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BEFORE THE
SCIENTIFIC AND MEDICAL FACILITIES
WORKING GROUP
OF THE INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE
TO THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE
ORGANIZED PURSUANT TO THE
CALIFORNIA STEM CELL RESEARCH AND CURES ACT

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PUBLIC MEETING

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DATE: May 31, 2007

TIME: 3:19 p.m.

LOCATION: Miyako Hotel
1625 Post Street
Sakura A Room
San Francisco, CA 94115

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Certified Shorthand Reporter
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San Francisco, California May 31, 2007

P R O C E E D I N G S

VICE CHAIRMAN SERRANO SEWELL: Hello. My name is David Serrano-Sewell. I'm vice chair of the Facilities Working Group for the Independent Citizen's Oversight Committee. I'm going to call this meeting to order. Ms. Becker, if you would please call roll.

MR. KELLER: I'll be calling the roll.

VICE CHAIRMAN SERRANO SEWELL: Thank you, Rick.

MR. KELLER: Marcy Feit?

Deborah Hysen?

MS. HYSEN: Here.

MR. KELLER: Ed Kashian? Robert Klein?

Stuart Laff?

MR. LAFF: Here.

VICE CHAIRMAN SERRANO SEWELL: Sherry Lansing? David Lichtenger?

Joan Samuelson?

MS. SAMUELSON: Here.

MR. KELLER: David Serrano Sewell?

VICE CHAIRMAN SERRANO SEWELL: Here.

MR. KELLER: Jeff Sheehy?

MR. SHEEHY: Here.

MR. KELLER: Janet Wright?

DR. WRIGHT (Telephonically): Here.

VICE CHAIRMAN SERRANO SEWELL: Hello, Janet? Do we have a quorum?

VICE CHAIRMAN SERRANO SEWELL: Bob Klein is en route.

MS. PACHTER: He's en route, but we need eight for a quorum.

VICE CHAIRMAN SERRANO SEWELL: If there's no objection, then I'll just proceed with the calendar and we won't take any action. And then when Mr. Klein is here -- he should be here in about ten minutes -- we'll have a quorum.

We have the newest member of our Facilities Working Group and that is Stuart Laff. We are fortunate enough to --

DR. WRIGHT: This is Janet. I can't hear.

VICE CHAIRMAN SERRANO SEWELL: Oh. Sorry, Janet.

DR. WRIGHT: That's better.

VICE CHAIRMAN SERRANO SEWELL: What I just said is we're one short from quorum. When Bob arrives we will have one more, which is eight, and until such time we'll just proceed with the meeting and we won't take any action. Then when Bob is here we can take some official action. There was no objection from the

committee members or, from what I could tell, the public.

DR. WRIGHT: Great.

MR. KELLER: Mr. Chairman?

VICE CHAIRMAN SERRANO SEWELL: Yes?

MR. KELLER: The quorum requires 65 percent of the eleven members which is eight. So one more would give you seven and if you for the purpose of conducting business I believe that we have access to David Lichtenger by telephone, but only for a very brief time. So that would be the time to pass on the facilities grant administration policy.

VICE CHAIRMAN SERRANO SEWELL: Thank you, Mr. Keller, for that.

So moving on. Our newest member, Stuart Laff, a respected member of the real estate community, someone who lives in Los Angeles. We were fortunate enough to recruit him to serve on this Working Group. He has spoken with our chairman David Lichtenger and others on this Working Group. The ICOC at our last meeting ratified our recommendation to have him come serve on this committee.

So welcome, Stuart, and thank you for joining.

MR. LAFF: Thank you.

VICE CHAIRMAN SERRANO SEWELL: And if you wouldn't mind saying a few words and some introductory comments about yourself, that would be greatly appreciated.

MR. LAFF: I started my facility career with Atlantic Richfield and I was responsible for the relocation from five cities into Los Angeles where I ultimately took over all of the facilities responsibility for Atlantic Richfield, which included architecture, engineering, and construction and operation services.

I then went into -- started my own firm, Programming and Planning, which I did for about seven years and then went to First Interstate and I was head of facilities worldwide for First Interstate. And we again had architecture, engineering, construction and operations.

When Wells Fargo merged with First Interstate I went over to Deloitte & Touche and started a real estate consulting practice. I then moved that practice to DMJN H&N, which is a very large architectural, engineering and consulting firm.

VICE CHAIRMAN SERRANO SEWELL: All right. Thank you.

This next item for consideration will be on

item number 7, public informational meeting regarding further facilities request for applications.

MR. KELLER: I'm sorry, Mr. Chairman, but item, I believe, 4 on your agenda update I think. I sent you the folder. If I didn't, I apologize.

VICE CHAIRMAN SERRANO SEWELL: Oh, that's right.

MR. KELLER: That general counsel Tamar Pachter is going to give an orientation.

VICE CHAIRMAN SERRANO SEWELL: Thank you.

MS. PACHTER: Thank you, Mr. Chairman. Good afternoon.

My name is Tamar Pachter and I've been the general counsel of CIRM for almost two months. And the acting president asked me to do a quick little facilities orientation, Facilities Working Group orientation, and you're going to be the guinea pig for the other Working Group.

So what I'm going to try to do is whip through some slides quickly and, if you have questions, jump in or I'd be happy to take questions at the end.

Just to give you a little bit of my background, I've been practicing law for 20 years both in public and private practice, state and federal.

And before joining CIRM I was at the Attorney General's Office and I represented CIRM in the constitutional litigation that just resolved in favor of the agency and Prop 71.

On behalf of CIRM the first thing I want to do is thank you for your service in helping us jump-start stem cell research here in California and really for the world. We are now the largest funder of stem cell research in the country and I think maybe in the world.

This is going to give you a little introduction to both CIRM and the Facilities Working Group.

To give you a sense where we're going to go, I'm going to give you a sense of the overall structure and functions of CIRM including the ICOC, the staff at the Institute and Working Groups; an overview of the Facilities Working Group functions, structure, governance and what happens with your records; and a very quick overview of the whole grant process so you can see where you fit in.

The California Institute for Regenerative Medicine was created in November 2004 with the adoption of Prop 71. Its purpose is to fund grants and loans for stem cell research and research

facilities in the hope of finding cures for diseases and injuries that afflict Californians.

CIRM has three parts. It is the Institute, the ICOC, which is the governing board, and the Working Groups. Those are the three structural parts of CIRM.

The ICOC governs CIRM. It's a 29-member body appointed by elected officials and chancellors of UC and it includes patient advocates, university officials and business executives. The members of the ICOC receive no salary for their service. They are all volunteers. And the ICOC, one of its functions is to appoint the president of CIRM.

CIRM's staff is headed by the president and the staff is limited to 50 full-time equivalents. Currently we're at 22 and at the board meeting next week the acting president is going to present a budget for basically doubling the size of the staff over the next year.

As a result of the resolution of the litigation we have a greater ability to fill out our staff and we're here to accomplish the work.

The staff at CIRM serves at the pleasure of the president and is exempt from civil service. They are mostly scientific staff, but also we have on staff

financial expertise, administrative expertise and legal expertise.

The ICOC makes all the funding decisions, develops strategic research and financial plans, sets the research standards, sets IP policy, issues public reports and commissions the annual audit, adopts policies governing CIRM and the Working Groups, selects the Working Group members and adopts administrative regulations. The job of CIRM staff is to support that work.

The president and the staff have both support functions and independent functions. Support functions, among them are to support the Working Groups by helping to recruit Working Group members and support the development of the recommendations of the Working Groups to the ICOC, and to support the ICOC's process of acting on the recommendations submitted by the Working Groups and to implement its decisions.

Among the independent functions of the Institute are grant review, funding, administration, management and compliance, everything that happens after the ICOC approves grants for funding. We're also responsible for the budget of the Institute and cost control and for management of IP agreements and all other contracts of the Institute.

So the staff supports the ICOC and the Working Groups as a whole as entities, and within the policy mandates set by the ICOC as a whole. Our administrative staff is very limited and will remain limited because we are limited by statute to 50 full-time equivalents and the majority of that is devoted to scientific staff.

So there are three Working Groups that support the work of CIRM. The Grants Working Group. They have much much fancier names actually in the statute. The Scientific and Medical Research Funding Working Group, which we refer to shortly as the grants Working Group. The Scientific and Medical Accountability Standards Working Group, the Standards Working Group. And you are the Scientific and Medical Research Facilities Working Group which we refer to shortly as the Facilities Working Group.

All these Working Groups have some common functional attributes. The membership is appointed by the ICOC and the criteria for your appointment is set in the statute. You're required to have four meetings a year. CIRM staff coordinates and has a designated liaison to each Working Group. Here that liaison is Rick Keller.

And each Working Group has a chair and a vice

chair who work with the staff and with the ICOC chair to prepare for the meetings.

And there are also some common restrictions on the Working Groups. The Working Groups are advisory bodies, not decision-making bodies. Your function is to make recommendations to the ICOC which is the decision-making authority.

The Working Group recommendations must be reached by a majority and there is a provision in the law for a minority report. You are governed by a conflict of interest policy that's been adopted by the ICOC. And your records are generally not subject to the Public Records Act and I want to talk a little bit more about that later.

The purpose of the Facilities Working Group is to make recommendations regarding the building of facilities and capital equipment. Under Prop 71 CIRM can award up to 10 percent of the bond proceeds of $3 billion, net of costs, for grants to built facilities for stem cell research. And the idea is that these will be built in the first five years of funding because they are providing NIH free space.

The ICOC can award less than this 10 percent of the bond proceeds, but it can award more.

The Facilities Working Group has eleven

members, four real estate specialists who are appointed by the ICOC, six members of the grants Working Group, who are patient advocates who are also ICOC members, and the ICOC chair.

Welcome, Bob. Welcome back from Canada.

There are also provisions for alternate and ad hoc members, all of whom must be appointed directly by the ICOC.

The functions of the Facilities Working Group are to make recommendations to the ICOC on criteria, requirements and standards for facilities grants; to make recommendations on the actual award of grants and loans for facilities and equipment; and to make recommendations on oversight procedures to insure grantee compliance with the terms of the grants.

So we've got the before-grant, grant, and after-grant responsibilities.

With regard to the recommendations for criteria, requirements, and standards, Proposition 71 includes some minimum criteria. And these include: Milestones and timetables for achieve them; priority for applications that will provide facilities available for research no more than two years after the grant award; eligibility only for non-profits located in California; compliance with reimbursable

building cost standards, competitive building leasing standards, capital equipment costs standards, and reimbursement standards; and compliance with prevailing wage laws.

So whenever you're considering recommending criteria these are the minimum that the statute requires.

Finally, the statute also requires that awards must be made on a competitive basis and tells us that what this means is at a minimum applicants must pledge 20 percent in matching funds and priority given to those who provide in excess of that minimum.

And what do I do now? Is it okay?

And capital equipment costs must be allocated when the applicant can recover costs from other users.

A little bit about governance of the Facilities Working Group. The rules for governance come from Prop 71, which we've talked a little bit about, bylaws that were adopted by the ICOC and a conflict of interest policy that was adopted by the ICOC.

I'm not going to go over all the bylaws. I wanted to hit some highlights for you. Hopefully all of you have a copy of the Facilities Working Group bylaws. They provide for a chair from among the real

estate specialists who is responsible for chairing the technical review of applications; a vice chair, from among the patient advocates, who chairs the programmatic reviews. So on the Facilities Working Group David Lichtenger is the chair from among the real estate specialists and David Serrano Sewell is the vice chair.

Your business is conducted in open session. A quorum is 65 percent of the members eligible to vote. So it will take eight to do business. And the bylaws also require that members of the Facilities Working Group may not communicate with any applicant about an application to CIRM. This is probably one of the most significant restrictions in the bylaws.

I'd like to talk a little bit about public meetings because many people who are doing the Working Groups don't have a lot of experience with trying to do business in public, and it is challenging. It requires a fair amount of preparation that the chair and vice chair do in advance with staff so that we can move through the business at hand.

And part of what we're trying to do here is build public confidence in what it is that we're doing. And so that preparation is very important and moving to the business at hand is very important.

Often as today we need to do something in order that the ICOC can act on it at its next meeting. And so we as staff try to prepare you and prepare ourselves to move through the business at hand and be able to answer any questions that arise.

MR. KLEIN: Tamar, before you pass over a prior point, you said no applicant can communicate with a member of the Facilities Working Group. It's very important to point out that was adopted based on once the application is filed. So if we're in the back of the room and at a break and someone asks a question, that's not an issue. No applications have been filed for the major facilities that we're trying to get definitions of today. It applies once an application has been filed.

MS. PACHTER: I wanted to talk a little bit about the Facilities Working Group conflict of interest policy. This is a policy adopted by the ICOC. It applies only to the non-ICOC members of the Facilities Working Group because there's a separate document that controls conflicts of interest for ICOC versus the Working Group.

It addresses financial, professional and personal conflicts of interest. These are often difficult areas and if any of the real estate

specialists ever have any questions regarding how the conflict of interest policy might apply to them I encourage you to call me anytime. We're happy to provide that support.

Conflicts of interest are -- with respect to the Facilities Working Group, the disclosures are made just to the agency and they are audited by CIRM staff and they are also subject to audit by the Bureau of State Audits.

If a conflict exists, if you have a conflict with any application under consideration, you are restricted from participating in any way in the discussion or decision of the Facilities Working Group either in the meeting or outside of it.

I also wanted to talk a little bit about the records of the Facilities Working Group. They are generally not subject to the Public Records Act as are most of the records that CIRM has. Actually, in a sense they are.

CIRM's records are subject to the Public Records Act, but generally the Facilities Working Group records are not. There are a couple of exceptions in proximity to one itself. The Facilities Working Group records are published to the extent they are forwarded to the ICOC as part of the Facilities

Working Group recommendations because that becomes part of the ICOC's decision-making process.

