IVF and not for research purposes.

David Magnus: Well, it means a small number of patients would be doing this form.

Shabbir Ahmad: We don't expect too many...

Gregory Stock: I would agree with David, that it's not required to be in the form. It's seems highly redundant to check these off.

Henry Greely: It is arguably required though depending on how you read information sufficient to establish the provenance and what you mean by provenance there.

David Magnus: Could you do that in aggregate where you assert that all of our oocyte procurements meet the standards?

Henry Greely: Yeah, yeah, but remember there are two different things going on here. There is the statutory obligations that the SCRO report to the state.

And one could imagine... the work in the statutory language. But one could imagine the aggregates there. There is also the statutory language saying each research program shall establish a written record for each woman with this information. That can't be aggregate.

And further, the statute says, the SCRO, ultimately the SCRO, shall report that information to the state, information that's contained on that individual record.

Let's look at the oocyte retrieval information, 8, 9, 10, 11, 12, 13, and 14. This is - I think it's - unless you count this as part of the provenance, the provenance including what message were used, et cetera, it's hard to see this as required by the statutes.

Well, some of it refers like the methods, or how many times, was the subject reimbursed, do the subject receive a postprocedure medical. Well.

Medical exam arguably is relevant to the adverse - whether there were any adverse events as a result.

But some of this we do have to know how many oocytes they had because you got to - they're required to report on the number and the disposition. Right? Information regarding every oocyte that has been donated or used.

So how hard do we think 8 through 14 are? And how useful do we think they are? I mean date of retrieval obviously is fairly straightforward. How many were retrieved? How many were discarded? How many were used by your facility? How many were used by another facility?

Theoretically, 9.2 through 9.7 would add up to the number that is in 9.1. Right?

Man: Right.

Henry Greely: So as you know, we got X oocytes from Jane Doe and we used them in the following ways that add up to X amount...

((Crosstalk))

Man: Right.

Henry Greely: And that to some extent at least responds for the statutory requirement that we have information about the collection and disposition of every oocyte.

Ten looks more like - unless you take a very broad view of what's meant by provenance, it looks like a more informational question, not what necessarily required by the statutes, but not unreasonable. I don't know right now - what

are - are there alternative methods of oocytes retrieval that are being used today?

This discussion of things like *in vitro* maturation of ovarian tissues slices or even cadaveric ovaries or so on, but I don't think anybody uses this for research at this point.

At some point, though, there will, perhaps be, the artificial - the creation of artificial oocytes through taking embryonic stem cells and differentiate them to become oocytes, but nobody is there yet now.

Gregory Stock: I think a few researchers in Canada doing in vitro maturation, so I think there is a possibility.

Henry Greely: Okay.

Gregory Stock: I mean, you know, it should be fairly straight forward.

Henry Greely: So right now, the answer will always be the first. But, this is interesting and potentially useful information. It's not, I think statutorily required information unless you take that really broad view of what provenance means.

Man: Uh-huh.

Henry Greely: Eleven, how many times does the subject undergone oocyte retrieval or donated oocytes for research? That one I think is even harder to argue that it's relevant to provenance, but it is – as hence as the statutory requires. It is interesting data and of some interest if you are worried about exploiting data.

David Magnus: It is data that might be important for (unintelligible)

Henry Greely: Twelve, how much we can subject to reimbursed for direct expenses. Now, if you're looking for - if you're trying to assess whether the statute is working or not, that...

((Crosstalk))

Gregory Stock: I think that would be very hard because it might have...

Henry Greely: You won't be able to do it the same day.

Gregory Stock: Yeah, and you might not be able to do it at all. How are you going to get that information. You have to get it from the person, but then they are submitting receipts maybe..

((Crosstalk))

Henry Greely: But your center is reimbursing.

Gregory Stock: Yeah, but that...

((Crosstalk))

Gregory Stock: You can't go in and get somebody's - how much did you pay so and so.

((Crosstalk))

Henry Greely: Wait a second. If a standardized IVF clinic is doing this. Somebody at the clinic cuts the check for the woman for reimbursement.

Man: Correct.

David Magnus: And so we're really saying - and now you guys have to go back be in touch for these things and track down that...

