A "PLAN FOR A PLAN":

THE DEVELOPMENT OF A SCIENTIFIC STRATEGIC PLAN FOR THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

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PRINCIPLES OF THE PLAN

The development of the scientific strategic plan for the California Institute for Regenerative Medicine (CIRM) will be guided by the following principles:

- 1. *Science in the Service of Therapy*. The strategic plan should be solidly based in world-class science and clearly directed toward the development of therapies and diagnostics.
- 2. *A Working Plan*. In addition to overall goals and objectives, the strategic plan should provide a set of directions for action by proposing specific types of grant programs, setting priorities, developing approximate budgets and providing a coordinated timetable for scientific and clinical initiatives. The plan should give a detailed program of action for the first two years, with progressively more flexible plans for future years.
- 3. *Expert and Stakeholder Participation*. The plan will be developed in consultation with experts and stakeholders, including basic and clinical scientists, patient advocates, and representatives from non-profit research institutions, philanthropic institutions, the private sector and government.
- 4. *Transparency*. The development of the plan will be carried out in through a transparent process. One or more public meetings will be held and participant names and accounts of all meetings will be made available. Progress in development of the plan can be followed from the CIRM website.
- 5. *Fiscal Responsibility and Accountability.* The plan must ensure that CIRM public and private funds be used prudently and responsibly to maximize scientific and medical benefit. The plan will have built-in milestones by which to judge progress.
- 6. *A Living Plan*. The plan should have a built-in expectation that at periodic intervals, it will be reviewed, progress evaluated and strategies updated in response to new scientific opportunities or challenges.

PHASES OF PLAN DEVELOPMENT

The phases in the development of the scientific strategic plan for the CIRM will be as follows:

1. Preparation

- a. Define scientific mission and overall goals (ICOC)
- b. Develop project workplan
- c. Complete organizational and operational structure and assign roles
- d. Identify stakeholders (internal and external) to be interviewed and / or include in focus group or other meetings
- e. Develop an external web site for communication to / from the public

2. Data Gathering and Assessment

- a. Review results of Scientific Meeting (October, 2005)
- b. Develop interview templates
- c. Conduct internal and external interviews, including with ICOC members as appropriate
- d. Conduct focus groups and other meetings as appropriate
- e. Develop periodic information summaries from the interviews

3. Analysis: Identify and Organize Themes

- a. Analyze, compile, and summarize results of interviews, focus groups, and other meetings
- b. Identify possible focus areas for research
- c. Define short-term, medium-term and long-term strategic objectives and goals
- d. Prioritize and sequence ideas, suggestions and needs to meet goals and objectives
- e. Establish specific action steps needed to meet goals and objectives, including appropriate grants mechanisms
- f. Organize these action steps into a time line with specific milestones and success metrics
- g. Develop preliminary outline for the Plan

4. Development of the Scientific Strategic Plan

- a. Develop / refine the vision and mission statement for the Institute
- b. Develop annotated outline of the plan.
- c. Set proposed dates and budgets
- d. Describe grants mechanisms to be used and how they will achieve Institute objectives
- e. Develop detailed 2 year plan for RFAs based on the scientific strategic plan
- f. Present draft to ICOC and other stakeholders for comment
- g. Develop final draft of strategic plan

Role and Engagement of ICOC

<u>Overview</u>

- 1. Several ICOC members will be on Advisory Committee.
- 2. All ICOC members will be invited to one or more public meetings conducted by CIRM to discuss elements of the plan. Members of the public will also be welcome to attend and will be given time for comment.
- 3. Several ICOC members representing special expertise will be interviewed.
- 4. An update on progress, with opportunity for suggestions from ICOC members, will be presented at each ICOC meeting.
- 5. The draft plan will be presented for comments.
- 6. Adoption of the final plan, with modification as necessary, will be the responsibility of the ICOC.

Constraints Imposed by the Bagley-Keene Act

- 1. The ICOC has assigned responsibility for development of the plan to the CIRM President and staff. To maintain plan development as a CIRM function, rather than as an ICOC function, the ICOC as a body may make suggestions, but may not formally approve or direct the CIRM staff with respect to how the plan is developed.
- 2. Individual ICOC members may make suggestions at public meetings held by CIRM, or at the time updates are given at ICOC meetings. In addition, individual ICOC members may participate in committees or be interviewed, **BUT**
- 3. At the end of the process, the total number of ICOC members on the committee and those interviewed must be well below a quorum.
- 4. Approval and formal motions by the ICOC must be withheld until presentation of the final draft. At that time modification of the draft and / or redirection of the process are appropriate.

ORGANIZATIONAL STRUCTURE

The development of the CIRM scientific strategic plan will be organized and structured as follows:

Advisory Committee (will meet monthly):

Zach Hall, Chair Robert Klein, Chair of the ICOC Ed Penhoet, Vice-Chair of the ICOC Patient advocate(s) (TBN) Representative(s) from the private sector (TBN) Senior scientist(s) (TBN) Senior clinician(s) (TBN)

Function: To serve as advisors to the President of CIRM; the Advisory Committee will not have decision making authority.

Coordinating Committee (will meet weekly)

Zach Hall, Co-Chair Mary Maxon Arlene Chiu CIRM staff (TBN)

Staffed by the consultant, including senior partner

Function: To monitor scope and progress of the project; to approve procedures; to monitor and modify assignment of duties, as necessary; to propose changes in work plan or scope, as needed.

Daily Working Group (meets daily) CIRM scientific staff (TBN) Consultant staff (1-3 members, some part-time)

Function: To organize and perform interviews and meetings; to track and organize data for analysis; perform analysis; to keep records and the results of those analyses; to update public information.

Participation by the Public

- 1. The public can attend and make comments and suggestions at the meeting held for the ICOC.
- 2. The public can make comments and suggestions at the ICOC meetings after each update.
- 3. There will be a website to receive public comments and suggestions.