ICOC LOAN TASK FORCE

DRAFT POLICY COMPONENTS

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. The goal of a loan program is to fund the translation of research into research tools, medical diagnostics and devices, and therapeutic products. These loans will be targeted at the funding gaps in product development that will serve to leverage participation by follow-on investors, such as venture capital and other capital markets, and result in more products that enter the market. For the state and CIRM, the advantage of a loan program versus a grant is the ability to recycle CIRM research funds, enlarging the return for each CIRM research dollar expended. In addition to loan principal and interest, loans may also feature warrant coverage, depending on the type of loan, which will constitution additional interest-based return on the investment in light of risk posed.

Early stage companies and not yet at the stage of commercialization would be the prime targets for a loan program in light of the lack of funding available in what is known as the "valley of death" for translational development of products. Established companies indicate a loan program would be valuable because there are more research and product development projects worthy of pursuit than can be funded with existing funds available to the companies.

II. Loan-Making Process

CIRM loans will undergo a four-phase evaluation prior to funding (and prior to a scientific merit evaluation by the Grants Working Group), as described generally below. Loan disbursements will be made based on achievement of milestones agreed upon in advance between the loan recipient and CIRM.

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

After an application is submitted, 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. This part 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. The report should provide as complete an assessment as possible of both the current profile and future outlook for a company. Established companies are more likely than new companies to have a D&B report.

3. Litigation Assessment: Applicants will be asked to disclose and a background check will be made to identify current or pending 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. The intent is to provide information responsive to evaluative criteria to be adopted by the ICOC that will indicate whether or not the applicant possesses necessary management and a credible plan to secure necessary follow-on capital to complete the research. Applicants will describe the total projected budget and timeline 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.

If an applicant fails to meet any one of the criteria, the applicant may be given the opportunity to cure the defect(s) and resubmit the application if appropriate.

B. CIRM Loan Milestones:

When appropriate, loans approved by the ICOC may be made in tranches, with each tranche 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 determine the achievement of the individual milestone. Once the milestone is deemed accomplished, the next tranche of the loan will be funded accordingly.

III. Terms of Debt

Loan contracts would contain the following elements:

A. Debt Structure/Terms: The goal of the Loan Program is to recycle research dollars to provide additional funding for new grants and loans. Terms must be structured to encourage repayment earlier rather than later, while ensuring that the capital structure imposed does not impede further capital financing. A goal of five to seven years for repayment.

Accelerated terms of payback would occur whenever there is a change of control of the company and any liquidity event, such as a M&A, out-licensing or IPO. In addition, the loan rates may increase with second-round financing or other large loans or infusions of cash.

B. Interest Rates: The rate would be adjusted per risk analysis and/or balancing feasibility and program goals. The rate might be a floating rate based on prime, such as Prime + X%, with interest accrued annually payable as a balloon upon maturity. See also "Security" below.

C. Subordination: Subordination of CIRM loans to other market and venture participation makes the project more attractive to a future lender and other downstream investors, which is critical to getting the therapy to market.

D. Warrant Coverage: The policy will encourage warrant coverage where possible. Warrants represent interest yield and premium for risk. The terms will depend on whether the loan is a non-recourse product loan, or whether the loan is a recourse loan which the company promises to repay regardless of the success or failure of the product. The warrants will be negotiable regardless of whether or not the loan ultimately is paid back. Warrant coverage will be based on the loan amount and tied where possible to the most recent valuation. (*Ranges to be discussed.*)

1. *Non-Recourse Loan*: In the event of non-recourse loan, CIRM will require warrant coverage of 50% - 100% of the loan amount (not to

exceed x% of the company). Thus, in the case of a $1 million loan, CIRM will acquire warrants worth $500,000 (50% of the loan amount) in the company.

2. *Recourse Loan*: Where a company agrees to guarantee the loan regardless of the success or failure of the product, CIRM will require a lesser amount of warrant coverage – 10-25% of the loan amount (not to exceed x% of the company), for instance.

In addition, where CIRM has made a non-recourse loan and the product fails or is abandoned and the IP is not pledged, CIRM may take ownership of the IP.

IV. Covenants

Loan contract would contain the following elements, derived from CIRM's Intellectual Property and Revenue Sharing Requirements 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.

- Funding for California Operations: Terms of the loan require that borrowed funds be expended for use in the State of California.