((Crosstalk))

Henry Greely: Well, but you're going to have to go back to some of these things like how were the oocytes used. You won't know that for at least a couple of days and then sort of saying for the statutorily required on adverse events. I guess...

((Crosstalk))

David Magnus: I am sympathetic to, given the burden that these are going to impose to being as restrictive to the statute as possible. I am sympathetic to that.

Henry Greely: So you would wipe out 10, 11, 12...13 and 14

David Magnus: Actually, I would keep 11, because of the safety issues.

Gregory Stock : And I think 10 is alright. It is so easy.

David Magnus: Yeah. It is trivial.

Gregory Stock: Ten is trivial at the time. Eleven is trivial.

((Crosstalk))

David Magnus: Right. And I will definitely get rid of 12...and 13.

Gregory Stock: 13?

David Magnus: Received a medical examination.

Otoniel Martinez-Maza: At what point?.

((Crosstalk))

David Magnus: Yeah when? I mean - and what does that mean? You know if they saw their primary care physician.

((Crosstalk))

Gregory Stock:: But well, you could put down and even any subsequent immediate post procedure...

((Crosstalk))

Henry Greely: You could use a slightly different question – did your center perform or provide a post-procedure medical examination.

((Crosstalk))

David Magnus: And what's the reason for this? Are you trying to capture an adverse event? Or you're trying to capture a preventative action? Or...

Henry Greely: Or you're trying to get a sense of what the practices are and whether they're safe in it. Whether they are what you think as, what the legislature might think is safe enough. Maybe. Or you are looking...

((Crosstalk))

Otoniel Martinez-Maza: I mean, I don't even know what exactly what is meant by that. I don't know what they mean by medical examination. They are undergoing a medical procedure - a clinical procedure - that would require an examination at the time it is being done.

((Crosstalk))

Henry Greely: Number 14 goes with 13.

((Crosstalk))

Gregory Stock: ...suggesting does the person – is the person...

((Crosstalk))

Otoniel Martinez-Maza: Some sort of post procedure days, weeks after.

Elliot Dorff: Yeah, the question would have to be much less ambiguous.

((Crosstalk))

Shabbir Ahmad: 324.1 E part. That's on Page 6.

Henry Greely: That it ensures the subject be given a postprocedure medical examination to determine if the subject - so that is asking the question about a statutory requirement.

Shabbir Ahmad: But that is from IRB that is - I don't know whether the committee feel that should a reporting requirement or not. But that requirement specifically says

an institutional review board will review and approve scientific and medical research shall require.

((Crosstalk))

Henry Greely: Shall require, right. So that makes thirteen another one like 4, 5, 6 and 7, where...

((Crosstalk))

David Magnus: They are not required.

Henry Greely: Hold on. Well, no, it isn't...

((Crosstalk))

David Magnus: Right. And 4, 5, 6 and 7 arguably are the reporting requirement either.

If they aren't, then we should dump them.

((Crosstalk))

Henry Greely: I said they arguably aren't, it depends on how much you mean by provenance.

David Magnus: But clearly, 13 and 14 are not reporting requirements because...

Henry Greely: Hold on. I mean I'll finish my thought on this. So you have the objection - we have the discussion on 4 through 7 about would make sense to have them

required to report something for which if they do not do would be a breach of the law. That applies to 13.

So on the one hand, it's easy to say yes because you are supposed to.

Man: Right.

Henry Greely: On the other hand, it is another piece of information. On the third hand - we really have lots of hands. On the third hand, it is a regulatory reminder to people – kind of a check list – did we do this or didn't we.

Fourteen is different. Fourteen is not - you know, how many days after - is an information gathering issue that's not something that this statutory requires. How many days? So that raises a slightly different issue in 13.

David Magnus: So I think that's - I think it's - it must be statutory required, asking people to answer questions about things that are required for approval by the SCRO make this longer, burdensome and wastes people's time and that we should do what we absolutely have to. We have to - I don't know whether we have to have 4 through 7. If we don't, then I think we shouldn't...

((Crosstalk))

Gregory Stock: ...but it seems to me that 4 through 7 could even be condensed into a single questions if you are worried about it, but it seems to me that we were talking about the burdensome nature. I can see many things as burdensome, but to go through and check off something that is trivial.

David Magnus: For each and every person...

((Crosstalk))

Otoniel Martinez-Maza: But how many people will actually do it.