And there are also exceptions made by the ICOC about certain records that it chooses to make public. For instance, it chose to make the applications that we recently considered on the shared labs public.

And, finally, I'd like to give a little overview of the grant process so you have a sense of where you fit in. The facilities -- and this is at a very high level. There's some point I get into this, but this will give you an overview.

So the Facilities Working Group will recommend criteria, requirements, and standards for facilities RFA to the ICOC. The ICOC will consider that recommendation and approve it with any changes.

Based on those approved criteria the CIRM president and staff will present to the ICOC for discussion a concept plan for a facilities RFA. And after that discussion at an ICOC meeting CIRM staff drafts and issues a facilities RFA based both on the approved criteria and the discussion at the ICOC meeting.

Institutions then submit applications to CIRM in response to the RFA. The staff reviews those

applications according to the RFA and the approved criteria, submits those staff analysis to the Facilities Working Group and schedules a Facilities Working Group meeting for review of the applications.

Before the meeting the members of the Facilities Working Group are confidentially reviewing the applications and, again according to the criteria and the RFA, and then meets publicly to discuss and vote on its recommendations.

The chair and David Lichtenger conducts the technical review and once the technical review is complete the vice chair David Serrano Sewell conducts the programmatic review.

At the same time the Facilities Working Group is conducting its review the Grants Working Group is conducting a parallel review of the science to be conducted at the proposed facility. And what happened with the shared labs is there was a part 1 of the application which was the scientific submission that the Grants Working Group considered and part 2 which was before the Facilities Working Group.

CIRM staff then drafts summaries of the Facilities Working Group recommendations and the Grants Working Group recommendations separately. There are two separate summaries for the ICOC's

consideration. And the summaries for the Facilities Working Group and the Grants Working Group are publicly posted in advance of the ICOC's meeting.

The ICOC then meets publicly to consider the Facilities Working Group and Grants Working Group recommendation and votes to approve the applications for funding. It can make changes in the recommendations. It can fund applications that neither of the Grants Working Groups recommended or funded. That discretion is entirely up to the ICOC. And we're going to go through that process for the first time this Monday and Tuesday in LA at the ICOC meeting. We'll be considering the first facilities grant. So that's going to be an interesting process.

Once the ICOC votes and determines what applications it has approved for funding, that's just the beginning of the process as far as CIRM is concerned. Staff then conducts an administrative review of applications that are approved for funding to insure that all the criteria for funding have been met.

On successful completion of that administrative review, the CIRM president issues a notice of grant award. That is to be signed by the president and sent to the applicant and then returned

to CIRM.

And it's only after we receive that, the signed notice of grant award, that CIRM authorizes the controller to issue warrants for initial grant funding, and that will usually be the first year of grant funding.

After the funding goes out CIRM scientific and grants management staff monitors the grantees through a grant administration process that includes annual reports, cost review, project review and compliance review, through the life of the grant.

CIRM staff has authority to withhold funds for failure of compliance of the terms of the grant and it makes regular reports to the ICOC on the status of grant applications.

So I've blown through that. Are there any questions?

VICE CHAIRMAN SERRANO SEWELL: Members of the committee, are there any question for Ms. Pachter?

Tamar, thank you. In conclusion?

MS. PACHTER: In conclusion you can see that you're a very important part of the overall grant process in making recommendations for the ICOC for both pre-grant, grant approval and for grant oversight. And thank you very much for your service.

VICE CHAIRMAN SERRANO SEWELL: Thank you, Ms. Pachter, for that summary. It was greatly appreciated and it's helpful even getting a refresher. We've known it for a couple of years and there's always something new we can learn.

In talking with Mr. Keller I think what next we will do is we have some coordination issues with David Lichtenger. So we want to move next to the facilities grants administration policy.

Is that correct?

MR. KELLER: That's correct.

VICE CHAIRMAN SERRANO SEWELL: So we will move now to that action item.

MR. KELLER: David, are you on the line?

MR. LICHTENGER (Telephonically): I am.

MR. KELLER: Okay, David. Welcome.

With that I think we should put on record to establish that a quorum has been established relative to those telephonic and those present.

On your agenda for action is consideration of the draft facilities grant administration policy. We refer to this as the facilities GAP. This amends the current policy by expanding on existing policy that would apply to the shared research and stem cell techniques course awards or RFA 07-01.

If you received a copy of the draft at your meeting on May 2nd, that document has been revised in response to comments from the Working Group and further refinement of the technical nature prepared by staff.

The three major changes between the May 2nd version of the document and the document that you have now before you consists of three major changes. We relocated the section concerning requirements for California suppliers to the general provisions section rather than having it duplicated under construction requirements and equipment requirements.

Secondly, the requirement for grantees to submit a progress report to CIRM has been changed to the quarterly rather than semiannually as it was felt more timely.

Thirdly, the definition of "non-profit" and "not for profit" as used by CIRM has been clarified in the glossary section.

So with those minor, relatively minor changes and editing and wordsmithing we believe the document before you is appropriate and, if you have any questions, I'd be glad to answer them.

VICE CHAIRMAN SERRANO SEWELL: Bob?

MR. KLEIN: Under the "Equity Match," page 5,

D as in David, subsection 2, subpart 2 in parens. It says: "The source of funds for the construction or equipment identified as matching."

When it asked for documentation I would take it that if a research institution says that they are going to supply the funds for the cells that that would include the fact that they could, if they got a donor, they could later substitute the donor's funds for the funds that the institution was putting up, but they at least need to be an identified term source of funds that we could depend on. Is that correct?

MR. KELLER: I believe that the provision that you're reading from is in response to the fact that CIRM grant funds cannot be used as matching funds. So if they have another grant or -- from another source when we want to make sure that we have the trail to the actual source of funds for the match and because of that provision in Prop 71 that says it has to be other than grant funds.

MR. KLEIN: Yeah. I'm understanding that.

Lori, could you also comment on this section?

MS. HOFFMAN: Bob, you're correct. So, in fact, as long as it's not other grant funds, yes, an institution can substitute donor funds for campus

discretionary funds.

MR. KLEIN: So they could initially or because of the timing commit that they would put up the funds and then the donor funds that replace their funds, we just need a firm source of funding.

MS. HOFFMAN: That's correct.

MR. KLEIN: Okay. And that's probably good in the major facilities grants to indicate that substitution can also occur.

VICE CHAIRMAN SERRANO SEWELL: Jeff?

MR. SHEEHY: So where does this fit? Is this going to be put in --

MR. KELLER: This governs -- this governs the shared research laboratory grants that we'll be considering -- the ICOC will be considering next week. Before the large facilities grants go out or the RFA is issued we intend to make further revisions that would respond to information that's garnered from the information sessions that we're upholding in the next three weeks and other aspects so that we would basically indicate that this is for the shared labs only.

MR. SHEEHY: So this is for the shared labs only and this isn't going to the Administrative Law Code? Because I think the other GAP is in the

Administrative Law Code; right?

MR. KELLER: Yes, it is. It went to Office of Administrative Law.

MR. SHEEHY: So this is almost like a one off?

MR. KELLER: This would be an amendment to that.

MR. SHEEHY: Just to be clear. So like our other GAP it will go through the Administrative Law Code process. However, this particular GAP is only for this one grant; right?

MR. KELLER: Yes.

MR. SHEEHY: That's all. Just trying to understand.

VICE CHAIRMAN SERRANO SEWELL: Bob?

MR. KLEIN: Lori, maybe you could remind us in terms of sourcing of our funds for these grants. How much is budgeted to come out of our facilities set-aside funds versus our research category funds from the $48 million that is budgeted for this program including facilities and the courses?

MS. HOFFMAN: Of the $48.5 million that is budgeted for this particular RFA -- so this is the shared research lab RFA that we're talking about -- $16.25 million were budgeted, but we can go, in fact,

up to $19 million which was the agreement that we made with the Department of Finance based on not to exceed 10 percent of our current funding, which is the $150 million of general fund loan as well as the $45 million for the bank.

MR. KLEIN: So the balance of the 48 and a half million is really coming out of our research funding resources?

MS. HOFFMAN: That's correct.

MR. KLEIN: Okay.

VICE CHAIRMAN SERRANO SEWELL: Janet or David, do you have any questions?

MR. LICHTENGER: No.

DR. WRIGHT: I was going to move that we adopt this so we can get to a point for discussion.

MR. LICHTENGER: I'll second that.

VICE CHAIRMAN SERRANO SEWELL: There's a motion and a second. Any further discussion from the Working Group? Bob?

If there's nothing further to add, we'll take a vote. All those in -- oh. Public comment. I'm sorry.

Are there members of the public that wish to comment on this item?

Seeing no members of the public that wish to

comment, we'll then take a vote. All those in favor please say aye.

All those opposed?

Abstentions?

Motion carries.

MR. KELLER: Thank you, Mr. Chairman.

MR. LICHTENGER: Thank you.

VICE CHAIRMAN SERRANO SEWELL: Thank you.

What's our next item?

MR. KELLER: Thank you, David.

MR. LICHTENGER: Bye-bye.

DR. WRIGHT: Thank you, David.

VICE CHAIRMAN SERRANO SEWELL: Our next item is item 7 on my agenda that is the public information meeting regarding future facilities request for applications. This Working Group at its last meeting -- or excuse me.

Anyways, we had requested the ICOC, the body to which we report to, if we could hold some informational hearings to gather information in designing this facilities RFA, this $222 million RFA. Everybody agreed. And so that's the first of what will be four informational meetings.

The staff has assembled a group of persons that can speak with us today and share some of their

thoughts. Mr. Keller will have some introductory comments and then introduce each one of the speakers.

MR. KELLER: Well, I think the first thing I just want to mention is that as a backdrop to the public comments, we have here on display the mission of CIRM and we've included that in your packets today and made them available for those attending this from the public because I think the first issue is that we want to solicit information about how CIRM should move forward on their facilities grants in the context of the stated mission and our values.

In looking at the values, we have established that there are many of these that have very specific applicability to facilities. So, for instance, obviously accountability, collaboration, excellence, innovation all have -- and certainly urgency all have direct application to the business associated with CIRM funding of facilities grants.

We've actually added two additional values that we think -- that really pertain to facilities and that is the fact that we have responsibility to judge kind of the functionality or applicability of design to meet specific programmatic objectives.

And so we've put these values as the backdrop with the idea that we would now solicit comment on

what are some of the specific needs within the research community and within the group of -- that is in a position to respond and partner with CIRM in meeting our objectives. And so with that I'll ask if there's any questions or I'll ask the first speaker to come forward.

MR. KLEIN: Thank you. Thank you, Rick.

My understanding of where we're trying to go here in terms of the outcome of this hearing and building through the other hearings is to drill down and get real good hard answers on what are the policies, what are the rules and what are the definitions.

And we've talked in our last hearing about a lot of those policy issues and rules and definitions, but if we can as an outcome produce a core set of those policies, rules and definitions that we really need to focus in on consistently, and on each hearing we'll add some from the staff, we'll add some from the public that are additionally identified.

So hopefully over the period of these hearings we'll fill in the detail and everyone out of this hearing that read these transcripts as well as the staff reports that summarize them will have a solid idea of how these are going to be judged and how

policies are balanced when we talk about a policy for urgency.

We've got core values of collaboration and innovation. So the Center For Excellence which is the collaboration of several institutions, how does that weigh. But when we get to definitions, the initiative says two years after award.

Well, we just went through a presentation where "award" is defined as when the president signs the certificate of award, if that's -- if that's correct and my understanding. So it's two years from that date, is that what the critical path charts that are submitted in these applications need to show.

So with that level of specificity I think hopefully we'll keep our eye on the ball and it's going to be a useful outcome to this process.

VICE CHAIRMAN SERRANO SEWELL: Are there any other initial comments from members of the Working Group? If not, Rick, you can introduce the first speaker.

MR. KELLER: First, I'd like to introduce the first speaker, Dr. Jeff Bluestone from the University of California at San Francisco.

The format today will be that we're allowing a ten-minute presentation with the idea that there

will be opportunity for brief question and answers from the Working Group at the conclusion of the presentation. I'll be the timekeeper on the ten minutes and with one minute to go I'll indicate to the speaker that it's one minute, go. Thank you.

DR. BLUESTONE: Just kick me.

Well, I want to first -- my name is Jeff Bluestone. I want to thank the committee for a chance to speak to you today.

I come to you today as a representative of the research faculty at UCSF, but as importantly I speak to you as a hopeful user of the extraordinarily promising technology and research that's being done by CIRM, its grantees and the community.

As director of the UCSF Diabetes Center and an immunology researcher I'm involved in diabetes research and research in multiple autoimmune diseases. So the opportunity for stem cells and stem cell research to affect the diseases I care about is enormous. I see every day the ravages of these diseases and the need for replacement therapies to treat the tissue destruction that results from these chronic ailments.

But on a personal level I'm also here because like many of you I've been affected personally by this

disease. My father, a long-time diabetic, has lost limbs, partial eyesight, and most recently lost his kidney function which had to be replaced by one of my own kidneys. And so I care a lot about what you are doing and I greatly applaud your effort.

So the next few minutes I hope to share some of UCSF's and my perspectives on the facilities investing plans for the CIRM and how I think they might best serve the mission and strategic plan for the CIRM, the values that have been listed up above, and the stem cell research both supported by the CIRM and the community at large.

I'd like to position this discussion in terms of the age-old questions why, what, where, when and who.

Let's start with why. Why do we need these facilities? Well, the last three years since Prop 71 was passed it's shown an enormous growth both in the interest and in the training of stem cell researchers. The chance to exploit this growing community depends on first-rate specially designed facilities to bring together basic scientists, translational researchers that are currently spread out within our own campuses in little nooks and crannies around our campuses.

We'd like to recruit more junior faculty, people who see a future in stem cell research now that the funding has been passed, but there's no room for them in many of our institutions.

