Accelerating the Development of Stem Cell Treatments: Clinical Stage Programs

The mission of CIRM is to accelerate stem cell treatments to patients with unmet medical needs. To better serve this mission, CIRM has overhauled the manner in which it does business, referred to as "CIRM 2.0." Under CIRM 2.0, CIRM has implemented a streamlined process for awarding and administering grants that allows frequent and predictable submission opportunities followed by rapid review, quick funding decisions, streamlined contracting and the prompt initiation of research. Post-award, CIRM has been an active partner with its recipients to further increase the probability of timely success.

Through the CIRM Clinical Stage Program, which was launched as the first CIRM 2.0 program, CIRM has expedited support for clinical stage candidate stem cell treatments that demonstrate scientific excellence. Under this initiative, CIRM has established an open call for proposals and accepts applications on a monthly basis for three complementary award types. CIRM provides funding for eligible projects that are completing late stage preclinical development through any stage of clinical trial activity.

CIRM 2.0 has resulted in dramatically increased timeliness and efficiency of funding high quality research projects and has significantly improved outcomes and milestone achievement of CIRM-funded projects. Given the urgency of CIRM's mission, CIRM is committed to constantly improving our programs to better serve and advance the mission. This concept plan further describes the three proposed Program Announcements listed below.

- **CLIN 1:** Funding Opportunity for Late Stage Preclinical Projects
- **CLIN 2:** Funding Opportunity for Clinical Trial Stage Projects
- **CLIN 3:** Partnering Opportunity for a Stem Cell Therapy Registration Clinical Trials~~Funding Opportunities for Supplemental Accelerating Activities~~

Given the open opportunity to apply and amend rejected applications, requests to appeal the outcome of a GWG review will be limited to demonstrable conflicts of interest as defined in the CIRM Grants Administration Policy.

~~REQUESTED~~ FUNDING ALLOCATION

CIRM will request funding for this program from the Board on an annual basis as part of the Board's consideration of CIRM's annual research budget.

~~CIRM requests up to $50M to cover issuance of awards across these three Program Announcements during the remainder of the 2014/2015 fiscal year.~~ The Indirect Cost rate will be set at 20% for not-for-profit institutions. For-profit applicants are not eligible for indirect costs. ~~There is no preset cap for individual awards. Instead e~~Each application will undergo a thorough independent budget review prior to review by the GWG.

ELIGIBILITY REVIEW

CIRM has the sole discretion to determine whether an applicant has satisfied the eligibility criteria for a program. With the exception of those criteria, identified with an asterisk in the CLIN program announcements, that are subjective and are subject to appeal to the Grants Working Group, CIRM may exercise its authority at any time before an award is executed.

CLIN 1: FUNDING OPPORTUNITY for LATE STAGE PRECLINICAL PROJECTS

OBJECTIVE

The objective of this funding opportunity is to complete late stage preclinical studies necessary to attain an active IND/IDE with the FDA and initiate start-up activities to prepare for a clinical trial for a stem cell-based therapy.

AWARD INFORMATION

What activities will CIRM fund?

CIRM funds will support the following activities under this opportunity:

- All activities necessary for the conduct and completion of preclinical studies that will enable the filing of a well-supported IND/IDE with the FDA for a clinical trial with a single therapeutic candidate
- Assay development
- Process development
- IND/IDE-enabling preclinical safety, efficacy, and toxicology studies
- Manufacturing to support IND/IDE-enabling studies
- cGMP manufacturing to supply the intended ~~Phase I~~ clinical trial(s)
- Clinical trial start-up activities

CIRM funds cannot be used to support the following activities under this opportunity:

- The conduct of a clinical trial beyond start-up activities
- Patient recruitment, screening, or enrollment
- Studies for therapeutic candidate discovery including lead optimization or lead candidate selection

How will funds be awarded?