Henry Greely: You got to fill out a form on each subject onto the statutes. You got to have a written record of this information. Given that you have to fill out a form anyway, how - one of the pluses and minuses is having these extra questions. That seems where we are.

((Crosstalk))

David Magnus: I think asking questions that we already know the answer to seems to me to be burdensome.

Henry Greely: Okay. On the other hand, it's not very expensive.

Elliot Dorff: That's right.

Henry Greely: And on the third hand, maybe it's serves as a minor reminder for people or as a checklist for them. I'd say that without - I don't know how I come out on this...

((Crosstalk))

Gregory Stock: Is there an individual - is there an individual that will sign and assert that this information in this form is correct?

Henry Greely: It's an interesting question.

Gregory Stock: If there is an individual that is required to assert the information in the form is correct, then I think for something as trivial as indicating that consent was given ensures that procedures are put in place to require that and there is some benefit that there's very little problem in terms of the time involved to check off something like that.

Elliot Dorff: Does somebody sign this? It looks like there's no place for a signature?

Man: Right.

Shabbir Ahmad: No signatures. We did not think about that.

((Crosstalk))

David Magnus: I think being very clear about who fills this out, who they send it to, and having a line of authority because if this isn't handled the right way, I think it's going to be a form that nobody will ever fill out even they are statutorily required to

((Crosstalk))

Henry Greely: Why would nobody filled out a form that's they are statutory required to do?

David Magnus: Because unless somebody who's a funder or a SCRO or an IRB that just reviews the protocol. The most genetics research does not require IRB by law...

((Crosstalk))

Henry Greely: But this is oocyte research. It's a special...

David Magnus: I understand.

Henry Greely: ...where everybody knows that it's very sensitive and has special legal requirements.

((Crosstalk))

Henry Greely: But the SCROs will be the intermediaries because SCROs have to report it

((Crosstalk))

David Magnus: I am just saying that we have to be very clear.

Henry Greely: Under the statute, the research program makes the written record- and must keep the written record and then appears that the statutes the SCROs is the one that has to report is to the state.

((Crosstalk))

Gregory Stock: In my view, I would recommend that there is a signature for the researcher that the SCROs that require this investigator have to submit this form. So it's no effort from the SCRO.

David Magnus: Right.

Gregory Stock: And transmit the completed estimation and that, in which case, it's not a bad idea to put a few of those that ensures compliance, so that they...

Elliot Dorff: A reminder.

Gregory Stock: ...if in fact nobody is signing this, then I think it's meaningless to put that sort of information in, because what happens if it is not even checked?

Elliot Dorff: Right.

Otoniel Martinez-Maza: Should this be signed by the investigator or by the... You know?

((Crosstalk))

Elliot Dorff: The investigator.

((Crosstalk))

Otoniel Martinez-Maza: And you'll feel like - we're separating that portion of things from the individual procurement.

((Crosstalk))

David Magnus: Right. So are we.

((Crosstalk))

Otoniel Martinez-Maza: It should be the person in charge of the procurement.

((Crosstalk))

Gregory Stock: If the person in charge of the procurement signing it, then you going to get a signature from someone who then has no certainty that this information is in fact correct. So it needs to be at the level of the researcher or investigator.

((Crosstalk))

Otoniel Martinez-Maza: The investigator would not know whether they had a medical examination.

Man: Right.

David Magnus: The problem is, when people are conceptualizing a lot of these requirements, they really good to know how this is going to work in practice and what is turning out is the best for models that are being - emerging are you separated out...

Man: Yeah.

David Magnus: ...here's an oocyte procurement facility, and they're going to go out and get the material - and embryos we can have embryos too - They are the ones that do that. And then these are the researchers that are going to use the material. The people who are getting the oocytes don't know everything about how they were used, and the people actually doing the research don't know how many got procured.

Man: That's right.

((Crosstalk))

Gregory Stock: If that is the case, then I think that this form is misguided. It is not useful. And if there are elements that need to be - that is supposed to be filled out and they're not being filled out by the parties that are responsible for that or that will know that is done, then it's not...

David Magnus: That's why it makes more sense for it to be - to be honest, it makes more sense for the SCRO to fill out this information.

Man: Yeah.