As a scientist it's important to be able to walk down the hall to see a colleague. It's important to have a diverse community of students and research fellows that can work with each other to bring knowledge and technology to bear on a particular problem. This is a major interdisciplinary program that can't be tucked away or scattered across our campuses, but must be placed in dedicated contiguous space.

Thirdly, we need to provide core resources and core services for stem cell research whether it be imaging, sorting, cell tracking, human cell culture. All of these core facilities need to be co-localized where the scientists, students, post docs can walk and do the research they need.

And as importantly we need to keep these facilities secure and fire walled from the federal funding that challenges all of us in getting this work done.

What type of facilities should we create? There's a tendency to create very large structures

that might be located one in the north or one in the south or one in Central California. However, I think proximity to an epicenter of research enterprise is vital. Thus, the facilities should be located at academic institutions because it's essential that the stem cell research be carried out in a scientific and vibrant environment.

The facilities need to be -- need not be one size fits all. There should be larger facilities that can exploit the scientific communities within small regional areas like a university or within a city while emerging programs should be supported with dedicated space that will catalyze breakthroughs and drive discoveries.

So the large programs should have dedicated facilities for stem cell research and the smaller programs isolated areas that can be used for similar programs, similar research efforts.

Where should the facilities be built? I've already mentioned I believe they need to be built within a research academic institution, but these institutions must be selected first and foremost on excellent scientific environment to foster not only the basic research but the translational research and as importantly to the institutions that have active

collaborations with industry who will partner on many of these research efforts.

There needs to be excellent science outside stem cell research. There's a tremendous value in collaboration, but that collaboration needs to be in local institutions where scientists across multiple fields can work together. There needs to be a strong translational research effort around where the facilities are built so that clinicians and clinician researchers can take the discoveries made in the laboratories directly from the bedside -- from the bench to the bedside and then to the community.

As I mentioned, the collaborations with industry are best done when the industries are located close to the sites of these facilities so that investigators from the academic centers can work hand in hand with industry representatives so that these therapies can be transitioned as necessary.

When should the facilities be built? Well, as Bob Klein already said, as fast as possible. The term "urgency" has been used. With all the CIRM and institutional investment that has already been laid on the table here, the fact that institutions around the state have started to create and build programs that CIRM has started to fund many of the training and seed

grant efforts, the lack of space has now become limiting -- the rate limiting step and the sooner we can get space to do this research, the better.

But we need to know that this isn't like building a grocery store or a bowling alley. The federal and state regulations that have been imposed pose unique challenges on rapid building. So unlike a freestanding private enterprise building facilities for effective stem cell research will take a concerted effort by state, local and federal agencies to work together effectively to get these done. So speed is important, but process is critical.

And, finally, who should have these facilities, the ones that are described above? Well, I think there should be four major criteria that should be used to drive the process. First and foremost is the scientific excellence and facilities excellence. We need the best scientists; we need the best facilities.

I've already mentioned urgency. I'll mention it again.

The third is leverage. How do we take these buildings and leverage them for our whole research community to make sure that what we grow out of these facilities really takes on a larger purpose.

And, finally, collaboration. The CIRM should issue an RFA as soon as possible that calls for facilities dedicated to stem cell research and then allocate the funds for facilities at institutions that have a history and predicted future of excellent stem cell science and a community of outstanding scientists from other disciplines and active industry corroboration.

The facilities must work effectively between large and small institutions within small geographical areas to maximize research translation and the interface of academia and industry. The ICOC has a track record and commitment for funding the best science. This shouldn't change.

So, in conclusion, the ICOC and CIRM have made extraordinary contributions to the community already based on perseverance and commitment. The commitment to training programs, seed grants and comprehensive grants has already left their mark on the state and research enterprises.

The effective use of resources to build facilities that will support the wealth of excellent scientists in their training and research endeavors is essential to allow stem cell research in California to realize its full potential.

As I said in my Prop 71 ad three years ago, I want to be able to continue looking in the eyes of every seven-year-old boy and girl just diagnosed with type 1 diabetes and tell them we're doing everything we can to treat and cure this disease and the many others that affect friends and families. Your help will be another great step in helping me live up to my commitment.

Thank you.

VICE CHAIRMAN SERRANO SEWELL: Thank you, Dr. Bluestone.

Do members of the committee have comments or questions on the doctor's presentation?

Jeff?

MR. SHEEHY: I actually have a whole series. So I apologize.

Thank you for your presentation.

VICE CHAIRMAN SERRANO SEWELL: That's always when the first speaker comes along.

MR. SHEEHY: You mentioned core facilities. Which core? I mean, so what we're really trying to do is draft an RFA. So really we're trying to go into a certain level of detail. What should be components? You're talking about core facilities that should be part of what we asked for in the facilities

application.

DR. BLUESTONE: So first and foremost we need to have a facility to house, store and grow the cells that we care most about which are the embryonic stem cells, and this is vital and central to any facility that needs to be built. But we also need the ability not just to house them and store them but to grow them, to modify them and to test them first in animal models in some cases but certainly in a variety of test systems.

The second thing I think we need in core is imaging, finding out where these cells go and how these cells go is going to be critical and having imaging facilities that can both be used for small animal studies on up to human analyses is going to be critical. So I think imaging is another core that's going to be essential.

And distribution facilities. There are not going to be an unlimited number of these facilities around the state and it's going to be critical that whomever is blessed with getting these facilities has a responsibility as they develop these embryonic stem cells not just to store them but to actively distribute them around the state. So having the infrastructure to be able to do that is critical.

The other cores that one will need are going to be standard cores that I think exist in many facilities we have now, but have to have a dedicated person and dedicated equipment. These are sorting facilities so that we can isolate rare cells among mixed populations to be able to grow them, expand them and them differentiate them.

It will be biochemical cores that allow us to understand the infinite mechanism by which these cells work. And a molecular biology core that will allow us to put genes in, take genes out and to understand the basic functioning cells through genetic engineering and molecular biology.

So those are some of the cores that I think will be essential.

MR. SHEEHY: So if we were to do a major facility, because we're talking about all different sizes, you would probably expect they would have all of these cores at a minimum?

DR. BLUESTONE: Absolutely.

MR. SHEEHY: Great. Now, in terms of your still evaluating something that we said on the cores, do you think those need to be GMP facilities? Would that be a requirement that we should put into this? How important is that at this stage?

DR. BLUESTONE: I think it's very important that GMP facilities be available for translating this research into a clinical state. I don't know that GMP facilities have to necessarily be localized at the site. A lot of the things that I talk about as being core to the success of these facilities has to do with the interaction of science and the ability to do this cutting edge research.

Once a cell is in production and will require GNP facilities that's something that can be outsourced. It certainly would benefit to have a GMP facility on a campus or in the city that it can be used, but it doesn't necessarily have to be within the building.

DR. WRIGHT: This is Janet. I have a question whenever there's an opportunity.

VICE CHAIRMAN SERRANO SEWELL: Janet, Jeff has got a few more questions and then I'll go to Bob and then we'll go to you.

DR. WRIGHT: Great.

MR. SHEEHY: You mentioned the translational opportunities and I think this comes up in collaboration, too. I'm trying to get -- because, you know, this is translational -- it's always -- it's one of the most confusing words in science. It means a

lot, but it's also very hard to really pin down when you're trying to really tease that out in terms of realities. Is that really a question of geography? Because you talk about relationships between industry and an academic research center. Is that like -- for instance, just using because we're talking about UCSF because the Bay Area, it's relatively easy to imagine.

Is that a geographical consideration? How do we kind of maximize that impulse when we come up with this RFA?

DR. BLUESTONE: Let me speak from experience. I'm actually a PhD scientist. Yet I oversee tens of multi-million dollar clinical trials networked in this country. And what I've learned as a PhD is that the best and most effective way to move discoveries in the laboratory -- I've cured a lot of mice in my days -- into things that will affect people is to have clinicians and clinical researchers very close by to be able to come to lab meetings, to be able to come into the lab and look down the scope, be able to interact day to day with the PhDs.

It's very hard to do it all, but if you have PhDs very close to the clinical researchers you can very rapidly transmit knowledge, information and

material as needed. So I think proximity geographically is very important.

I think the same thing can be true for industry. The closer you are to the people that are going to take what these discoveries are and productionize them, move them into a drug that can be put into people, the closer you are, the easier it is to get everybody on the same page.

MR. SHEEHY: And I try to be -- I'm just trying to be really pragmatic. Is there a way that we can ask for that in this RFA? Because that's really our goal here is to draft an RFA.

Do you see where I'm going?

DR. BLUESTONE: Sure. And I think the best way to ask for it is to ask for evidence of it, to ask institutions to demonstrate that they've successfully been able to merge the basic and clinical research efforts successfully in moving things from animal studies into human disease settings, to ask institutions to demonstrate collaborations with industry where they've moved products and discoveries that they've had in the lab into a production area.

VICE CHAIRMAN SERRANO SEWELL: Bob?

MR. SHEEHY: I was just going to say thank you. This was extremely helpful.

MR. KLEIN: Sure. There's a fundamental question here in that we certainly have this focus or priority of needing these facilities to accommodate and provide sanctuary for embryonic stem cell research. On the other hand, many of the researchers that are doing this research, they also may even be working with amniotic cells or fetal cells.

So since we're after -- we're attached to a mission that is patient driven and outcomes driven we've got to follow the best science. We know that the NIH is going to have a deficiency that is highly likely in its funding across all areas of stem cell research in the next few years in particular because of the huge deficits the country is now going through.

So how do we deal with the issue of addressing who's going to be using this space? Because I assume that even though we have some significant research interest in the embryonic stem cell area we're going to have some complementary research being done in these other areas of stem cell research where there's a lot of crossover.

In fact, there's some research going on at UCLA with adult stem cells that involves a gene modification where to scale it up they're going to need embryonic stem cell research. So there's a

synergistic relationship. So how do we express our priorities and yet have it broad enough to accommodate the spectrum of researchers that can really lead us to the best science in the best areas?

DR. BLUESTONE: Yeah. I certainly agree that science is driven by a combination of hypothesis and creativity and serendipity and you would hate to shut off doors or pathways just like Prop 71 was all about, not shutting one door on science.

So I think the important thing is to ask institutions to demonstrate an ability to both facilitate and take advantage of the potential interactions and collaborations, to show how, for instance, pilot projects or other projects might be introduced into the armamentarium of an institute so that individuals working in one field will be encouraged to work in embryonic stem cells, to show and demonstrate it through everything from journal clubs in laboratory meetings as well as co-publication that people are moving the science back and forth between these different disciplines.

Because it's not just which ones are going to work. I mean, that's a major issue. But it's also about how one will inform the other. The kinds of genes that we're going to learn about in one cell type

will invariably affect how another cell type and in one type of cell and other types of cells. So I think institutions that can demonstrate that they have effective programs and plans for making sure that scientists don't operate in silos and independent, but there's various science which is so essential whether it be immunology or stem cell or adult stem cell research; that it's actually the kind of work that's being discussed in a collaborative, integrative way. And that's the way you'll bring the most to bear on the problem.

MR. KLEIN: We're actually going to be asking for an expression of their priority to accommodate embryonic stem cell research so we know that there's a sanctuary for that, but then asking them to identify what portions of space they really in a synergistic way be dedicated to other disciplines that interrelate in or other areas in relation to that.

DR. BLUESTONE: And how those other areas are going to feed into the central core mission of the CIRM. Because they have those split out. They won't be useful unless there's a clear plan on how those advances will be communicated into the central mission.

VICE CHAIRMAN SERRANO SEWELL: Janet, did you

have a comment or question?

DR. WRIGHT: And it changed a couple of times because Jeff actually got to my question about industry. I'm going to go and pose the -- I believe they have been touched on a bit.

Dr. Bluestone, we really appreciate this advice and guidance. What obviously we want to do is try -- by issuing the RFA we want to drive the kinds of collaborations we were just talking about as well as -- and not so much institutions and researchers, clinicians, but with industry.

So others -- I understand that by asking for evidence of the central partnerships in the past we signal that that's what we're looking for, but can we give very specific other ways that we might incent or encourage those kind of collaborations other than just saying that's what we're looking for? Not just based on you their past but how can we help drive folks towards doing this even to a greater degree?

DR. BLUESTONE: Yeah. So I know that -- I think I believe that there's some clear statements about the funding going to non-profits. So the money will be going to institutions that are set up as non-profits, but I think when you talk about partnerships in the past and I think in this case you

talked about even money that's coming in as matching funds, there's no reason why the institutions can't demonstrate both an experience and an opportunity for collaboration with industry by demonstrating economic interactions as well as just scientific ones.

It seems to me that if industry is going to benefit most from this that it should contribute to this enterprise as well, and how you facilitate that without funding industry is to make sure that industry is putting up some resource or resource in kind, perhaps equipment, perhaps project partnerships or whatever and really show a demonstration that the industry is on this, too.

Because I think if the industry invests in some way into these -- these overarching facilities, the larger facilities that are housed here, that it will end up fostering good partnerships and good relationships.

So I guess the bottom line is I think money talks.

VICE CHAIRMAN SERRANO SEWELL: Deborah?

MS. HYSEN: Yes, I have two. The first one. The series of grants that we looked at really ran the gamut from fully fleshed out details to conceptual. And as a scientist I was wondering what role do you

play with the facility folks in the development of these grant applications in terms of putting together your wish list, if you will, and how do you get to convey to them your needs?

DR. BLUESTONE: I think just like your group is stitching -- composed of individuals from all sides, the patient advocates, the scientists and the real estate experts, the same thing has to be done in the institutions that are developing these things.

Simple things like how do the scientists bump into each other, the design of the facility makes that happen. Can you see down the hallway? Can you walk from lab to lab easily? Can you have shared spaces, common spaces, common equipment areas that facilitate interactions?

