CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

M E M O R A N D U M

TO: **MEMBERS, CIRM GOVERNING BOARD**

FROM: BOB KLEIN

SUBJECT: **TIME COMMITMENT OF CHAIR**

DATE: MARCH 4, 2011

Dear Board Members,

A survey was conducted regarding Board members' perception of the amount of time required for the Chair to fulfill the functions set forth under the initiative and required to optimally advance the mission. I have heard a number of mis-characterizations of the results; and therefore, I would like to provide a chart specifically tied to the survey responses provided to the Board members. In reading the specific descriptions provided by the survey respondents, I would point out that I did not provide a response since I wanted to understand the distribution of positions without any influence from my vote. If I had voted, the time commitment would have been 80-100%, to fulfill critical functions that have permitted the agency to meet its performance objectives, within a dense thicket of overlapping laws.

Time Distribution

On close examination of the respondents, 11 respondents were in the categories comprising the responses from 50% to 100% time, with the distribution of those responses shown on the attached chart. Another two responses were in the category of "no more than 50%" time; one response was in the category of "20-50%;" and only two responses were in the category of "20%." I am therefore perplexed to hear that it has been represented to some individuals that the "majority" of responses were in the category that would be less than 50%. Clearly, I believe this is incorrect.

Empirical Data and Objectives

Frankly, I believe we should look at the empirical data on the historical time requirements and analyze the time requirements for the objectives that can be identified – either potential and/or essential – for the next 36 months to understand the potential time requirements. Finally, there are mission critical issues dealing with the timely and adequate funding of our grant cycles; implementing an effective public communications and information program; an optimized ability to understand and effectively meet our governmental and legal requirements and mitigate our risks; an ability to serve as Chair without direct or perceived conflicts, including associations and funding dependencies that could lead to the perception of influence; and, a clear dedication to patient advocacy, medical science and stem cell research specifically. For a more in-depth perspective on the Chair's roles in meeting those mission objectives, please see the memo

entitled "Role of the Chair" (attached), which I jointly developed with James Harrison and **released after the survey was conducted. I believe that we should analyze each candidate in terms of their capacity to contribute and to lead on these mission critical objectives; based upon our perception of the person's ability to add value, we should set the percentage of effort and the related compensation.**

Best Practices

Pursuant to our standards for best practices on transparency, this memo will be made available to the public. Joan Samuelson's email, already distributed to the Board, has already been made available to the public.

Bob

Recommended Time Commitment of Chair: Board Survey Results

20%-50%
(with 50% as the limit)

RESPONSE	NUMBER OF BOARD MEMBERS
20%	2
20-50%	1
No more than 50%	2

50%-100%

RESPONSE	NUMBER OF BOARD MEMBERS
50%	3
At least half time	1
Half to full time	1
60%	1
50-75%	1
80%	1
100% (Full time)	3

ROLE OF THE CHAIR OF CIRM'S GOVERNING BOARD

Given the completion of the Board survey, the Chair would like to provide a substantive, informational basis for discussion regarding the Chair's responsibilities and time requirements.

In addition to the statutory duties of the Chair relating to finance, public communications and government relations, the Chair also has oversight responsibility. Proposition 71 specifies that the Chair is responsible for supervising the agency's compliance with "public accountability requirements," including open meeting laws, the Public Records Act, conflict of interest laws and the APA (Administrative Procedure Act) regulatory process, as well as the Annual Report. In depth requirements are spelled out, in public communications for the Annual Report and for presentations to the Citizens' Financial Accountability Oversight Committee. Given the scrutiny under which CIRM operates, the Chair has taken great pains to ensure that the agency is in full compliance with these laws and requirements. These efforts include reviewing each agenda, monitoring the number of Board members who discuss a particular topic outside of a noticed meeting and reviewing responses to Public Records Act requests. The Chair has also taken a leadership role, in coordination with Board subcommittees and Board counsel, in negotiations with the Legislature to adopt policies to enhance the transparency and effectiveness of the Working Groups.