David Magnus: And they can, then, divide it up and say, this is part of the information. We're going to give to the people who are running the facility or collecting the oocytes...

Gregory Stock: That is a lot of work on the part of the SCROs.

((Crosstalk))

David Magnus: It is, but I am saying that's the only group that can fill out the statutory information. There isn't anybody - the way this research is conducted - there isn't anybody, anyone one individual, who has all this information.

Gregory Stock: So you break this down into two forms where it goes to those different parties...

((Crosstalk))

David Magnus: But not everybody does it that way. So that's how we're doing this. It's how UCSF is doing it, I gather UCLA....but I don't know if everybody is doing it that way.

((Crosstalk))

Gregory Stock: But it doesn't mean that those two forms could not go to the same party. Where we know that there are separations in functions then the forms should

be split in some way. Where parties can have responsibility, otherwise I think it will be useless, and if it is useless, then we might as well compact them to the very minimum that is required.

((Crosstalk))

Pat Rodriguez: I have a question, if the item that you find burdensome were not included, 4, 5, 6, 7, 11, & 14, would you have the same comments about the difficulty of filling out the form?

David Magnus: We'll think about that.

Man: Thank you, Elliot.

((Crosstalk))

David Magnus: If you do that, then I think - that's right, we can just get rid of 4 through 7, especially. Then, all the rest of this is really handled by the oocyte procurement group, right?

Man: Yeah.

Otoniel Martinez-Maza: I think most of this will be handled by the oocyte procurement...

((Crosstalk))

Woman: That is the intent to be handled by the oocyte procurement entity.

((Crosstalk))

Otoniel Martinez-Maza: What they might not know, or they should know, what kind of research it is used for. I would assume that they would need to coordinate with the investigator.

((Crosstalk))

David Magnus: Nine, they might or they might not know.

Otoniel Martinez-Maza: Yeah, nine, but everything else, yeah, that is with...

((Crosstalk))

Gregory Stock: But wait a second, you say it is all by the oocyte retrieval group but certainly 4 through 7 is by the oocyte retrieval group and 12 through 14.

Man: Uh-huh.

((Crosstalk))

David Magnus: It's nine that is the problem

Otoniel Martinez-Maza: They'll know 9.1 and 9.2, but they're going to have to be defining what is human embryonic stem cell research, what is medical research other than that and...

((Crosstalk))

Gregory Stock: I mean, if that's the case, it's not clear, you know, we didn't have objection to 9.3 to 9.7, particularly. But in fact, maybe we should delete those. It's the one area that they could not respond to.

So instead, we say that this is going to be by the oocyte retrieval unit and we eliminate anything that is not clearly accessible...

David Magnus: Yeah. That is statutorily required.

Henry Greely: The disposition.

David Magnus: So I think that is the problem.

((Crosstalk))

Gregory Stock: If you said retrieved, discarded or you transmitted, retrieved is certainly fine, just as the number that we retrieved...

Man: Right.

Gregory Stock: And if you were to say, discarded or transmitted or somewhere - what is...

Henry Greely: Greg, I don't think this is actually going to be that much of a problem, because oocytes have to be used fresh. So within a day or two, usually less...

Man: Right.

Henry Greely: ...of the retrieval. They have gone some place. And the procurement group, it is not like these are not like frozen embryos...

Man: Uh-huh.

((Crosstalk))

Henry Greely: ...that can be sent off years later.

Man: Right.

Henry Greely: Although you might want to add a box. There is egg freezing, it is not very good, it doesn't work well, it tends to have a very low success rate, but you might want to have a box for frozen.

((Crosstalk))

Man: Yeah.

Henry Greely: Okay.

You know, I've been looking again at some of the SCRO comments, which are quite antagonistic toward this form.

Henry Greely: Which moves me a little bit toward David on 4 to 7. If it doesn't - if it's not meaningful, I'd inclined not to have it. I do think 9 is required. I think 8, there's nothing in the statutes that I think requires 8, but the data retrieval, that's...

David Magnus: It's also identifiable information.

((Crosstalk))

Henry Greely: But on the other hand, you might have the same women who donates twice in a year. And the data retrieval will, then, serve to distinguish between the two

times she's done it. I mean, which would be useful to know. Right? If she has an adverse event at the second donation as opposed to the first.

