LOAN NARRATIVE - DISCUSSION MATERIALS

The following is intended as a tool to guide input and discussion regarding the parameters and elements of CIRM's Loan Program.

I. Preamble

Public-private partnerships involving research and development activities among industry, government, and universities can play an instrumental role in introducing key new technologies and valuable products to the commercial marketplace. Experience shows that partnerships involving government participation in research and development activities with industry, universities, and government laboratories can greatly facilitate the translation of basic research discoveries to products with societal benefits.

The mission of the CIRM is to foster and promote stem cell research with the aim of improving human health. A secondary goal is to strengthen California's biotechnology industry and create collateral economic benefits such as high-paying jobs and increased tax revenues. CIRM believes that the funding of commercial research organizations focused on stem cell-related projects is a key component to achieving the overall mission of the Institute. Increased interest by the commercial research sector in stem cell-related research projects and the successful translation of basic research discoveries into commercial products for public use are primary success indicators (among others) that can be used by CIRM to track benefits of commercial sector funding.

To achieve the goal of commercialization of stem cell research-related products, CIRM will fund non-profit and for-profit (commercial) research institutions in California via options that include grants and loans. As required by law, all CIRM-funded research activities must be conducted in the State of California.

II. Loan-Making Process

As with CIRM grants, CIRM loans will undergo a four-phase evaluation prior to funding, as described generally below. Loan disbursements will be made periodically based on achievement of milestones agreed upon in advance between the loan recipient and CIRM.

A. Request For Applications

The first step in the loan/grant process is a request for applications ("RFAs"). CIRM will specify in the RFA whether the applications are sought for a grant, a loan, or both, as well as the amounts available for each. For those applicants applying for a loan, a two-part application will be submitted. Part I of the application will describe the scientific research program that will be supported by the loan. This section is identical for both grant and loan applications. Loan applications will also submit a second part, titled "Business/Financial Feasibility Review." The purpose of this part is to provide basic information responsive to evaluative criteria to be adopted by the ICOC that will

indicate whether or not the applicant possesses the management and fiscal strength necessary to complete the research.

B. Preliminary Qualification Assessment – Initial Business/Financial Feasibility Review

After an application is submitted, Part II of the loan applications will be evaluated by CIRM staff, supported by appropriate outside consultants, to determine whether the applicant meets the financial and managerial requirements established by the ICOC. Part II of the application will consist of four primary components, much of which will consist of proprietary or confidential information that will be kept confidential by CIRM:

1. Background Evaluation: Principals of the applicant organization or its sponsor, including principal investigators and those charged with overseeing expenditures of CIRM loan funds, will undergo a review of their background to ensure no anomalies exist that would raise questions about the appropriateness of handling state funds.

2. Credit Evaluation (Dun & Bradstreet or similar credit report): This report is an informative, in-depth evaluation of a company's financial stability. This report combines D&B's proprietary statistical scoring with business, payment and financial information all in one report. The report should provide as complete an assessment as possible of both the current profile and future outlook for a company.

3. Litigation Assessment: Applicants will be asked to disclose and a background check will be made to identify current litigation, and risk of future litigation, that might create an obstacle to the research proposed.

4. Business Plan/Financial Feasibility: This section will address the applicant's resource and management capacity to perform. Applicants will describe the total budget necessary for achievement of the scientific aims of the research program, the contribution of CIRM funds toward the overall budget, and how the applicant has secured, or will secure, commitments to complete total funding for the specific program. Milestone payments may be conditioned on securing necessary gap funding.

CIRM staff will determine whether the applicant has met threshold criteria established by the ICOC for each element described above. If an applicant meets the threshold for each criterion, the application will be forwarded to The Scientific and Medical Research Funding Working Group (the "Grants Working Group," "GWG"), for a review as described below. If an applicant fails to meet any one of the criteria, **{Optional Language: Option A: [**the application will be returned and will not be

eligible for further consideration by the ICOC**] or Option B: [**the applicant will be given the opportunity to cure the defect(s) and resubmit the application if appropriate**]}**.

C. Scientific Grants Working Group Review

The third step is a confidential review by the Grants Working Group. The GWG consists of 15 basic and clinical scientists from institutions outside California, seven patient advocates who are members of the ICOC, and the Chair of the ICOC. The 15 scientists of the GWG will meet in closed session to evaluate Part One applications for the breadth and depth of the applicant's stem cell research program and the contribution of the CIRM loan to that program. The applications will be evaluated based on criteria established for that particular RFA by the ICOC. After the scientific reviewers of the GWG complete the scoring of each element applied for in each Part One application, the full membership of the GWG will conduct a programmatic review in closed session of all Part One applications. The GWG will recommend to the ICOC either that an applicant's program is meritorious in all the stem cell research elements for which it applied, in fewer than all the elements for which it applied, or in none of the elements for which it applied.

D. ICOC Review

The ICOC will conduct a thorough and independent review in open session of the applications and will consider the recommendations of the GWG, confidential and proprietary information supplied by the applicants, and an evaluation of this information vis a vis the goals and objectives of the RFA. The ICOC makes all final decisions whether to award a loan. The ICOC will consider confidential or proprietary information in closed session as permitted by law.

E. CIRM Loan Contracting

Loans by the CIRM will be conditioned upon achievement of agreed-upon milestones. If the ICOC approves an application for a loan, the CIRM will assign a coordinating officer from within the CIRM to work with outside consultants who are experts in the relevant therapy development to determine the particular milestones for payments under each loan. Once the final loan terms are reached and agreed upon, the loan will be funded accordingly.

III. Terms of Debt

The Task Force seeks input and specific terms that might comprise the following elements of the Loan:

- Debt Structure/Terms: E.g., five to seven years.
- Interest Rates: Adjusted per risk analysis and/or balancing feasibility and program goals.

- Subordination: Should CIRM loan be subordinate to bank, working capital lines, venture loans, et cetera?
- Security: What would be appropriate?
- Milestones: Appropriate benchmarks for payments over five to seven year term.

IV. Covenants

The Task Force seeks input about the propriety of including any of the following elements from CIRM's Intellectual Property policy for for-profit organizations:

- Access for Californians to CIRM-Funded Stem Cell Therapies: CIRM requires grant recipients to provide drugs and therapies at benchmark prices described in the California Discount Prescription Drug Program (CalRx) (or its equivalent) for:

    1. Individual Californians Participating in CalRx; and
    2. California Entities Purchasing Drugs and Therapies with Public Funds

- Access Plan at Market Launch for Uninsured Californians: Must provide an industry standard plan of access for uninsured Californians not otherwise covered by existing government programs (such as Medicare, Medical, CalRx, Veterans Administration, Health Families Program, AIDS Drug Assistance Program, Genetically Handicapped Persons' Program, California Children's Services Program, et cetera) or private insurance.

- Publication-Related Biomedical Materials Sharing: Requires sharing of materials for research purposes in California at cost where the organization publishes the discovery in a scientific paper, and where sharing the material does not conflict with the business model or otherwise create an onerous financial hardship, until such time as the material is broadly commercially available.

- Press-Release Requirements: Requires notification of CIRM in advance of press-releases referring to CIRM-funded research.

Would the following components of the for-profit policy be applicable in the context of the Loan Program?

- Requirements for Licensing to Third Parties: Preference for non-exclusive licenses; access and discount requirements attach to exclusive licensees.

- March-In Requirement: State may require issuance of licenses under specified unique circumstances – e.g., to alleviate health emergency.