Due to the size of the Board and the expertise of its members, the Chair acts as a resource manager by recruiting the involvement and input of Board members in areas in which they have expertise.

As part of his responsibility to provide oversight, the Chair also reviews draft policies, reports, requests for applications and other materials before they are presented to the Board or made available to the public. By performing this function, the Chair ensures consistency with the Board's directions and with its communications and legislative strategy, and promotes efficiency by addressing areas of concern before the matter is presented to the Board or the public.

Below, we provide a brief summary, including examples, of the manner in which the Chair has carried out these responsibilities.

Process for Review of Applications

Under Proposition 71, the Board must make all funding decisions. Although Proposition 71 specifies that the Working Groups are purely advisory bodies and are therefore exempt from open meeting, conflict of interest and public

records laws; the Fair Political Practices Commission has suggested that it believes that the members of the working groups could become subject to the Political Reform Act, if over time, the Board routinely adopts the working groups' recommendations without making substantive changes. To ensure that the Board has access to substantive scientific and medical information necessary to make a decision regarding an application for funding, the Chair devised a system for evaluating confidential information in closed session.

Pursuant to this system, the Chair establishes several small groups of Board members, composed of qualified members (i.e., members who do not have a conflict of interest), drawn from each of the academic, industry and patient advocate categories, to review proprietary information in applications of interest to Board members. Each group then reports back to the Board regarding the information it has obtained, after members with an interest in the application at issue are excused from the room.

This system enhances the Board's ability to make well-informed decisions regarding applications and it demonstrates that the Board is exercising its authority to make final decisions. Indeed, on a number of occasions, the Board has modified the recommendations of the Working Groups, including the Grants Working Group, thereby demonstrating that the Board exercises its independent judgment.

Peer Review – the Chair as Bridge to the Board in Collaboration with the Vice Chairs of the Grants Working Group and the Patient Advocates

Under the design and structure of Proposition 71, the Chair -- in collaboration with the Grants Working Group Vice Chairs and the Patient Advocate members -- acts as a bridge between peer review and the Board. The Chair must -- by design -- attend every Grants Working Group meeting -- fully prepared -- and take extensive notes to understand the context and conflicting points of view that affect the viability of recommended grants and loans, as well as future, potential Extraordinary Petitions and the Scientific Staff's research of potential errors or contradictory positions. Follow-up with the President, the Chief Scientific Officer and/or (now) the VP for Clinical R&D is essential to properly schedule and run the Board meeting to consider recommendations. During peer review, the Chair may also be called upon to clarify Board policy and/or collaborations at/or between participating institutions and companies.

The Chair has been instrumental in: 1) establishing and conducting a process for the Board to review proprietary information contained in applications in closed sessions of the Board; and 2) preparing with the President, and/or Board members, for the discussion of Extraordinary Petitions and the peer review results.

Management of Board Agenda and Work Flow

The Chair is also responsible for managing the Board's work flow and agenda. Because the Board includes individuals with expertise in a variety of areas, the Chair serves as a resource manager, drawing upon the expertise of Board members to serve the agency in a variety of capacities, from leading the development of policies and programs, such as the loan program, to engaging in the agency's public communications efforts. For example, the Chair has drawn upon the expertise of Ed Penhoet, Duane Roth, Michael Goldberg and Ted Love to assist in developing CIRM's intellectual property and loan policies and to provide financial advice. Likewise, the Chair has drawn upon the communications expertise of members like Jeff Sheehy, Sherry Lansing, Leeza Gibbons and Floyd Bloom to develop or advance communications strategies. The Chair relied upon the technical expertise of Phil Pizzo and Ricardo Azziz to work through issues relating to the criteria for principal investigators. And the Chair requested that Marcy Feit and David Serrano Sewell lead the Board's effort to develop a research program to incorporate the California State University and Community College systems into CIRM's programs, leading to the adoption of the "Bridges" program.