The successful buildings in science, and I've been involved in building a couple of them, the successful buildings are ones that have people bumping into each other. It's kinetic energy that exists when people are walking down a hall.

So if an institution hasn't spent a lot of time thinking about that, thinking not just about the bricks and the mortar and, you know, will it stand up in an earthquake in San Francisco and LA, but, rather, things about how the scientists day to day are going

to function in an aggressively interactive way, then they really haven't done their homework.

MS. HYSEN: The second question is and it goes back to institutions. What has been your experience in a university setting with building a large medical building and then having the industry gravitate toward you? Because we may be looking at areas where there is no industry and the very notion that a populated area might receive subsequent funding from us might drive industry there, and I was wondering if you have any experience when you've built facilities that industry has come to you.

DR. BLUESTONE: Yeah. This would be speaking beyond my expertise, but I think if you look at what's been going on at Mission Bay, which is the new UCSF campus, and the companies that have directly located right near UCSF to just be around that research, it's quite significant and it's growing.

So I think these high level academic research enterprises do attract. Look at Route 128 in Boston or look at the Genentech in the Bay Area, San Diego. It's very clear that good science is the place that venture capitalists want to be near, that companies want to be near because you can communicate, you can collaborate and you get your work force.

VICE CHAIRMAN SERRANO SEWELL: Thank you, Dr. Bluestone.

MR. SHEEHY: I had one more question and I'm sorry and not to keep you on the hot seat for too long.

DR. BLUESTONE: I enjoy this.

MR. SHEEHY: But this has been so helpful because you've really given us very concrete things that we can include to help us make decisions. And one of the things that you said that came up I had not thought about before, but in talking about the match I thought it was very interesting that you brought up the idea of industry contribution.

It might be -- you know, we're going to get -- when we get the match from an institution it's going to be -- it can be anything. Right? They come through. So in weighing the value of a contribution from an institution are there certain things that you as a researcher would prefer that the institutions put on the table as opposed to other things?

I don't want to get you in trouble.

DR. BLUESTONE: I'm probably already in trouble.

MR. SHEEHY: We do know there's going to be cash. Right? And it seems like that one thing that

we ought to value more highly than other things, one of your previous comments might be if they had gotten a collaboration contribution from an industry partner that showed interest from industry in participating in the development of the science.

Are there other things like that or other things specific to an -- you know, that are more from a researching point of view that we should look for when we're weighing these matches? Because this might actually be a very critical piece of our -- you know, how we evaluate these grants when we decide one is better than the other. Because it's really going to be the matches that we're going to have a qualitative as well as a -- we ought to look at the raw number, but if there's a quality thing we can put it in there, too. That would be extremely helpful.

DR. BLUESTONE: Are you talking about specifically with industry or in general?

MR. SHEEHY: Just in general. Because we already require 20 percent and so we're going to have a little bit of wobble. Some institution will give 30 and another might give 35, but within that 20 or 30 or 35 percent that they match it seems like an industry piece of that would be more valuable than just the straight -- you know, than a donor match, for

instance, because it reflects a certain direction to what the facility -- you know, towards the translational aspect of the facility.

Are there other things that they might put on the table in terms of a match that we should value more highly all things being equal?

DR. BLUESTONE: It gives me an opportunity to kind of raise a concern that I've had that -- that in general that if the only thing that drives this is money, if the only thing that drives who we elect as President in a race is the most money, if the only thing that drives who gets these buildings is who's got the biggest donor in their pocket, I think we will have lost something.

As the University of Chicago Gary Becker who's got the Nobel Prize, what he was able to do as an economics professor was determine how do you value things that are not easy economically to value. And the things that I think that needs to be valued in this besides the straight cash and the match are what -- what -- what added value you get because you have a training program, for instance, that's going to be near or at that facility that's going to train the next generation so you can amplify it.

The partnerships with industry I talk about

don't have to be cash. They can be industry working together by providing, you know, manpower. It can be providing in-kind equipment. It can be providing cutting edge opportunities to do things you can't otherwise do.

The other things that count as much as money, I think, are the academic excellence of an institution. Because, you know, the creativity doesn't always come by -- you can't buy it. It has to be there.

So I would hope that the committee would use the match as a way to encourage partnership in all those fronts, not just with money but also programmatic partnerships, evidence that they can, in fact, partner with clinicians, clinical researchers, industry, the educational arm because all of those are going to be as important to the success of the building as whether you get $20 or $150 million from a donor.

MS. SAMUELSON: I have another comment.

VICE CHAIRMAN SERRANO SEWELL: Sure.

MS. SAMUELSON: Dr. Bluestone, in thinking about -- you mentioned funding the small geographic areas.

DR. WRIGHT: Can you speak up a little?

MS. SAMUELSON: Sorry, Janet. You mentioned funding in small geographic areas and I'm assuming that you're saying "if we build it, they will come" or is it that actually geographically we need a geographic spread of these facilities for some other reason other than it will -- that spread will -- will encourage -- would-be scientists or scientists who would go to this field to get into that.

What is that about? And here's the other reason for it: Because it seems to me we want this proximity of the great minds in many disciplines to come together and -- and move the science and the results as fast as possible.

And it isn't necessarily clear to me that we have to do it in some community that doesn't have those resources right now. Because I don't care if my cure comes from one city or another obviously. Right?

DR. BLUESTONE: So -- so I'm not -- at the risk of sounding opinionated, I'm not a gigantic fan here of allocating based solely on some kind of a need for affirmative action. I think what you want to do is you want to get what you need done and you've got to find the right places to do it. But I think you need to keep track of the fact that, just as I said

earlier, you can't figure out which cell type is necessarily going to get the cure, so serendipity plays a part, I also don't think there are only three places in the world that can do this.

Creative innovative small places should have some seedability to try to do it. Now, how that's done geographically is not of concern here. It's if there's at least a small pocket of scientific excellence to build from.

When I referred to geographical proximity very parochially what I was saying is is that one of the things that can be great is, if you're in an academic institution that has a community hospital nearby, that has perhaps another institute nearby, that's got an engineering school nearby, that that facility will not just benefit because of the scientific excellence at the institution itself, but the geographical proximity of other institutions and other entities that can mix and match in applying that.

VICE CHAIRMAN SERRANO SEWELL: Thank you, Dr. Bluestone.

DR. BLUESTONE: I'm sorry.

VICE CHAIRMAN SERRANO SEWELL: I appreciate it.

Can you introduce the next speaker, Mr. Keller.

MR. KELLER: I'd now like to invite to the podium Dr. Irving Weissman from Stanford University who's the director of the Stanford Institute of Stem Cell Biology and Regenerative Medicine.

DR. WEISSMAN: Thank you and thank you for having me. Jennifer Corey is going to hand out a much longer version of my presentation than I hope takes here simply because I know I can't cover all the points in the depth that you desire because of the very brief time. We're starting the beginning of the clock now.

So I am Irv Weissman. I am Director of the Institute of Stem Cell Biology and Regenerative Medicine and also Director of the Comprehensive Cancer Center. And I am the entity the Peter principle was invented for.

I have been a stem cell scientist since the mid 1970s. We were fortunate enough to be the ones who developed the general method to isolate stem cells from tissues, blood-forming in mouse and man, brain-forming in man, muscle in mouse and so on.

We also -- in order to translate our research I have formed companies, cofounded companies,

SyStemix, to take advantage of the ability to develop a mouse that had a human blood-forming in an immune system both to test HIV, authenticate HIV taken from patients as the causative agent of AIDS and also eventually to isolate the human blood-forming stem cell. And that mouse model alone was sufficient for the FDA to allow us to do over 60 patients to give them back cancer free blood-forming stem cells after they had been treated with an otherwise lethal dose of chemotherapy and radiotherapy.

I've also cofounded a company, Stem Cells Inc., to take to the clinic human brain stem cells which we were lucky enough to isolate, three patients with a fatal pediatric neuro-degenerative disease now have those first human brain stem cell transplants in them.

That means -- not that I'm saying we're great. I'm just saying I have a lot of experience in trying to understand how a mouse experiment can be taken as fast as possible to humans and to know how to deal with the FDA and how to deal with your own institution, and, unfortunately or fortunately, why you have to form a company and maintain your own vision in that company to make sure it happens.

I was also head of the National Academy of

Sciences panel which looked at both human reproductive cloning, but much more importantly, the ability to make patient-specific pluripotent embryonic live stem cell lines by nuclear transfer or by other means and pushed through the notion that these were not just for the commercial enterprise of therapeutic cloning cells from you for you, but also to get patients who have genetic diseases, many of which you know, where for the first time you can have a cell line that makes every cell type in the body and then try to translate the idea that now that we know the genes that have gone wrong which cells are effective.

Because I can tell you we don't know in Parkinson's or Lou Gehrig's or Alzheimers, just to make an example, whether it is the neurons that have an intrinsic genetic defect of the genes that we are know that are involved or the supportive cells or the cells that project to it.

We don't know any of that and we won't know it until we can get human pluripotent stem cell lines that have the authentic disease and make it. So I'm going to be -- I'll try to move on a little bit.

I just want to say that we only have one goal and you only have one goal, and that's to advance -- build the facilities that advance stem cell research

so that we can understand, understand and treat human diseases.

You will be beset by all kinds of political and geographic and other issues. There will be issues of equality, but there's only one goal that you and the NIH should have, I think, and that is to advance medical science for the therapy of humans. All of us, of course, have been affected by the diseases and me and my family are just like them.

I want to remind you that stem cell research, as Bob Klein alluded to, is not just embryonic stem cell research. There are at least four kinds of stem cells that are important to understand, adult tissue-specific stem cells that regenerate our tissues and our body all the time, and it isn't until you do rigorous approaches to those stem cells that you find out that a blood-forming stem cell can regenerate the blood but nothing else no matter what you see in the papers, no matter what clinical trials you see.

A blood-forming stem cell makes blood. A brain-forming stem cell makes brain. A muscle-forming stem cell makes muscle.

Now, each of those stem cells have been isolated by actually my lab or my associates and we've been doing it for twenty years. It's slow. That's

why we wanted to be able to do human embryonic stem cell research where you have the beginning and the end of the process in a dish. You've got pluripotent stem cells, either patient specific or from the in vitro fertilization clinic. You've got heart cells. You've got brain cells.

Somewhere in between will be the stem cell. That's why we're doing it in my lab and that's why we're doing it at Stanford. We want to get those cells up, understand their properties, be able to understand how you can use them to treat and regenerate tissues. Of course, there are many other objectives to embryonic stem cell research or this nuclear transfer.

The one that was probably most unexpected and which we also have been deeply involved in is finding that cancers which derive from our own tissues have cells that have the properties that are similar to stem cells. There are in every cancer that we've looked at, cancer or leukemia or lymphoma or myeloma stem cells. They are rare cells within the tissue. They are the only cells in the cancer that has the property that normal stem cells have. When they divide they make at least one more copy of themselves, self-renewal.

The center of understanding self-renewal starting with embryonic stem cells or adult stem cells or cancer stem cell leads us to the fact that we use the same genetic pathways for self-renewal. It's not one pathway unfortunately. It's many pathways. But what we learn in embryonic stem cells applies to cancer stem cells and vice versa.

That's why you need to think about supporting at least some comprehensive stem cell facilities rather than a trick pony here and a trick pony there. I didn't mean to denigrate. I just want to let you know how I feel in case it hasn't happened.

So how do you pick? How do you pick the right places to put your investment in? Well, in my very long career of judging science there's only one thing when people have been out there doing science for seven years or more. It's track record.

Now, anybody can read our paper and see our hypothesis and make it sound better than we can even though they never did a thing in that field. Just to give you an example, when you go to buy a new car. You look in *Consumer Reports* for the reliability and the performance or do you read the ads or the TV?

You've got to go on track record. You will be fooled or people will try to fool you that are at

the leading edge of the field because they have other motivations to get into the field. That's not to say it would be exclusive as a field, but it means that we need and you need to be very careful that you find a rigorous successful scientist and people who know how to move things from the bench to the clinic.

Now, every stem cell that we've isolated, every cancer stem cell that we've isolated, we've proven what they are by putting them into the same organ of the immunodeficient mice. This is what Mike McCune and I started twenty years ago. That is, when we found a blood-forming stem cell it regenerated the blood-forming system of the tissues of the human in that mouse. When we got the brain-forming stem cells it regenerated the brain function or at least the brain cells and their migration.

And I'm only out of jail because Sam Brownback did not successfully pass the bill to send me to jail for doing those experiments, but we wouldn't have then treated those three kids with Batten's disease if we hadn't been able to show efficacy and safety first in a mouse model.

And why am I saying this to you? Because a huge component of facilities is a large barrier-sustained immunodeficient mouse facility. It

is absolutely required to have a stem cell facility and behind the barrier --

One minute? Okay. I'm going to really --

VICE CHAIRMAN SERRANO SEWELL: You have a couple more minutes.

DR. WEISSMAN: Thank you.

Behind the barrier you have to have the imaging because not only will you isolate, say, a human islet precursor cell, you want to know where does it go and how does it function without killing every mouse that you put it into. You want to have non-invasive imaging. That's a whole new field. You want to be able look is the breast cancer cell growing in the breast of the mouse and did my treatment stop its growth.

So you need, also, of course, I'll just say in passing compliance, oversight, QA, QC, all of the things that make a cancer center go. We have a comprehensive cancer center and that will make this go.

Now, at Stanford we have invested -- we have a facility off the main campus site about four miles away so that we could get people going way before -- actually, way before Prop 71 was passed. We have been building and spending and raising money, and I have an

agreement, which I hope you will help me enforce, with the university that all the money that we raise to renovate and lease that facility the university will pay back as part of its matching to build a new building which is right in the middle of campus.