((Crosstalk))

Man: Yeah, month of retrieval.

((Crosstalk))

David Magnus: I'm still not clear. I mean, to be able to track of who? I mean so the investigators will certainly know if they have an adverse event with somebody –oh they were a donor previously. And be aware of that and be able to use that information, so who exactly is suppose to be...

((Crosstalk))

Henry Greely: By the way, let me go back to something earlier. I just remember parity 3.7 is not in the statute. The argument for putting the questionnaire I assume is some sort of safety-related argument, but I don't know. So what...

((Crosstalk))

Kate Cordell: Previous public comment.

Henry Greely: Okay. And what was the - do you remember the rationale of the previous public comment?

Cindy Chambers: Safety.

((Crosstalk))

Henry Greely: In what sense? I mean, do we know - that you might be messing up with reproductive ability to somebody who hasn't had children?

((Crosstalk))

Henry Greely: So then nulliparis is the person who is the person of interest here? The person who is not been pregnant...

((Crosstalk))

Man: Then you could specify that again like (unintelligible).

((Crosstalk))

Henry Greely: but as I look at this again 10, 11, 12, 13, 14. They're not in the statutes SCROs are going to get - there'll be a lot of unhappiness about them.

Eleven, for purposes of safety, I think there's a stronger argument for. But 12, 13, 14 and 10...

David Magnus: You could rephrase, you could say, if known, how many times did the subject for the Number 11 and for one of them then if known, did the subject receive a post procedure examination. You know, and then it's not required, but again, the procedure is a subject of health

Otoniel Martinez-Maza: But they're required to do that...they should know.

((Crosstalk))

David Magnus: It's not - there's nothing in here that they shouldn't, in principle, know a lot of these things they are required to do, it is just that, we already told them they have to say you are going to do this.. There's another form that they have to fill out for us, they SCRO saying, "Yes, we're going to do this." Now we say, in addition to telling us, yes, we want you for each individual thing that you did this or you are going to do this.

Otoniel Martinez-Maza: I will agree with this. I think 12 through 14...

((Crosstalk))

Gregory Stock: A legal chain. We should establish somebody responsible.

David Magnus: The SCROs already track this.

((Crosstalk))

Henry Greely: ...to allow you to prosecute somebody for perjury.

((Crosstalk))

Henry Greely: Let's take that. I'm sensitive about the time. We've already gone over time, and some of us have flights to catch, but it's not urgent yet. We're not a fairly - there might be more that could be said about that page, but let's focus the next page, which is mainly the adverse event page.

Statute requests the record of all adverse health outcomes including, but not limited to, incidences and degrees of severity resulting from the AOP or any alternative method of oocytes retrieval.

Now the comments we got on this, generally, were not - didn't argue, for the most part, as to whether or not these should be reportable, because it says it's

clearly required. There was a fair amount of comment about the clarity of the questions and the extent to which definition - further definitions would be necessary.

If people were concern, for example, about vaginal bleeding, serious bleeding, was there any spotting at all, we're going to need - bleeding that's required sutures, you know, what would be necessary?

Do we have dropped down someone?

Kate Cordell: There's a lot of mouse over comments for defining AOP and other mouse over comments for definitions.

((Crosstalk))

Henry Greely: You guys are just too clever with the electronics for your own good. It looks like a lot of us looked at this in printed form like it looks like some of the commentators did. They didn't pick all that up.

((Crosstalk))

Man: Nice -- really nice.

((Crosstalk))

David Magnus: There are a lot of things that I liked about this form. I like the fact that it was operationally defined. So, like, severe, you know, outpatient...

((Crosstalk))

Otoniel Martinez-Maza: ...it was very clear outcome-based definitions.

((Crosstalk))

Man: ...roll over the 15.3.

Kate Cordell: Thank you to the committee for their prior feedback at the last meeting.

David Magnus: I like this, this is very good.

((Crosstalk))

Otoniel Martinez-Maza: ...looks very clear.

((Crosstalk))

Man: Yeah.

Henry Greely: Beckman or UCLA has a continuing question about an - has a continuing question about the unintended pregnancy or unplanned pregnancy question, Question 18.

David Magnus: I think an unplanned pregnancy is potentially an adverse outcome.

Henry Greely : I think that's fair although there are members of the legislature who might disagree with that but...