Each program requires substantial development, before Board engagement. For example, the Chancellor of the State College System and the President of the Community Colleges system met with the Chair, initially, to request a system for access and participation of the broad-based student populations to advance technical education and /or the research experiences that might lead to a future Ph.D. candidate in the UC System. After workshops arranged first with Zack Hall and then Alan Trounson to study the issue, the Chairman brought the Chancellors and system President before the Board for a second presentation, and the Chair designated a Board task force (Marcy Feit and David Serrano Sewell) to work with the agency's Scientific Staff to generate an effective "Bridges" program for this important educational and human resource group.

Given the size of the Board, the Chair is also responsible for leading the effort to forge a collaborative culture between the scientific, medical, patient advocate and industry representatives.[1] As part of the Chair's efforts to build a collaborative, participatory leadership structure, he recruited 30 chairs and vice chairs, over six years, drawn from all of the Board's constituencies for the Working Groups, the subcommittees and task forces. Maintaining this collaborative culture is critical to CIRM's success. Proper communication, and

[1] Attached to this report is a summary of an analysis prepared by the Office of the Chair of Board voting patterns.

responding to the needs and ideas of the Board members and alternates, requires a substantial time commitment. The ideas and contributions of the Board members are a vital resource; to optimally access this resource demands a significant, constant time commitment by the Chair.

The Chair is also responsible for managing a highly productive and complex agenda with difficult challenges to retain quorums and to move through highly complex scientific, financial, ethical, legal, social and political issues month after month.

The Chair serves as a resource for problem solving, policy ideas and statutory and political structuring of proposals to solve policy challenges presented to task forces of the Board. In a support role, the Chair has been available to assist task forces like Dr. Azziz and Dr. Pizzo's task force on grant application limits and policies and Ted Love and Duane Roth's task force on the "California Supplier" definition.

In every board, subcommittee and Working Group meeting, the Chair provides continuous, "real time" legal guidance to the discussion, monitoring and suggesting phrasing and specific, descriptive wording that is consistent with the agency's litigation record and constitutional/statutory authority.

Policies

The Chair reviews draft policies to ensure that they are consistent with the Board's direction and are in compliance with the mandates of Proposition 71 and state law. These policies range from administrative policies such as the contract and travel policies to programmatic policies, such as the Major Facilities Grant Administration Policy and the Loan Administration Policy, to standards such as CIRM's Medical and Ethical Standards and Intellectual Property Standards. The complexity of these reviews generally requires the coordination of four or more external and internal legal perspectives to avoid esoteric state statutory and/or judicial conflicts, political sensitivities and/or financial and/or biotech industry impediments to implementation.

For example, when the Board approved its major facilities program, staff developed a Major Facilities Grants Administration Policy to guide the administration of the program. The Chair revised the proposed policy to ensure that it was consistent with the Board's direction, including the up-front payment alternative, and with Proposition 71. The Chair's review involved several rounds of revisions to the draft policy before it was presented to the Facilities Working Group, and then to the Board, for consideration and approval. These edits focused

on substantive issues, including the option for up-front funding of major facilities, as well as technical issues such as compliance with the California supplier regulation and the manner in which grant disbursements would be made under the two funding options (up-front and last-dollars-in). The Chair's detailed review of this policy ensured that the program met the Board's goals in designing the Major Facilities Grant program.

The Chair also played a lead role in working with staff and other Board Members to formulate CIRM's response to the National Institutes of Health's draft guidelines for human embryonic stem cell research. These efforts included forming a Board taskforce, reaching out to other stakeholders, including the Interstate Alliance for Stem Cell Research, and leading the conceptual development and structure of the Board's response with Dr. Geoff Lomax and Elona Baum, which ultimately led to CIRM's written response for submission to NIH.

Most recently, the Chair has taken the lead in developing, with staff, the multiple payback option as an alternative to warrant coverage. This included the review of several draft versions of the proposed policy and consultation with biotech stakeholders and five sources of legal/financial input before the Board's adoption of the policy in December 2010.

