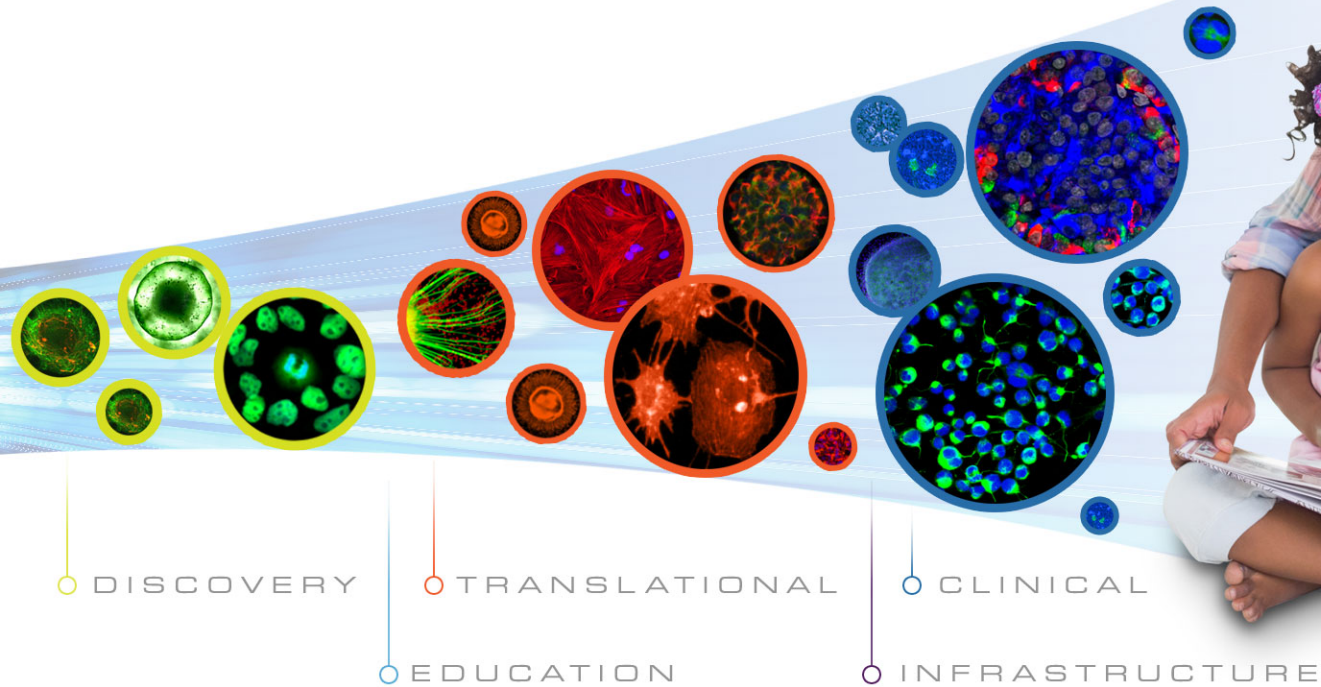


CIRM

CALIFORNIA'S STEM CELL AGENCY



Governing Board

Consideration of Loan Election Option

James Harrison

IP and Industry Subcommittee

- IP and Industry Subcommittee met on May 18, 2015, to consider loan election policy for Clinical Stage Program (PA 15-01, 15-02, and 15-03) awards.
- Unanimously recommended approval of proposed policy.

CIRM Loan Program – Background

- CIRM established loan program in 2009.
- Original aims included re-investing loan proceeds into new research programs and offering industry alternative to grant program.
- To date, CIRM has made five loans, two of which are outstanding.
- The Board has approved multiple amendments to the loan policy since 2009 to make it more attractive to industry.

CIRM Loans

Loan Number	Loanee	Status	Award Amount	Amount Disbursed	Amount Forgiven	Amount Repaid
TR2-01844	iPierian, Inc.	Forgiven	\$3,679,947	\$2,410,000	\$2,410,000	\$0
CT1-05168	Geron, Inc.	Repaid	\$24,846,856	\$6,405,771	\$0	\$6,459,170
DR1-01423	Viacyte, Inc.	Active	\$22,999,933	\$22,999,933	\$0	\$0
DR2A-05416	Stem Cells, Inc.	Forgiven	\$19,309,403	\$9,580,807	\$8,901,641	\$679,166
DR2A-05735	Capricor	Active	\$19,782,136	\$9,155,857	\$0	\$0

Evaluation of CIRM Loan Program

- Reviewed loan program in order to evaluate whether it should be maintained in light of goals of CIRM 2.0.
- Concluded that program, if modified, could serve goals of CIRM 2.0.

Proposal – Loan Election Policy

- Permit recipients of CIRM’s clinical stage project awards (PA-15-01, 15-02 and 15-03) to elect to treat their awards as loans within the earlier of submission of an application for marketing approval by the Food and Drug Administration or seven years from the effective date of the award.
- Require awardee to repay the loan balance within ten days of making the loan election, unless the parties agree to different terms.
- Set rate of repayment based on the date of repayment, and require higher rate the later the repayment occurs. (CIRM is in the process of gathering additional information in order to determine the appropriate rate of return.)

Proposal – Loan Election Policy

- Loan election would become final only after the awardee has satisfied the terms of the election.
- CIRM's access, pricing, and march-in rights regulations would continue to apply an awardee that elects loan option.

Advancing CIRM's Mission

Loan option would advance CIRM's mission to accelerate the delivery of stem cell therapies to patients with unmet medical needs in three ways:

1. Designed to encourage industry involvement in the commercialization of CIRM-funded inventions by offering an alternative to the traditional grant and loan options;
2. Creates an incentive for awardees to repay CIRM early, so that the agency could use the proceeds to make new research awards; and
3. Increases efficiency by eliminating complexity, reducing the administrative burden of negotiating separate loan agreements, and enforcing a separate administrative policy to cover loans.

Recommendation

Recommend approval of loan election policy for Clinical Stage Program awards and request that the Board delegate responsibility to the Intellectual Property and Industry Subcommittee to set the rate of return on an interim basis, pending final approval by the Board of the Grants Administration Policy for Clinical Stage Project Awards.