((Crosstalk))

Henry Greely: ...Maybe only male members.

Yeah. But he also raises the question of the time, you know, for how long to follow that.

Let's get back to your concern about time limit, because presumably might have to wait for several months, and you might not know this. So it might be, you know...

((Crosstalk))

Man: Yeah.

David Magnus: I think it's right. So I think it is not saying that you have to know all possible adverse events saying all known adverse events...

((Crosstalk))

Otoniel Martinez-Maza: ...adverse events, another adverse event.

Man: Yeah. I think that's (right).

Man: Yeah, rather than other...

Man: Well, I will...

((Crosstalk))

David Magnus: I think those "other" were other adverse events.

((Crosstalk))

Otoniel Martinez-Maza: ...treatment, oocyte retrieval of their adverse events.

David Magnus: So I think this is fine.

((Crosstalk))

Henry Greely: Do we have anything else to say on this form?

Gregory Stock: I would just echo it seems like a really good job was done on this form.

David Magnus: Yeah, I really like this.

Henry Greely: Now, do we have any commenters still on the phone?

Emily Galpern: Yes.

Henry Greely: Okay, Emily. I suspect you might have some comments on - or comments on this form.

Emily Galpern: (Unintelligible) the moderator on the call, okay, that's better. Thank you.

Can you still hear me?

Henry Greely: Yes.

Emily Galpern: Okay. I couldn't hear everybody's comment, so some people were much fainter than others. So - but what's the - I think there are a couple of things - the two things that I had said were thinking of the dropdown menus under Number 2 for race/ethnicity, income and primarily language just match those of the census categories, which just seems like that would be most useful.

I mean the whole idea of this form is to collect information to be able to see overall...

((Crosstalk))

Emily Galpern: Sorry, what's that?

Man: If they do now do that?

Emily Galpern: Well, one says, the race/ethnicity says, American Indian, Asian-Indian, and had three different categories. That was one thing. So I don't know why Indian...

Henry Greely: Okay, the others said that state category. So we may have an issue here with California having its own set of categories, which are different from the Federal categories. It might be difficult for a California department not to use the California categories.

Emily Galpern: Oh, yeah. Well that's fine to use the California one.

((Crosstalk))

Shabbir Ahmad: Emily, Department of Finance has a demographic unit.

Emily Galpern: Okay.

Shabbir Ahmad: And the - all the data state that the originates from Department of Finance, they use those definitions, so...

Emily Galpern: Okay. So what is the difference between American Indian, and then there's Indian, and then there's Asian.

Man: Okay. Well, we're looking to it, okay?

Emily Galpern: Okay. And then with the - okay, the other one, you dealt with the defining of adverse reactions. Susan had a couple of additional comments that I think weren't addressed that I think maybe the - what the one was...

Henry Greely: She wanted deletion of...

Emily Galpern: Right, that was done.

Henry Greely: Right.

((Crosstalk))

Emily Galpern: And then, it sounded like you talked about - I couldn't totally hear that conversion about other, but it just seemed maybe a little confusing the way - the order was - I mean, I don't feel really strongly about this, but...

Henry Greely: And she proposed an additional question about physician surgeons having a professional interest in the outcome of the research. That would be another one where it's - that's banned by the statutes.

((Crosstalk))

Emily Galpern: It is banned if they have a financial interest, but they have to disclose that they have a professional interest.

And then another thing that's also in the statute is the Subject B, provider then objective and accurate statement about the existing state of the research. As well as Number 10, which you were suggesting not required - I'm sorry, not Number 10, Number 13, did the subject receive a postprocedure of medical examination, but that's in the statutes, as well, so why would that question be eliminated?

Henry Greely: Right. Well, this - the other side of that is, why would you ask the question if the answer has to be yes.

Emily Galpern: Uh-huh. Uh-huh. So that was Dr. - I can't actually tell who was talking, whether Dr. Magnus is talking about...

Henry Greely: Everything you didn't like is David.

Man: Yeah.

((Crosstalk))

David Magnus: ...testing that those things have to - they already tell the SCRO that they're going to do this. They already have to say in writing. So why...

Emily Galpern: Okay.

David Magnus: ...ask them something that they already have in writing have committed to.

Emily Galpern: Okay.