Reports

The Chair also reviews draft reports as part of his oversight function to ensure accuracy, consistency with CIRM's communications and legislative strategy and consistency with the Board's directives. These reports range from economic impact reports to the scientific strategic plan report to the Annual Report.

For example, the Chair spent a significant amount of time reviewing several iterations of two draft economic impact reports. One of the reports focuses on the direct and indirect impact of CIRM's research funding on California's economy, including tax revenues and employment as well as the development of biotech clusters; the other report examines the potential impact of a therapy to treat polycythemia vera, which arose in part out of CIRM-funded research. The Chair's review included an examination of the draft reports for technical accuracy and the strategic implications for participating companies, including those with publicly traded stock. These strategic, legal and financial considerations led to delaying one report until sufficient underlying documentation could be aggregated.

The economic impact report benefitted from research materials aggregated by the Office of the Chair and analysis confirming the reconciliation of

the report to conservative State of California job creation and revenue models of the legislative analyst. In addition, on a substantive level, the Chair worked with staff to ensure that the model used in the report was inclusive and highly predictive and that the report was well-vetted, internally and externally, before it was released.

The Chair has also been deeply involved in preparing reports, including reports to the Little Hoover Commission, the Legislature and Constitutional Officers, and to the Citizens' Financial Accountability Oversight Committee. For example, the Chair's Office compiled a detailed report of the activities of the Governing Board and the Office of the Chair for the External Advisory Panel, which released a complimentary and constructive report on CIRM's scientific progress, to educate the members of the panel regarding CIRM's structure, its policies, the role of the Board and the agency's programs. The Chair and the two Vice Chairs also made presentations to the panel.

Requests for Applications

The Chair also reviews draft Requests for Applications (RFAs). This review serves two goals: (1) it protects the Board against potential conflicts of interest by ensuring that the directions set forth in the RFA are consistent with state conflict of interest laws; (2) it ensures that the RFA is consistent with the concept plan approved by the Board and maximizes the agency's ability to fund the best scientific proposals. The Chair's office also consistently builds flexibility into RFAs to permit the President to accommodate a great scientific proposal that otherwise might inadvertently be barred by inflexible drafting of the RFAs.

To protect against conflicts of interest and to ensure compliance with legal requirements, the Chair and Board counsel review each RFA before it is posted. At the request of the Board, the Chair implemented this review to ensure that CIRM has a second level of protection against conflicts of interest. In 2007, CIRM issued a request for applications that required deans to provide letters of institutional support. As a result, several applications were disqualified to protect against a conflict of interest which could have led to penalties for the deans and a legal basis for the opposition to challenge the validity of the grants. The review by the Chair, the Chair's Counsel and Board Counsel also serves to ensure consistency between requests for applications and the related concept plan approved by the Board. This review includes both technical, legal compliance issues, as well as substantive issues such as whether the RFA includes requirements that could unnecessarily eliminate a promising application from consideration, as stated above.

Public Communications

The public (non-science focused) communications responsibilities of the Chair are extensive and diverse. For litigation, finance, governmental (executive branch), legislative (state and federal) and general Board policy issues, the Chair is called upon, on a weekly and sometimes daily basis, to communicate with press, institutions, governmental organizations and officials and many other entities regarding CIRM and stem cell research, generally. For example, when the Federal District Court of the District of Columbia issued an injunction preventing the National Institutes of Health from funding human embryonic stem cell research, the Chair immediately called a staff meeting to analyze the decision and develop CIRM's response. The decision, though damaging to the nation's stem cell research, constituted a stark reminder of the importance of stability in scientific funding and the critical role played by CIRM in the stem cell research field. The Chair's ability to quickly respond to issues like this, to coordinate with staff and Board members, as necessary, and to frame CIRM's response consistent with the agency's overall strategy and goals is critically important.