That is the Stanford Institutes of Medicine. We will have both stem cell facilities of all four kinds of stem cells. We will have up to eight new hires or total hires in that area. We'll have up to eight hires in the cancer stem cell area.

We will have in addition to that probably the most important thing I can say to you are what we already established at our offsite facility, and those are hotel benches we call them where a clinician who treats a patient with that disease or isolates the cancer from the patient, who knows the disease, that physician and his or her fellow join with us on a bench.

And those are not benches owned by any particular scientist. They are benches for collaboration. I don't think collaboration works when it's at a distance. It has to work next door to each other. As Jeff Bluestone said, it's really how you meet with the people.

We'll have all the kind of facilities and

training that we've already outlined. We have something else at Stanford which has enabled a rapid advancement of our subject, and that is we have a bioengineering department that's right there in the medical school and buildings will be right next to it.

I know. Thank you.

And there are scientists like Steve Quake developed microfluidic machines so that we can analyze not a million cells to see how a particular gene got turned on and off, but one to 500 cells within nanoliter volumes.

I can't emphasize how important it is that's in the center of a campus that's got physics, engineering, chemistry, medicine and medical treatment.

So I'll just end by saying we're fully equipped and desire to move forward like many of you and we hope that this moves forward fast. We do, by the way, have raised all of our matched funds already and more than a 20 percent match.

VICE CHAIRMAN SERRANO SEWELL: Thank you, Doctor. I know that some of you have some questions or comments. Does anybody want to lead them off?

Joan?

MS. SAMUELSON: Yeah. Is there anything that we could add to our grant portfolio that would create the incentives for folks to work with at Stanford?

Here's what I'm getting at: Without prejudging our evaluation process, the Stanfords of this world are going to be competitive. There may be great ideas at places in remote locations without the full gamut of sophisticated scientists and across many disciplines.

How can we increase the likelihood that great ideas at those places or commitment to working in this field at those places would be advanced by coming and collaborating with Stanford?

DR. WEISSMAN: So there's two ways that I can think of, the first one we've already established. Those benches, those collaborative benches are not limited to Stanford.

MS. SAMUELSON: Right.

DR. WEISSMAN: So people will apply who are CIRM-funded at different places to come and use the CIRM-funded benches with us and, if our steering committee thinks it's good science and if there is a collaborator there, it will happen.

Second, and it's really critical, you better have a couple of meetings a year where all the fellows

within the facility as well as the lab chiefs meet and discuss and have a pure scientific meeting and have it over a couple days or three days so that people can talk about the new advances.

Now, I hate going to all these meetings that I do and I hate all the fundraising as well. But I'll tell you that even though I go to maybe six or eight stem cell meetings here that everybody is new on the thing, I always learn something new. This is a field that's moving incredibly fast. When we put on the very first stem cell meeting -- we did it in Taos, New Mexico about what? 15, 20 years ago -- we barely had 100 people. Now you have five, six thousand people applying to come to these meetings.

This is a moving field and it's moving around the world and, if we want to make sure we're at the head of it, we'll do not only our facilities and our grant programs but have at least two meetings a year.

MS. SAMUELSON: And speaking of around the world, what is the role of the scientists outside the borders of California in those meetings or in other collaborations?

DR. WEISSMAN: Of course, they come up with great ideas and great research. Yamanaka from Japan has pointed a way that now has been repeated by Rudy

Jaenisch and others that you might be able to -- certainly my labs can do nuclear transfer to get patient-specific or individual-specific genomes in a pluripotent stem cell line without any eggs.

Now, that would be a blessing if we didn't have to think about eggs and donors of eggs. It's not there yet that we're safe to say let's not do the eggs, but that came from a scientist thinking of a different way to do it in Japan, fully collaborative. He visited us three weeks ago to see how we were setting up our stem cell center so they could at least try to copy the organization of the stem cell center that takes it from science to medicine.

VICE CHAIRMAN SERRANO SEWELL: Jeff, did you have any questions or comments?

MR. SHEEHY: Yeah, I had a couple of questions.

The first one I may not -- it may be answered by Bob before I can get it to you, but I was intrigued by your talk about -- I'm wondering if personnel can be a match, does it have to be cash, buildings, and what you might think of that.

If, for instance, you were to hire several superstars and say that they are going to work at this building, is that a measurable match? That actually

might have more value in the larger scheme of things than cash. I mean, I'd rather have this gentleman from Japan decide to come work at Stanford and contribute to our effort than have a major --

DR. WEISSMAN: If you will help me find him and get him.

MR. SHEEHY: But just as general thing is that -- is that -- is that a -- as a match -- you know, because we're going to have in-kind matches of equipment. You know, we're going to have in-kind matches of bricks and mortar, to do personnel, you know, commitment to hiring new scientists.

MR. KLEIN: Well, I mean, just as a pragmatic information related to that, if we're going to reach the number of facilities suggested in our strategic plan, from a pragmatic viewpoint there's going to need to be 100 percent or more matches by another -- a number of institutions.

But once they get to the 100 percent match, you know, they could be the tipping point to have these great recruit commitments or dollars for these tremendous recruiting objectives set aside or reserved or committed by the institution. That's something we could discuss and hopefully get Dr. Chiu to comment on at some point, but it certainly creates a way to

competitively draw out the ability of our great institutions to recruit the best talent to California.

VICE CHAIRMAN SERRANO SEWELL: Maybe you could ask him. Did you have a question?

MR. KLEIN: But I would suggest, A, we've got to get to 100 percent of the matches on a lot of it and even go better than just to cover with our dollars the number of facilities being built. But once we get there as a deciding factor between different critical donations or the size of our commitments, it might be a tipping point kind of a decision. It's just -- it's up to the committee and the board, but it's a very interesting idea.

MR. SHEEHY: Because it seems like our rate-limiting thing may be four years out, that every scientist that can get a grant has got a grant in California.

DR. WEISSMAN: That would be wonderful. For those of us living off the NIH and watching our grants go one by one, it's -- it would be wonderful.

I'm not sure because I have no authority or knowledge about whether that would be considered a match, but I never thought that going out to the public and raising money for our effort would be as valuable as it has.

We have partners now, people who are fully invested and every time I want to go raise money I have a couple donors that want to go with me to demonstrate to the next donor that they can help raise money. This is -- even though, of course, they are high net worth donors who are very philanthropic they have an infection -- an infectious way of presenting why they decided to invest so much money in something that's not going to make a product, but it's going to help people.

It's very important to go through this process and they now understand clearly why we have such a high standard for the quality of the scientist that come in. Because you put money into second rate people, it's going to be second rate stuff that comes out. I hate to say it, but you have to be rigorous, you have to be straightforward, and you have to examine the qualities and the accomplishments of the people that are applying for the money.

VICE CHAIRMAN SERRANO SEWELL: Joan, is there a follow-up question?

DR. WRIGHT: I actually have one here when we have time to do it.

VICE CHAIRMAN SERRANO SEWELL: Sure.

MR. SHEEHY: And I think you are uniquely

placed to answer this question if there is a good answer. If there's some aspect that we can put into this facilities grant that would actually facilitate the development of new companies by researchers within -- is there some aspect that we might throw in? Because that might be one way to accelerate translation.

DR. WEISSMAN: Yeah. In a way I think you have already, but let me just try to make it clear.

As somebody -- I'll take off my Stanford hat -- who's been involved in trying to start and sustain companies that have such a long lead time before a product that believe in the venture capital -- the venture capital industry is not interested in funding.

So, as you probably know, venture capitalists are more like investment bankers. They say give me something that's in a phase 3 FDA trial for starters. Well, you know, that's about seven, eight years of work to get there.

So the most important thing you could do is to help universities and non-profit institutions at the beginning to take their work through a phase 1 trial if they have an approvable trial from their work.

That's the yes and no for that. You may decide that you want to provide incentives to industry to come work with us, but I've got to tell you. I've started companies, I'm still at Stanford, and every day I have to think about the conflict of interest and talk about it with my dean and with our conflict of interest officers. I'm very worried about the conflict situation.

So I think it's important for you to set up guidelines that are equally careful to make sure that we're not financing a personal profit for an investigator at an institution as a guideline, but what you're doing is trying to move it as fast as possible to the clinical trial phase.

MS. SAMUELSON: Does Janet want to go?

VICE CHAIRMAN SERRANO SEWELL: Yeah. I was going to -- unless you had a follow-up question, Jeff, I was going to go to Janet, Bob and Joan.

Janet?

DR. WRIGHT: Okay. Dr. Weissman, this is so helpful and I'm kind of pulling threads from things that Dr. Bluestone said and with you. I'd like to hear your thoughts about this.

Dr. Bluestone talked about the importance of designing the facilities to encourage scientists to

bump into one another and share their thoughts, Dr. Hall's water cooler science context. And you mentioned how critical it is for scientists to meet periodically, to get together, perhaps against their natures, and share things because this is a young science moving so quickly.

Then when Jeff talked about having personnel as matching, I'm wondering if we need to emphasize in the facilities RFA the importance of systematic connectivity, if you will, a mechanism by which scientists will be not coerced but intended to get together systematically and it's built into the way RFAs work or the ways their grant would be awarded. I'm wondering what your thoughts are about that.

DR. WEISSMAN: Sure. So I've been sitting with the Stanford architects, oh, now about eight months. And the architects all come in with these beautiful facilities that they've designed in the architect's mind that will promote interactions.

And we have -- I won't mention their names -- two relatively new buildings at Stanford that are just spectacularly beautiful, huge open space, no wall between the lab, supposed to promote interactions. And my fellows that are in those places say, "It's too distracting. It's too noisy. I can't even go and

talk to somebody or do my own work."

Another favorite plan of architects -- I'm not against architects. Please don't take anything personally -- is they like to say, well, we can save a lot of money if we put all the offices over here and all the labs over here. And so they remove the one person who needs to be in the lab every day, the person who's the leader of the lab.

And they think they are going to talk to the other people in the other offices, but we're all just shuffling paper. The only good thing that happens to us is when we're shuffling paper, when somebody in your lab bursts in because it's right there and says "I've got a surprising result."

So please don't let the architects have free rein. Ask scientists what it's like to work in a facility and try to advance the science.

Now, I said the "don't" part. The "do" part is interaction centers, you know, a place where you go have coffee. If you're -- if you have a cell sorter suite, a place where you can sit out there while your cells are being sorted and talk to the other people who are doing the experiments.

DR. WRIGHT: This is the scientific laundromat idea.

DR. WEISSMAN: Yes. And that's the right way to do it.

DR. WRIGHT: And what about having matching funds or what are qualified as matching the IT or whatever is necessary to create a network of scientists that will then communicate over this network in ways other than their biannual meeting or quarterly meeting?

DR. WEISSMAN: Well, you hit on a very important point and that is IT. How can you have a common IT system that the clinicians in the hospital use and the scientists use so they can share data? How can it be when you have a new machine that sorts cells or analyzes cells or follows intravital imaging that it's going to be common?

I think it is important that you pay attention to it and I think every lab person has to have at least a computer at a level that they can interact. I think you have to have streaming videos of the seminars that you had to miss because you were at the bench.

So all of these sorts of things help a lot.

VICE CHAIRMAN SERRANO SEWELL: Bob, did you have any questions?

MR. KLEIN: Yes, I did.

DR. WRIGHT: Thank you, Dr. Weissman.

MR. KLEIN: On your page 9 of your extended comment you say on facilities -- this is on point 11 in the bold: "Thus, facilities that bring together leading investigators in the fields of stem cell biology, bioengineering and cell imaging would naturally result in productive collaborations that would advance the goals of CIRM. Those interactions may occur between universities or within a single university or group."

And this is a very similar comment that Jeff got out of Dr. Bluestone earlier, and there is in the major facilities -- because we in our strategic plan have identified within the major facility categories the largest characterized facility as truly being a major center and then there is an intermediate center and eventually smaller centers.

The key here is -- is I'm taking your comments and Dr. Bluestone's comments that we have a high degree of interdisciplinary demand for knowledge and in broad teams that need to be available within the institutional structure for these major facilities, major centers.

And so if you bring together in quotes "center of excellence," that means it's been talked

about publicly bringing together three or four institutions in a center of excellence, they can aggregate all of these areas of specialization. And there are some institutions that because they've reach critical mass both in the number of investigators and then the two of them in one institution, they reach critical mass as well without aggregating with other institutions.

So where I'm going with this is I think to the point Jeff made earlier is that in our major centers within our grant category should we be requiring all of the cores that Dr. Bluestone articulated and other cores to get the real interdisciplinary capacity at one site to get the greatest productivity potential.

DR. WEISSMAN: I think you should require the grant applicant to outline what would be the best. I'll give you an example. I mean, I wanted to have every imaging possible for our facility and brought in our imaging expert Sam Gambhir who has built an MRI facility, magnetic resonance imaging for animals, and it's spectacular.

And it costs probably 6 or 8 million bucks and it has huge magnets that have to be shielded from the rest of us. He said bring your mice over to this

facility. But what you could duplicate is positron emission tomography or fluorescence analysis or intravital microscopy which you can stick a probe in and watch the living organism and the cell go through. There are a lot of those that are possible.

But I think you're going to learn a lot about the value of the people who are applying by what they say. Just don't prohibit. Right? Say come in with your most innovative ideas of how you're going to make it interact, but show us how to do it.

If you legislate it from the top, then everybody, of course, will have it in whether they need it or not.

MR. KLEIN: So if I can just finish it, imaging is critical. Let everyone figure out what their imaging solution is, but the other point that Dr. Bluestone made with Jeff was proximity is critical, where in their applications. We should probably ask them in their advocacy to explain the complementary resources they have that are proximate enough to really be of value.

DR. WEISSMAN: Absolutely. So that has to be there. You have to have at least mockups of plans, if not real plans, of how you're going to do it.