Yeah, the other thing, I think in terms of around Question 10, the usefulness of checking whether it was assisted oocyte production or an alternative

method, is - I mean if alternative methods are developed and come into greater use, is then being able to tell if a lot of women are experiencing certain, say, a high percentage of women are experiencing a certain adverse health outcome, in turns out that they were from an alternative method or they were all from AOP, I mean, then you could trace back more easily.

David Magnus: But there are no alternative methods.

Emily Galpern: At this point, but - and maybe then the department could just modify the form, but I know that it takes a long time for forms to get modified. So it seems like why not put - why not include it.

Man: Okay. That's...

Emily Galpern: That's what we're trying to see, right? I mean the whole reason to get the data is to see if there are - you know, to try to document where adverse health reactions are coming from, if there are a high number, which, hopefully, there wouldn't be.

Man: Right.

Emily Galpern: And then, let me just see if there's anything else.

Geoffrey Lomax: Right. Just jump in, throw a couple of quick comments because I'm being called away, and I'm time...

Emily Galpern: Sure, go ahead, Geoff.

Geoffrey Lomax: Just one statement for the record just to be clear, at one point, it was mentioned that Item 7 on the subject form was requirement under the CIRM

regulations, and that is actually not accurate, so it's just for clarity in the record.

Henry Greely: The physical and psychological screen?

Geoffrey Lomax: Correct.

Henry Greely: It's not required by CIRM.

Geoffrey Lomax: And one other item that - just to offer as a consideration for your discussion, at one point, you were kind of trying I think balance the sort of feasibility or practicality of interaction between SCRO researcher and the sort of reporting requirements.

And just as a point of interest, I am aware of research organizations that do deal with SCROs on a sort of contractual basis or on a research basis, but they're not housed in the institution.

So just to sort of remind you, there is sort of a qualitative difference between a research institution that may have to procure SCRO resources as opposed to having resources in house, and that certainly would affect the sort of cost and sort of regulatory impact that would be quite different for that type of arrangement.

And I don't think that was part of the thinking in that discussion and I think this one do alert the committee to that reality, which could be -- if you're trying to balance sort of burden with efficiency in an attempt of the legislation -- something that, you know, may factor a bit differently on the burden side.

Henry Greely: Okay, thanks.

Emily, more from you?

Emily Galpern: I don't think so at this point. Thanks.

Henry Greely: Okay. All right. Well, we're down to four members of the committee, so we're well below the quorum. We're not going to take a vote on anything. But I think we've given the department a substantial -- and I hope helpful and useful -- advice.

Would you let us - give us some thoughts on where you go from here? Does the department intend to put a draft out for comments on the next draft to go to the final form.

What are your plans?

Shabbir Ahmad: I knew you are going to ask me this question. This is plus/minus timeline. December, we will revise these forms based on the discussion over here and with consultation of department counsel and within the department.

And the revised forms would be posted on web site, our web site, and would also be given to the - these committee members for their comments.

Now, if you - Hank, if you want to call a teleconference or you want to have in person meeting, we can do it any way you want. Or if you want to invite individual comments from committee members, that is fine.

((Crosstalk))

Shabbir Ahmad: Or if they want to send us directly and we can compile and send back to the committee. So - and anyway...

Henry Greely: And they will be roughly when? In January?

Shabbir Ahmad: It's in January. It's in January, yes. And from January onward, I think it will be four to six weeks for public comments.

Henry Greely: Okay.

Shabbir Ahmad: And by the end of February, we will finalize the forms and we will submit it to - now, this does not have to be - I will check with our counsel later, this does not have to be approved by the director of the department. The statute doesn't say that.

But we do send such sensitive information up to agency level. So that process may take a few weeks.

Henry Greely: Okay.

Shabbir Ahmad: So what we think that by, probably, April, late March, the form should be ready for SCROs and the research firms to be used. And we expect that we would receive the filled forms from SCROs and the research projects in September.

Henry Greely: Okay.

Shabbir Ahmad: Or probably late - so that's the rough timeline that we want to stick to.

Henry Greely: So SCROs and other interested public commenters will actually have two more bites to put the draft out your Web site. Plus, then there'll be a formal commenter, right?

((Crosstalk))

Shabbir Ahmad: There will be one formal commenter, yes.