Major New Communications Time Commitment – Clinical Trials

Biomedical history from the era of the polio vaccine, to the Gelsinger Gene Therapy trials, to the AIDS clinical trial for Gilead's combination therapies, provide a consistent lesson in the importance of a complex, quick, scientifically accurate medical and patient advocacy message – coordinated with the biotech therapy developer – whenever a significant negative or positive clinical trial result is announced. The Chair has recently spent time over the last four months in discussions and obtaining high level support for CIRM's efforts to develop a coordinated public communications strategy to insure a real-time, highly informed scientifically and medically factual response to any negative announcement of clinical trial results, in coordination with the public validation of highly informed patient advocate leaders. The ISSCR leadership and industry leaders have been active in the preliminary design discussions for this effort.

Within the next 12 months, there may be 8-10 of these complex communications teams monitoring, in real time, the progress of CIRM-funded, FDA-approved, human clinical trials. The Chair's Office, the ISSCR leadership, Patient Advocacy leadership, the biotech company, and communications experts must be prepared to respond 24/7 with a highly articulated, objective and consistent message, to assure the public that the predictable, sensationalized news turbulence surrounding any negative clinical trial event should not derail vital medical progress, with appropriate safeguards. All public messaging (if any) directly delivered by the Chair's Office on negative events will proceed only after a sign-off by the President and the Vice President for Research and Development,

as well as the company to the extent possible. Scientific communications outside of the company will be delivered by independent scientists who are not associated with the trial and not a part of CIRM's scientific staff, to the degree possible.

Finance

The Chair is responsible for responding to requests from the Department of Finance and the State Treasurer relating to CIRM's bond funding needs. Since the fall of 2007, when the State was the first in the nation to publicly sell bonds to fund stem cell research, the State has issued $505 million in Build America Bonds (2009), and $161.545 million (2009) and $159.155 million (2010) in taxable bonds. These funds, in addition to the $45 million in bond anticipation notes, privately placed, during the litigation, have permitted CIRM to provide stable funding to its grantees and to assure CIRM's international collaborators that CIRM has the funds necessary to support joint research programs. The Chair's Office has been heavily involved in each of these bond sales, providing critical information to the Department of Finance and to the Treasurer's Office to justify CIRM's inclusion in the State's bond offerings among the State's other pressing needs. Each bond sale required CIRM to present detailed information regarding its current and future grant programs and expenditures. The Chair has coordinated closely with the Governor's Office, the Department of Finance, and along with Vice Chair Torres, with the State Treasurer's Office, on each of these bond sales.

Often, the requests for information require a very quick turnaround. For example, on February 9, 2010, the Department of Finance requested detailed information regarding CIRM's bond expenditures and future funding needs, with a response due by February 16th. Developing this response required the Chair's Office to obtain information regarding historical expenditures, the speed with which CIRM was distributing grant funds, and projections of the timing for future strategic requests for applications, including the anticipated timing of disbursements. In addition, the Department of Finance requested a detailed justification regarding CIRM's reserves. This effort required staff meetings, conference calls with the Department of Finance, and coordination with the President's Office regarding anticipated programs.

Finance – Philanthropy, Private Capital and International Matching Funds

The Chair's Office has been directly involved with interfacing, supporting and/or advocating for approximately $250 million of the $900 million in philanthropic and/or institution contributions, to date, to CIRM's mission. Separately, private capital sources, at the UC and/or biotech/pharma levels have sought authoritative support and assurances of California's commitment to this field to build a viable foundation for the base stability of this new field.

In excess of $100 million of new, private capital has entered California's stem cell research and therapy development efforts through these initiatives. Similarly, key leadership commitments and strategic international funding partnerships have led to $100 million in matching fund commitments, funding the world's leading international scientists and clinicians, partnering with California's CIRM-funded researchers. Initiating and sustaining the original funding commitments of the strategic leaders of this 10-nation scientific leverage for California's stem cell research has been a leadership initiative of the Chair's office.

CONCLUSION

This is not intended to be an exhaustive compendium of the Chair's duties and responsibilities, but rather is intended to offer concrete examples regarding the types of activities in which the Chair engages on a routine basis.