And I want to say again this concept of 30

benches per floor at least in our facility that are collaborative benches will overcome much of the problem that people might say, "Well, you know, there's this university and this non-profit and this non-profit. Why don't we built a great facility in between all of them but where nobody is close to their own home?"

Instead of that have the bench concept so people from one place can come and work in the other place for a while or have their fellows spend a year in the lab doing it.

VICE CHAIRMAN SERRANO SEWELL: Doctor, we have time for one more question, but I wanted to first ask Stuart or Joan if they had a question or a comment.

Stuart, do you have a question or a comment?

MR. LAFF: I more have a comment. As I was sitting here listening to both you and Dr. Bluestone, this is the way facilities are built in every discipline. The Rand Corporation in the '40s decided they were going to design their building by the number of chance encounters that were going to occur, and they absolutely did that.

They built a new building and now they have these breakout areas where these people can now get

together and have a cup of coffee or whatever they are doing and that's how they encounter. So it's pretty interesting to hear you say that.

VICE CHAIRMAN SERRANO SEWELL: Joan?

MS. SAMUELSON: Given that this is about funding facilities as opposed to grants and in terms of trying to keep the incentives to have the group pushing towards their results all the time, if you're gone for whatever reason, you move to Hawaii or get hit by a bus, whatever, what can we do with the funding of these facilities that will best insure that over the life of this enterprise until these things are cured the -- the same passion will remain there when we don't have the opportunity to continue in an RFA to ask for it?

DR. WEISSMAN: Well, all facilities have a natural life span. So that's one way unfortunately.

MS. SAMUELSON: I think we're too impatient to wait.

DR. WEISSMAN: Yes, I know. And I'm pretty impatient, too, to get it going.

I think that you'll find that I'm not the only one who's very passionate about translational medicine with stem cells at Stanford. I have a whole cohort of people and some of them actually can

administer things where I can't.

So I'm not worried about that. I think you could put into a plan that they have to nominate a successor to be the head of the facility or something like that and then you get to look at it, but it's not going to take back the facility. It might take -- well, there is an interesting issue.

A lot of the elements of a facility have ongoing warrant costs to keep the machines going. And so you might have some ongoing expenses that are built into the facility's application.

MS. SAMUELSON: And we might then build in some authority on our part to be, in essence, a collaborator, a partner in that building's enterprise?

DR. WEISSMAN: I'm not going to say anything that's going to get me in trouble with Stanford. This is all my personal opinion, by the way.

VICE CHAIRMAN SERRANO SEWELL: Thank you, Dr. Weissman. I think we've gone through that. I appreciate your comments.

MR. KELLER: I very much appreciate the fact that we had the written testimony as well and thank him for that.

Our next speaker is Dr. Lily Mirels from

University of California Berkeley, Special Assistant to Stem Cell Initiative from the Office of the Vice Chancellor for Research.

DR. MIRELS: Hello. Thank you very much for the Facilities Working Group and to CIRM for organizing this meeting. We greatly appreciate the opportunity to express our opinions an how CIRM can most effectively and efficiently support stem cell research.

Obviously I can't compete with Dr. Bluestone or Weissman in my expertise of stem cell research, but I encourage you from the perspective of someone with my background of working as an administrator not to forget the vital contributions of basic science to the success of this enterprise.

First certainly we want to have facilities where translation discoveries can take place. It's very important, but we have to be sure that we know what to translate. We need to have the basic discoveries that will bring, ultimately bring the successful cures.

Because we're a university without a medical school, we see our opportunities to contribute CIRM's goal of "turning into stem cells into cures" in these ways.

We'll build on our strengths in molecular, structural and developmental biology to understand the fundamental mechanisms of stem cell self-renewal and differentiation. And to this end we've just established a collaboration with a Canadian mouse regulome project to work out gene regulatory networks in a mouse and human embryonic stem cell differentiation.

We'll also build on our strengths in bioengineering to develop clinically useful products such as chemically synthesized extracellular supports for human stem cell differentiation. And we'll also continue to strengthen our collaboration with Children's Hospital and Research Center at Oakland to together contribute to the development of enhanced cures based on cord blood stem cells.

Now, how will Berkeley, how will this facility -- facilities RFA help working to achieve these goals? Well, Berkeley hopes to achieve our goals by providing improved facilities for stem cell searchers are who currently on campus, by recruitment of additional stem cell scientists and by creating an environment in which highly accomplished faculty members who have not to date worked on stem cell projects will be encouraged and to do so.

Facilities are crucial to this plan. Rather than establishing an isolated stem cell research facility, Berkeley has chosen to consolidate human embryonic stem cell research on campus, within multi-disciplinary communities of scientists. One such focus of stem cell research is the bioengineering/tissue engineering group, which you're familiar with in Stanley Hall because this was the subject of our previous shared research laboratory proposal.

The cornerstone of the campus's expanding stem cell biology program is a planned 200,000 square foot Li Ka-Shing Building. It will house a community of researchers in basic stem cell biology and gene expression, neurodegenerative diseases, cancer biology, computational biology and infectious disease, as well as bioethics and law, and stem cell center administrative offices.

But on this building it will be a mixed use building. So we will have one floor that will be dedicated entirely to human embryonic stem cell research and additionally one wing or the equivalent to one half of the cancer and neurobiology source will house stem cell researchers in this field.

And we think that this is a really great

approach because we're bringing in -- this will address, the Li Ka-Shing facility will address the campus's most pressing need, which is it will provide a greatly expanded capacity for human embryonic stem cell culture. This is necessary for derivation of new lines and growth of large volumes of cultured cells necessary for biochemical purification, and structural analysis. The facility will also provide much-needed space for recruitment of additional stem cell researchers.

And we really feel that it's particularly important to allow collaboration of these three different groups, our newly recruited scientists, our current stem cell scientists, and also scientists who are esteemed scientists in other fields whose work could easily be adapted or a new project started with the collaboration of their neighbors who are working on stem cell research.

You know, we have some examples of that now in bioengineering like Steve Connolly who is an expert in imaging and is now starting a project to track at very high resolution small numbers of human embryonic stem cells placed into living organisms and is starting to model them but eventually they will be produced for people.

And this is really because there is this connection with the bioengineering work and stem cell research currently at Berkeley and their conversations. We need to really applaud the idea of having a facility which brings together researchers in a way that they can interact, but it perhaps does create some complications.

You know, as an administrator I have some very simple, very sort of small issues relative to the large big picture of things that we've been talking about earlier in this discussion. And that is just in considering the suitability of our particular building for responding to a future -- a future RFA we have just simple simple questions.

For example, the building that's being newly constructed construction is starting in January 2008 and much of it is going to be done with donated funds. So the question -- one question is just a simple question when -- as the RFA is crafted.

What construction -- what aspects of the construction project actually have as a match. So, for example, it could be the foundation or the external core or the roof, could these be half of the donor contribution to that, is that calculated as part of the match? Or is that something for architectural

design or to fit out stem cell lab laboratories themselves?

Another example is both cancer cells. Our cancer floor and our neurobiology floor that will be one of two things. So half the space will be dedicated to cancer stem cells or to neural stem cells.

Now, would that count? You would count a wing that's dedicated to stem cell research as being part of a stem cell facility or is it disqualified because it's on a more general floor.

And so finally we believe that CIRM can best serve the goal of promoting stem cell research procurement by allowing institutions maximum flexibility in responding to their common needs and the opportunity to convince the Working Groups that these facilities are worthy of subsidies this way.

And I guess would I make a plug for the small highly motivated research group. I mean, these very large facilities that we're discussing are, of course, vital and provide an important role that we shouldn't forget of the importance of small motivated research groups making the initial discovery that will lead to the breakthrough that result in a cure.

Thank you.

VICE CHAIRMAN SERRANO SEWELL: Any comments or questions from members of the committee?

Deborah?

MS. HYSEN: When we looked at the smaller lab grant applications we had criteria and weighted it based upon our initial assessment of the reports for that criteria. As we go forward with these larger facilities we're going to have to be having that same conversation to see if that same weighting might apply.

My question to you because it -- I looked at one of the criteria and that was the ability to deliver on the project. And the background for that criteria is what is the history of the project team, what have they done before, was it on time, on budget, et cetera.

And I didn't get the sense in our review that we could tease that out. We couldn't really have a sense of that and as we go forward that's still going to be important to us because we want to know from an urgency standpoint that the team can deliver. And I was wondering from your perspective how do you think you can prove, if not Berkeley, per se, but how can an applicant improve or tell us more specifically how they can deliver their project in the time frames that

we would require?

DR. MIRELS: Well, to be honest I think my colleague Tom Ventresco could give a better answer than I to that. So I would ask that you --

MS. HYSEN: I think that's important because the criteria covers that on a couple of the criteria. So there's the ability, there's a timeline and that was just for -- I don't think -- maybe speaking for myself, but I don't think we got a really good sense from what we did receive that we can assess that properly.

DR. MIRELS: Might I invite Mr. Ventresco to speak?

VICE CHAIRMAN SERRANO SEWELL: Please.

MR. VENTRESCO: Good afternoon. I'm Tom Ventresco, Director of Space Management and Capital Programs at Berkeley.

You're asking an interesting question. It's always challenging for those of us on a campus that are charged with building new facilities how to keep our projects on time and on budget. At Berkeley we've had a similar experience as many other campuses have. In an academic environment there's always somewhat of a moving target in terms of what the scope of a project is.

In recent years we've implemented new processes to help control those types of factors that lead projects to go over budget and go over schedule. And I guess you would be right to ask for us to -- ask the applicants to indicate what kind of track record they have in delivering projects on budget and on schedule within the scope that they've identified in the project.

Beyond that --

MS. HYSEN: What if we were to say describe to us your processes to deliver these projects within a certain time frame?

For instance, I have expectations from the UC standpoint, and I know Berkeley is not here to speak for everyone, but they have the design build authority and they might leverage something like that to accelerate the construction process. And in looking at some of the submittals, for instance, I don't think that they leverage that.

And so one of the things that I was curious about is should we say what specific processes do you plan to use this time, what is your specific approach or plans to use at this time to give us the assurance that you have an accelerated path. Because we were saying eight months, nine months, seven months and I

don't think any of us got a real sense that that was, you know, a real schedule.

MR. VENTRESCO: Well, I don't want to speak for the other sister campuses in the system. Each one has their own set of processes they need to go through, but we do have flexibility to how we approach our projects. I can say at Berkeley we have and particularly for our stem -- our project that we're proposing for stem cell research a building that is already well under design.

We're planning on start doing construction on the basic building within the next eight months and then we're talking -- our plan is to implement internal completion of the building in various phases. And one of those phases would be, as Lily pointed out, completion of a floor for stem cell, partial floors for cancer -- excuse me, cancer research and neurobiology, neuroscience.

Part of those -- each phase could proceed independently according to our plan, but the other campuses may have, you know, their own approach to that and I think you should ask the applicants to just explain what their proposal is.

VICE CHAIRMAN SERRANO SEWELL: Bob?

MR. KLEIN: Yes, there's several interesting

points that have been brought up by this special presentation. One of them is, as I understand your point, you're going to finish different components of this 200,000 feet in different sequences. And it would seem to me that we're most interested in when our portion is finished.

So the fact that you choose to defer in finishing other portions shouldn't be of much importance to us so that we should be very focused on the critical path we ask for or, you know, when are we going to get some temporary certificates of occupancy on our portions because you may not be able to get a permit certificate of occupancy until the whole building is finished. So when are you going to get a temporary certificate of occupancy on our portion to get effective use of that space?

The other point is that you're going into construction in January, I mean, probably obviously in part to try to meet our two-year completion timetable because if you're in construction when we make our award really if we don't give you as much money you won't commit as much space to stem cell research because you won't have as much money for that use. But we're going to need to think about when costs start counting.

All of those costs are going to be audited anyway, but we certainly don't want to penalize people that are downstream and are taking a risk to get early -- early delivery.

But I had a question actually for your original speaker which was what other disciplines are in this 200,000 square feet? You named some, but I didn't catch all of the specialized contributing sectors that create the synergy.

DR. MIRELS: Well, I guess I could actually answer that, but there will be four floors of research science. So there's infectious disease. One floor that's purely dedicated to human embryonic stem cell research. Then there's a neurobiology floor which will have neural stem cells. And, also, the final floor will be cancer research again with half of the space dedicated to cancer stem cells.

And, in addition, there's a computational biology component and there are also on the ground floor, you know, unrelated to the CIRM-specific project but related to our university's mission of teaching there are lecture halls teaching and teaching laboratories on the ground floor. And then underneath the animal facility and an emerging facility for use of the researchers in the building.

MR. KLEIN: So you really have six floors?

DR. MIRELS: Right. Four with --

MR. KLEIN: Some below grade, for vivarium and imaging you have below grade facilities.

VICE CHAIRMAN SERRANO SEWELL: Jeff?

MR. SHEEHY: Yes. I had several questions. Is it even rational to consider putting out an RFA that would include Stanford, UCSF and you as potential applicants? They seem to be dramatic -- what you're describing has absolutely no comparison to what the two previous speakers were describing.

VICE CHAIRMAN SERRANO SEWELL: Is that a rhetorical question?

MR. SHEEHY: I'm just asking as an applicant --

VICE CHAIRMAN SERRANO SEWELL: The presenters are here at the request of the Institute --

MR. SHEEHY: No. But I'm just asking a question.

VICE CHAIRMAN SERRANO SEWELL: Let me finish. The presenters are here at the request of the Institute and staff to come and sort of give a thumbnail sketch and presentation to ask some general questions. I'm not sure if this is the right forum to get into your particular question.

We can amongst yourselves. I think that's entirely appropriate, but to throw that question at the presenter at this moment at this time would be taking them by surprise. Unless you -- if you're comfortable with answering it.

DR. MIRELS: No. I feel that -- I can give my opinion.

VICE CHAIRMAN SERRANO SEWELL: Absolutely. I don't want to stop you.