Henry Greely: But before the formal commenter, there also would be a series of like informal commenter.

Shabbir Ahmad: Yeah, informal. Yeah, yeah.

Then we are going to put on the web site, we will start like informal comments.

Henry Greely: Okay.

All right. Well, the other items on our agenda are thinking about what revisions the guidelines might need and thinking about the topic for our next meeting.

And David and I have a plane to catch fairly soon and everybody - and I don't know when you guys are flying back, and Greg and Otto have been here longer than advertised.

Otoniel Martinez-Maza: We have a brief window of freeway opportunity.

((Crosstalk))

Henry Greely: I think that's gone, right?

But the thing I was saying, maybe you can put this out in an e-mail to the entire committee, I think we should be thinking about things where we might want to change the guidelines or things where we might want to suggest the legislature change the law.

So for example, the law requires now some sort of SCRO oversight of non-embryonic stem cell research, but it's not clear how much meaning is in that or why it's there other than, historically, it's there. It might be useful for our committee to take a look at that and recommend it to legislature, you know? This doesn't really serve any useful functions, let's kill it.

These issues of new methods of creating pluripotent cells, we might want to either reconsider what we're doing in the guidelines or recommend to the legislature. You know, there are these new ways that are not clear when you say embryonic cells, whether it includes this or not, you might want to reconsider this. That's the sort of thing I had in mind. And I think we could - we should collect some suggestions. There are a couple of other very specific statutory sections - there's one about confidentiality that's causing some difficulty for us.

((Crosstalk))

David Magnus: There's a couple of older...

Henry Greely: Right.

((Crosstalk))

David Magnus: ...statutes that are a decade old that are still on the books...

((Crosstalk))

Henry Greely: Just one from the UCI in vitro fertilization...

David Magnus: Right.

Henry Greely: ...scandal of mid-90s.

David Magnus: And they're still on the books - and they actually are bare on this research and are problematic in different ways, and at best ambiguous, and at worst, one of them may conflict with federal law - so it would be good if we could get clarity and maybe recommend to legislature that they may need to clear up a couple of old statutes that actually is bare on this, so they may not have ever intended to.

Henry Greely: So, Greg, Otto, you have specific suggestions today, because I'll also send out the e-mail and give people a chance to add things to that list.

Otoniel Martinez-Maza: Yeah, I think it'd be very helpful to start a dialogue on whether we should be overseeing pluripotent stem cells that are not derived from embryos or from oocytes.

Henry Greely: Okay. Greg?

Gregory Stock: I think that most has been covered pretty well.

Henry Greely: Well that also - depending on the response we get and how meaty those look that will have some effects on when we might recommend to department that it will be good for us to have another meeting.

((Crosstalk))

Henry Greely: Shabbir, you and I should talk about whether we want to go to just individual comment or teleconference in January, for your next version.

Henry Greely: I think an in-person meeting might be pushing it given the huge turnout we had today. It might get smaller next time, or not.

((Crosstalk))

David Magnus: I think that we might think about some changes in the make up of the committee to either to add some people or we do have a number of –for meeting or forum requirements, which is always a challenge. We do have a number of members who never come, as you are aware. And we also have - and so it might be good to think about maybe changes in personnel

Gregory Stock: I would suggest that - I think the meeting in northern CA is easier for me, and I think that we should stick to that.

((Crosstalk))

Gregory Stock: And I think that that's part of the problem that far many more people when we were in northern CA.

Man: Yeah, we did...

((Crosstalk))

Henry Greely: Yeah. But, you know, I promise we would have one in southern California. I grew up in here.

((Crosstalk))

Henry Greely: We respect you southerners, but having them in northern California works better for a lot of us.

Okay, are there any other comments?

Shabbir Ahmad: I just want to thank you on behalf of the department for your time and dedication and it was a very powerful discussion today on these forms. I was expecting even hotter discussion, but it was a very smooth meeting thanks to Hank.

((Crosstalk))

Henry Greely: Well, in appreciation for your comments, I'll call for a motion to adjourn. Is there such a motion? All in favor signified by standing up.

The meeting is adjourned. Thank you all for coming. And thank you, if you're still on there, Emily and Geoff, thanks for calling in. And if you're not, thanks for calling in, anyway.

END