DR. MIRELS: I think that if the intent of the RFA is to create a translation facility, then it should be an RFA for a translation-only facility or a facility that's sort of bench-to-bedside facility, a comprehensive facility with all of these starting from basic science to -- to translational aspects.

I think that's really your choice as -- as -- you know, the CIRM as a whole and the Facilities Working Group specifically because if you feel that it's easier to assess people's proposals by doing such, that's reasonable. Or conversely I think it's also possible to say that the goal of the RFA or RFAs is to generate capacity to do top-notch human embryonic stem cell research and other forms of stem cell research in the State of California.

And we're open to the proposals of all comers

and I think so long as the RFA is broadly worded enough such that it's clear what is or is not considered responsive to the RFA, that would work as well.

VICE CHAIRMAN SERRANO SEWELL: Does that answer your question?

MR. SHEEHY: It does. I just -- I think that's more of a policy question for us that I've been posing, but I -- I'd also -- you know, so if you did not get funding from us, would you really build it smaller?

DR. MIRELS: Would we build it smaller?

MR. SHEEHY: Like your stem cell floors. Are those dependent on our funding? If we didn't fund you, what would happen to those floors?

DR. MIRELS: Well, that's a good question, of course, I can't answer alone. I think that the university has a strong commitment to stem cell research and it's certainly true that we wouldn't do zero, but it might set the timing, for example, because we might need to secure funding and we're -- some of the floors -- the infectious disease floor would be funded by the State of California.

So that's, you know, really not related to this, but the order in which the rest of the building

is completed depends on the needs of the university. And so if we're able in some way to -- to -- to get funding for other aspects of the building more quickly than for the stem cell research center, it would have to be put on hold and it would take us a little more slowly.

MR. VENTRESCO: Our intent is to have the most flexible design of the building to be able to respond to various research initiatives that are out there and in a very timely way.

So if stem cell research doesn't materialize, CIRM funding doesn't materialize with Berkeley, our researcher would, of course, seek other sources of funding to develop and then may be able to research. But, again, this building is built around basic science and instruction in those areas, the disciplines that we've mentioned, and it's a -- it's our intent to fill it out as the funding develops.

MR. SHEEHY: I just -- I mean, is it an anticipation of facilities funding that's driving this or anticipation of research funding?

Because research funding could put -- I mean, if you were getting research grants you would obviously want -- and you have been getting research grants. You would obviously want -- if you didn't

build out the space, you would probably -- you know, I can see in my mind centers of excellence, a great gigantic multi-disciplinary thing.

When you're talking about a major facility being a wing or a floor in an existing building and, you know, especially when we try to define what part of that is a match and what is not a match, it just seems to me really complex. But it seems to me that the institutions are going to make these more related to being able to really forcefully compete for research grants.

And the facilities grant would be great if you got it, but I don't -- I'm not -- I'm trying to figure out how materially that's going to approach your planning. Because if you don't build the research facilities, if you don't go ahead with your plan, you're not going to be able to compete for the research grants.

MR. LAFF: You don't have any place to research.

MR. VENTRESCO: That's correct. We definitely need the facilities to accomplish the research.

VICE CHAIRMAN SERRANO SEWELL: Bob, did you have a closing question?

MR. KLEIN: Yeah. Well, in terms of Jeff's comment, clearly we could come up with a policy that we want a certain portion of our funds to go into facilities that have the total breadth with clinical facilities there or adjacent to it and a great deal of -- of biotech interface to make sure we are really pushing the translational edge and we can fund other institutions we believe really can break through on those basic science issues who, by the way, might also be able to show a record of working with biotech in translational applications without the clinical presence.

So that might be an important presentation for them to make of what their history has been that they are getting to translational medicine without a clinical component. But the -- so if you have nine different facilities of different sizes, a basic science focus or two or three basic science-focused facilities might be a very important choice to fill out the whole breadth of what you need to address.

MR. SHEEHY: You know, I think I asked the other two speakers, they would say why would you build those nine, why don't you build the two to five true centers of excellence that are multi-disciplinary. And these others would come along getting funded

largely by their research grants and by their related research grants. So they have their own more organic flight path.

MR. KLEIN: Well, just from a funding viewpoint one of the -- it's a chicken and egg issue, which is that if you've got to have the research space to be able to generate the grant proposals and if there's no other funding source out there for the research space, you are rate limited by space so you can never get the volume of research grants generated that would then drive it.

And, by the way, if we get research grants from a facility that we've funded the space for, we don't pay for the space component in the -- in the overhead markup.

MR. SHEEHY: You know, we're talking about an institute -- I mean, not to --

VICE CHAIRMAN SERRANO SEWELL: It's a broader policy question for this Facilities Working Group to consider in their next meeting. Thank you to the both of you.

DR. MIRELS: Thank you.

VICE CHAIRMAN SERRANO SEWELL: I greatly appreciate it.

We want to hear now from the public. We'll

have a public comment now, but actually before that I want to take a two-minute break. Public comment on CIRM questions and issues will take up to three minutes per speaker. So we stand in recess for two minutes.

(Recess taken.)

VICE CHAIRMAN SERRANO SEWELL: We're reconvening the meeting of the Facilities Working Group.

At this time the Working Group would be interested in hearing testimony or comments from the public on what's just transpired and any other thing you'd like to opine on. We'll generally grant each person up to three minutes and people usually respect that. So we'll start with the first speaker. If you would please identify yourself before you start.

MR. REED: Don Reed, member of the public.

Two points. First, on the interaction issue, the University of California Irvine biology department, they made a decision when building it to try for limited walls and the scientists seemed to like it. The interaction is encouraged and it's easy to find out what everybody else is doing.

But as a teacher I once taught at a school which had no walls between the classrooms. It's an

Americanized school and there was so much communication going on between the students there was basically chaos. So I would go for a balance.

Secondly, to my layman's ear it sounded like there were three different approaches, if I understood you correctly. UCSD seemed to be more focused on embryonic. Stanford is more translational, which at this point would probably mean more adult stem cell research. Although Dr. Rene Pera joined them, it still seems more adult. And Berkeley seemed more basic.

I think each one of these is valid and to be -- I would hope that we would have all three to move forward. My personal preference is for Prop 71's initial goal to fund that which cannot be or is not likely to be funded on the federal level. So I would hope for the more basic and the more embryonic, but I think a balance of all three is valid.

Thank you.

VICE CHAIRMAN SERRANO SEWELL: Thank you, Don.

Any other member? Please.

MR. MARTIN: I'm David Martin. I'm from Children's Hospital Oakland Research Institute and I would just like to make a simple point in relation to

one of your core values, which is diversity, and I quote: "Empowering all Californians to contribute their ideas and insights to increase chances for success."

So we've heard a fair amount this afternoon about -- that would tend to suggest that the best strategy is to focus the resources on to what sounds like a very small number of spots.

So I would like to simply assert that it is likely that there are many much smaller institutions within California who could contribute if they were given the resources. And so I have a simple point to make in relation to the facilities grants, which is that if you want to give those institutions the chance to -- to build a facility and to contribute that you need to think about ways to make it easier for them to respond to the RFA.

And the -- one of the most important points I think is time, that you need to give them time to develop a plan in response to an RFA because many smaller institutions will not have the resources to do all of that planning and development before you produce your RFA.

And that's what I have to say.

VICE CHAIRMAN SERRANO SEWELL: Thank you.

MR. MARTIN: Questions?

MS. SAMUELSON: Yeah, I have one. Could you say a little bit more about why that diversity is important? I don't mean, you know, global good will. I mean practically speaking. Because I have an instinct that this is a real important point you're making.

MR. MARTIN: Well, I've been at large institutions and I have been at small institutions. So I happen to be at a rather small research institute at the moment. But what I understand very well is that the large institutions do not have a monopoly on the intelligent and productive scientists. So there will be many very good people at small places, but they do not have the infrastructure of administration to draw on if they want to build a new lab very soon.

So I think that if you -- if you -- I have always assumed that one of the intentions of CIRM was to draw people into stem cell research, to give people who might not otherwise do the things you want them to do the opportunity to do it. And presumably these facilities grants could be used as a tool to do that.

And it's more likely that, as opposed to some of these very comprehensive approaches that you've heard about this afternoon, the smaller institutions

will have more focused goals. But that does not mean that those things could not be very important contributors to the goals of CIRM.

VICE CHAIRMAN SERRANO SEWELL: Okay. Point well taken.

MR. KLEIN: I'd like just to say in reference to that, within the breadth of what we can consider in this RFA is that if -- for those who want to make small facility application, if they follow the suggestion of the speaker and made an advocacy of why they have a specialized area of expertise they can contribute, because they may have absolute cornered the specific area of expertise that is a critical link in developing therapies in some disease area or actually be closer to translational medicine in some specific disease area where they can make a convincing case of -- of a commanding expertise to deliver, I would certainly as one individual be open to looking at small grant to address that opportunity.

MS. HYSEN: Can I say something?

VICE CHAIRMAN SERRANO SEWELL: Certainly.

MS. HYSEN: Yeah. I think that that's the value of having the scientific group and the facilities group because from the facilities side we tend to look at it based on real estate criteria. And

the qualitative piece is how the real estate that you build translates into the programs that are performed in there and ultimately the cures that come out of that.

And we saw that our review from a facilities standpoint may be different than the scientists review of the same information. And I think that that's the balance because I -- we'd all be remiss if we didn't understand that there is something going on in that facility that we as real estate experts don't really understand.

And so I really appreciate the scientific piece balancing out what is -- at least from my standpoint a more critical analysis about the investment of the building and how that investment translates into satisfying the occupant's needs and goals.

VICE CHAIRMAN SERRANO SEWELL: Thank you.

Ma'am?

MS. HEINECKE: I'm Trudi Heinecke. I'm with the University of California Office of the President and have been doing capital and facilities planning for about 30 years particularly thinking about how you allocate scarce resources among competitors.

I think there is kind of a basic dilemma

here. I wanted to follow up on what this gentleman said. Those institutions that have resources, that have made stem cell research a priority, who are investing in personnel and equipment and program and need facilities to go to the next step have taken very seriously this aspect of urgency in trying to deliver within two years. And, therefore, most of the large institutions are quite far along on their plans.

And yet you're talking about setting criteria. They may have missed the boat because the criteria haven't been available earlier. And yet you have smaller institutions that don't have the administrative structure to invest and so are waiting to see can we find a niche somewhere.

And you may want to think about that. Someone else talked about -- I guess it was the gentleman from Stanford -- about not being overprescriptive in the types of facilities that you believe scientists need to do this work.

One of the issues and another way that you might think about it is you're buying capacity. Everybody wants CIRM to fund the capacity to do excellent science. And so rather than trying to define how you support that capacity in facilities in terms of square feet, because every institution has a

different approach, you might think about some kind of economy of scale or a critical mass in terms of numbers of researchers or something like that, a little different methodology that still gets you to an allocation where you're saying, you know, we think this facility will support 30 or 40 investigational teams, how do we want to support that versus a smaller facility which would support two or three teams, something like that as opposed to focusing on kind of the traditional ways of allocating money for facilities.

I do feel the need to talk about the fact that whereas in the shared research lab where you're doing renovations having a single measure of cost per square foot is relatively fair, but we have institutions whose costs are going to vary simply because of where they are located and if they have any open land to build on.

You could try and build the same building at UCSF and UC Riverside and it's always going to cost more in UCSF simply because where it's located. It's a very difficult site to build on. You have to have your workers bussed in from parking off the campus and so on. There are a lot of costs that are not under the control of the institution per se.

That's not to say we can't do cost-effective buildings, but I think you really need to recognize the difference in costs geographically and for other reasons. And, also, when an institution puts up another building there are a lot of choices about locations. Certainly in this instance people are trying to locate buildings where they are close to -- close to other scientific resources and so on. But there are other aspects of campus plans and environmental review and regents policies and all sorts of things that dictate the kind of building we can do.

And so I just wanted to have some ability in this process to recognize those differences.

VICE CHAIRMAN SERRANO SEWELL: Do you want to make a comment, Bob?

MR. KLEIN: I would just like to point out that in the locations, in the highly urbanized locations with the high building cost, there might also be a higher ability or greater ability to raise matching funds.

MS. HEINECKE: Yes.

MR. KLEIN: And those matching funds may go a long way to offsetting that cost disadvantage. In addition, there can be policy decisions and

discussions we're probably going to have to have on the issues that Jeff raised and issues like, you know, maybe if we have a policy with a priority for translational medicine that in a basic science building maybe there's a 2 to 1 match, you know, or a 3 to 1 match.

I mean, what are we buying and how much value we're getting and always making sure that the quality of the science is excellent.

VICE CHAIRMAN SERRANO SEWELL: Thank you.

Are there any other members of the public that wish to address the committee?

Seeing none, I want to thank everybody for attending. I hope it was as educational for you as I know it was for us.

Before I adjourn the meeting, though, if you'll indulge me in just giving committee members two minutes -- okay. A long two minutes, but it was a break, but two minutes on talking about these -- not going into detail these next three informational meetings because that's already been set, if you will, but, rather, Bob, at the beginning of the meeting you said there was rules, procedures, definitions.

At some point this Working Group is going to have to address those particular questions and they

need to be framed in such a way so the Working Group is prepared to digest them, share them with the public, share them with ourselves and have a really intelligible discussion at that public session.

So I just want to spend a couple of times on that. We've flagged a couple of interesting policy issues I know we'll want to revisit before we make our recommendation to the Working Group for the August meeting. What I've always felt is it's important to get as much of this stuff on the table now on the earlier side so that when we have our last two meetings there's enough time to have this discussion.

I hate to identify all the right issues and then have no time to discuss it because we do want to discuss it and do -- we will want to provide a recommendation to the ICOC. So I just wanted to throw that out there for just a couple of seconds because we're wrapping this meeting up and it won't go much past 6:00.

Bob?

MR. KLEIN: Well, in the continuum of issues needing to be addressed one of them that was addressed today was, you know, what's matching funds. We have heard that in our last facilities meeting.

VICE CHAIRMAN SERRANO SEWELL: The meeting

from day 1.

MR. KLEIN: It's important we get feedback from these institutions immediately because the extent that we give them a definition that's different from what they are working on they need some lead time to adjust. But, for example, in response to a question that was raised does the foundation count, does the roof count, from my perspective you spread those costs over the whole building and, if we have a third of the building, we have a third of those costs and they go into the match.

But we need to discuss that and get that on the table pretty soon at least in tentative language knowing it has to be confirmed by the ICOC. But these institutions need as quick a response as possible on these kind of issues. And I would hope in the next meeting we can try and inventory policy -- the high priority policy issues, rules, and definitions that need to be discussed and we systematically go through them so at least there's some preliminary feedback they get even though they are not going to be definitive until our final meeting.

VICE CHAIRMAN SERRANO SEWELL: Lori and Rick, does that seem reasonable? We've outlined a -- we've sort of identified a draft agenda for our next three

meetings.

MR. KELLER: I think we had posed the four questions with the idea of identifying some of the key issues and within the last one we were talking about the very specific areas of urgency, intervention and so forth that are part of our values.

I think that's where we're going to find more of the solutions, policy rules and definitions because that's -- that's where you have to do the policy, we have to understand how we make rules to implement that policy, and they have to be defined sufficiently that the applicants understand it with a lot of clarity.

VICE CHAIRMAN SERRANO SEWELL: Yeah.

MR. KLEIN: Well, I would suggest -- I mean, you're talking about raising this at the fourth meeting?

MR. KELLER: I'm saying that we're collecting all this across these meetings and having -- yeah, at the fourth meeting we would be in a position to give you a --

MR. KLEIN: I don't think we make -- I don't think we accomplish our purposes. I think -- just speaking as one individual member, I think we rigorously have to go through some of these definitions, rules and policies up front. We can go

through them -- we're going to go through them again in the final rule-making session, but unless we go through them up front and get some of these issues on the table we're not going to have the context for further refining them as we go and we're going to end up where we did on the shared lab space in not having adequate tangible definitions, rules and policies.

MS. HOFFMAN: Mr. Klein, we certainly agree with you, and the questions that Rick has just outlined for you were posted on our web site, made available to the public. As a matter of fact, Dr. Weissman addressed each one of those questions in his handout.

So I think that we are trying to get to those answers. At the fifth meeting, the July 12th meeting, hopefully that's where those Working Group members who have not attended many of these meetings will have a chance to refer to transcripts and then hopefully at that time you can all have this exchange.

We will have, of course, synthesized all the information, or perhaps at the end of each one of these meetings you can spend some time and talk about those definitions or policy issues that you would want to explore in the next meeting.

VICE CHAIRMAN SERRANO SEWELL: All right.

That might be.

MR. KLEIN: Well, let me then in that context --

VICE CHAIRMAN SERRANO SEWELL: Without losing focus of what we're talking about.

MR. KLEIN: Mr. Chairman, in that context was Lori's point about the end of this meeting. Is it possible that a couple of other facilities meeting members could at least give some, you know, feedback about what is matching funds, does the roof count, does the foundation count.

VICE CHAIRMAN SERRANO SEWELL: Yeah, sure.

MR. KLEIN: So at least there is some feedback in the question that's been specifically raised here.

VICE CHAIRMAN SERRANO SEWELL: Well, the 20 percent match question issue has been addressed from day 1, I think since the initiative passed from what I've heard anecdotally and just here. You know, "I think it means this," "I think it means that," and I know each one of us carry our own understanding of what we think it means. So there might be a baseline understanding sort of articulated here.

MR. KLEIN: At the least meeting we talked about it being cash, but they are saying if they spend

the cash on the roof and foundation it seems like it has to count because it's part of the whole --

VICE CHAIRMAN SERRANO SEWELL: Yeah. So are you asking is it okay for the committee members to provide their own -- a definition?

MR. KLEIN: As to their perspective on what counts as matching. Do all elements of the building and development processing including the architectural plans count if donor dollars go to -- go to those costs.

MS. HOFFMAN: I just would like for the Working Group to consider that there should be a definition for "match" and that we could also provide a definition for "leverage" because I know leverage is also very important.

VICE CHAIRMAN SERRANO SEWELL: Absolutely. I don't think we need to go through that exercise right now. I apologize.

MS. SAMUELSON: And it's just a little early. I mean, I'm educable on that, but I'm not sure I have an opinion on that. Well, I know I don't.

MR. KLEIN: Okay. Does anyone else have an opinion?

MS. HYSEN: Well, I don't know about the rules and regulations, but what I would like to gain

over the course of the next couple of hearings is a sense of how we build our criteria and how we value the criteria that we have to assess these applications because I think that's so important.

You know, we had -- I don't remember the criteria now, but did we actually give the weighting in advance to the applicants of the criteria and how they would be weighted?

MR. KELLER: No.

MS. HYSEN: So that's something I want to know, does that make sense to give the weighting of the criteria in advance and was our criteria appropriate and was the weight that we assigned to that criteria appropriate. So I would really like from my perspective to look at that because following some of the guidelines I probably weigh things differently than, you know, we saw when we really fleshed out what is the value of doing something timely.

There are going to be buildings that are in the process of being constructed right now and if we -- if we assign a high weight to that, and maybe we do, but if we assign a high weight to that, obviously the buildings under construction will have a higher value than the ones that haven't broken ground yet.

So those are the things I want to engage interest in.

MR. KELLER: Our plan is, so you know it, that the public information sessions will feed and have the opportunity for people to comment on those. In July when you meet and have a quorum and can act we'll present options here's -- here is the set of options that were discussed for, say, "match" or "leverage" or "urgency."

And part of that discussion can be then how do we put that in the context of a zero to 100 points in the RFA. All that then becomes a recommendation of this Working Group to the ICOC in terms of how they finally approve the issuance of that RFA.

VICE CHAIRMAN SERRANO SEWELL: That makes some sense.

MR. KLEIN: Yeah. The problem is unless we have -- we can't do it all in one day. So unless we schedule --

VICE CHAIRMAN SERRANO SEWELL: I hear what Rick is saying on match. What I hear Rick saying is, and correct me if I'm wrong, if misunderstood, but at the July meeting we'll have a quorum and that means the Working Group can officially take action. There will be a lot of things we will probably need to name

because it will be one of our few meetings where we'll have a quorum.

One of them will be to -- while I agree with you, Bob, it can't be the first time we talk about matching grants, but at that time we'll have to take action on matching grants.

MR. KLEIN: I agree completely. The issue is if we schedule in the next meeting a discussion on matching grants and leverage, two critical items, then we could start developing that and we'd get --

VICE CHAIRMAN SERRANO SEWELL: Begin that dialogue.

MR. KLEIN: We begin the dialogue. The public and the applicants could see where we're going. They could present information in the interim rather than waiting for the tail end for them to see anything and then all of a sudden we -- we've sprung on them an interpretation that they didn't really have time period to make contribution to point out the issues with.

VICE CHAIRMAN SERRANO SEWELL: Jeff, did you want to make a comment?

MR. SHEEHY: Well, I did. First of all, the specific point that was raised about -- you know, proportionality of a match over a building, they kind

of get some larger point that I think we ought to start to consider right now at least as part of our consideration either multiple grant rounds or tiered grant rounds. Because I do not accept as a match 30 percent of a building when I have 100 percent of the building to compare it to.

That doesn't -- that doesn't really -- you know, in some instances -- if we're talking about a building that's going to be a shared facility for stem cell research and that's competing with another shared facility for stem cell research, the proportionality makes sense.

But if you're talking about someone who is willing to build a totally dedicated building to stem cell research, then I would -- I would allow -- you know, and they say, well, 100 percent of our design costs are designing for stem cell research, so for 100 percent of that, that makes sense.

But I just get a little worried that we're spending a lot of time developing criteria and talking about grants when from the very first meeting that we're talking apples and oranges when we're looking at different institutions, and I don't know how we write that grant. At a minimum we should be thinking about a tiered grant because I do believe in diversity.

I think we should also start bringing up the idea of multiple grant rounds because this is the deficiency that the Grants Working Group has identified. There have -- especially as we get to the lower end. If we do decide to tier, and we are interested in building a capacity, spreading a little bit less money in a more -- in a less giant building fashion among more institutions so that more institutions can get their -- get into the game and then letting them come -- you know, putting out an RFA, letting people succeed, letting some people fail, giving the people that succeed -- that failed a chance to come back with an improved application so they get another shot.

What I see is one big round. Well, if the train -- well, the way the train is going is we're going to spend all this $220 million in one big round and let the best win, and I don't know if we really in terms of distributing this in the broadest possible fashion to create as much new activity as we can, if that's going to be successful.

VICE CHAIRMAN SERRANO SEWELL: Well, that point was well taken. However, let me say that the ICOC -- and I'm not speaking as a representative of the ICOC, I'm not their spokesperson. I'm the chair.

But it's my understanding at the meeting the ICOC's instructions to this Working Group and maybe we learned that's just not feasible. However, the expectation is that we will -- they granted as to the authority to have these hearings.

We will come back with a single set of recommendations for this $222 million RFA. It's sort of tiered, but that's where it ends. Their expectation, and I don't think I'm misrepresenting the ICOC, you know, based on the meeting we had in April in Sacramento was, you know, urgency is important, we need to move the ball forward. We don't want -- there's a need to -- for laboratory space. It's not happened because it's unmet need and so, therefore, we have to move with all great speed.

So anything that deters from that, I don't know what kind of reaction it will have on the ICOC.

Bob, you have a better grip on that one.

MR. KLEIN: We have diverse opinions there. But I think in terms of what Jeff is saying, we can come back with one RFA with recommendations on tiers. There's the centers of excellence and these are, you know, a major facility, but not a center of excellence. But these are small facility recommendations, but they are compelling areas of

critical science that are -- that are therapeutic advancement that can be addressed in small facilities. But you could have one RFA and one pool with different criteria for the different tiers that we're talking about.

VICE CHAIRMAN SERRANO SEWELL: Would we leave it -- we're getting way too far. Do we leave it up to the institution to decide what tier they wanted to apply?

MR. KLEIN: Yes.

MR. SHEEHY: I think a good example was the training grants where, you know, in an institution that was --

VICE CHAIRMAN SERRANO SEWELL: Yes.

MR. SHEEHY: Because every -- I just get nervous about putting out an RFA that only a few people can compete for. I think everybody who's doing -- who wants to do stem cell research in California should feel like that they can compete in some aspect for this RFA unless we're going to do multiple RFAs.

And so a tiered RFA would be -- we could even, if necessary, go as low as to do a shared lab. You know, we could go all the way from an expanded shared lab to a small facility to centers of

excellence. I mean, but everybody should get a fair shot of at least attempting to do stem cell research in California.

VICE CHAIRMAN SERRANO SEWELL: One last comment, and then Joan, and then we'll wrap it up.

MR. KLEIN: And, Jeff, in terms of your point, on an apples-to-apples basis, if you've got two floors of a 200,000 square foot facility and you've got -- or -- and you've got 80,000 square feet. So that 80,000 is -- you can -- if you proportionally allocate the roof and the foundation, it's the same construction cost as if you take an 80,000 square foot building that's all stem cell research and you have a real comparison on the square footage costs with the roof and foundation.

So you're going to get comparability and as long as you segregate out the area of the building that we could benefit from and only have it share that proportion of the structural system costs.

VICE CHAIRMAN SERRANO SEWELL: Thank you.

Joan?

MS. SAMUELSON: I'm thinking about something that's a little bit different and it might be handled with conditions or it maybe it's a separate RFA.

DR. WRIGHT: Joan, can you talk up just a

little bit?

MS. SAMUELSON: Sure. I'm thinking about the testimony from UC Berkeley and from the Children's Hospital of Oakland and our discussions after that. I'm wondering if there may be some opportunities that might be somewhat new. I know that medical history is full of examples where wonderful papers were published on a narrow scientific breakthrough that became obviously important to some specific disease or other -- curing it, treating it effectively, and it wasn't known at the time and decades in some cases went by when that information wasn't applied to anything.

I mean, here's Children's of Hospital of Oakland. It's right down the road from UC Berkeley. And it seems very possible to me that there are wonderful papers that are going to be published on some narrow aspect of stem cell science that might be enormously important to some disease that might be being treated at Children's Hospital.

If we could have those folks in the context of money for facilities of some sort one or both places, you're creating an incentive to get those minds together to think about it. Maybe that's pie in the sky, but my experience with these heartbreaking

examples of delay suggests that there's an opportunity there somewhere that could be worked on.

So I would certainly invite you folks and anyone else who has a thought about it to send your ideas along.

VICE CHAIRMAN SERRANO SEWELL: Thank you.

Janet, did you have any final comments? If not, we'll close the meeting.

DR. WRIGHT: No. Thanks, Dave.

VICE CHAIRMAN SERRANO SEWELL: Thank you, Janet.

And thank you, everyone else.

(Whereupon, the meeting was adjourned at 6:12 p.m. on May 31, 2007.)

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CERTIFICATE OF REPORTER

I, PETER TORREANO, a Certified Shorthand Reporter in and for the State of California, do hereby certify that the foregoing transcript of the proceedings before the Scientific and Medical Facilities Working Group of the Independent Citizens' Oversight Committee to the California Institute For Regenerative Medicine in the matter of its regular meeting on May 31, 2007 and held at the location indicated below

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was held as herein appears and that this is the original transcript thereof and that the statements that appear in this transcript were reported in stenotype by me and transcribed under my direction.

I certify that this transcript is a true and accurate record of the proceedings.

_____, 2007
DATE

_____
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