Funds will be disbursed pursuant to a Notice of Award. Awardees may elect, upon completion of their award, to treat their award as a loan pursuant ~~-~~to CIRM's award conversion policy. (See CLIN Grants Administration Policy, Ch. IV(C).) Except for the first payment issued upon initiation of an award, payments will be disbursed upon completion of specific operational milestones. CIRM expects projects to advance rapidly and will not accept applications under this PA that propose more than ~~two years~~18 months to the planned filing of an IND or IDE~~of funding~~.

Award Cap

CLIN 1 awards are capped at a maximum of $6 million per award (non-profits) and $4 million per award (for-profits).

ELIGIBILITY

What types of projects are eligible for funding?

To be eligible, the proposed project must satisfy the following requirements:

(1) Must be ready to initiate work on the funded project within 45 days of approval

Given the urgency of CIRM's mission, all approved awardees must initiate work on the funded project within 45 days of approval and authorization for funding by the Application Review Subcommittee of the Independent Citizens' Oversight Committee.

Because of the open and ongoing nature of this Program Announcement, investigators should only apply when their program has reached the stage where all eligibility criteria are met.

(2) Must propose studies to support the filing of a single IND or IDE with a single stem cell-based therapeutic candidate

CIRM will support preclinical studies that enable a well-supported IND for a therapeutic candidate that is either:

- A cell therapy where stem or progenitor cells[1] (collectively, "stem cells") either ~~comprise~~ compose the therapy or are used to manufacture the cell therapy. Minimally manipulated bone marrow, minimally manipulated cord blood or unmodified hematopoietic stem cells (HSCs), are eligible **only if** being developed as a novel method of addressing a rare or unmet need unlikely to receive funding from other sources.
- A small molecule or biologic ~~that~~ **(i)** that acts on or is dependent on ~~that stimulates/recruits~~ endogenous stem cells ~~as the primary MOA~~ for its therapeutic effect~~repair/regeneration~~, ~~OR~~ that is dependent on~~specifically~~ targeting~~s~~ cancer stem cells for its therapeutic effect ~~as the primary MOA~~, that modifies a stem cell therapy, OR where a stem cell is necessary to manufacture the therapy, and **(ii)** is being developed for a rare or unmet need unlikely to receive funding from other sources.

[1] Under Proposition 71, progenitor cells are "multipotent or precursor cells that are partially differentiated, but retain the ability to divide and give rise to differentiated cells."

CIRM will support preclinical studies that enable an IDE filing for a medical device (including a diagnostic device) that is:

- A device where human stem or progenitor cells are a necessary component of ~~either compose~~ the device or are used to manufacture the device.
- A device intended for clinical use with human stem or progenitor cells where the stem or progenitor cell contributes to the therapeutic MOA of the combination product.
- A device intended to address a critical bottleneck to clinical development or use of a stem cell treatment AND where testing with a human stem or progenitor cell confirms the clinical safety and efficacy of the device.
- A device where the therapeutic MOA requires the recruitment or incorporation of an endogenous stem or progenitor cell.

(3) Must demonstrate appropriate stage of readiness

All projects developing a cell-based therapy, a combination product including a cell therapy component, or an eligible biologic product regulated through CBER must have completed a pre-IND meeting or equivalent ~~meeting~~ with the FDA ~~and have correspondence from the FDA confirming agreement with the IND-enabling preclinical plan~~.

All projects developing a medical device (including a diagnostic) must have completed a pre-IDE submission meeting or equivalent with the FDA ~~and have correspondence from the FDA confirming agreement with the IDE-enabling preclinical plan~~.

All projects developing an eligible small molecule or biologic candidate regulated through CDER must have selected a lead molecule and have already performed proof of concept studies and have pharmacokinetic/pharmacodynamic (PK/PD) data with that lead.

The proposed IND/IDE filing must be no more than 18 months from the project start date~~All projects, regardless of type, must be within 24 months of filing an IND/IDE with the FDA~~.

(4) Must include a project manager

The project team must include a Project Manager with experience in managing development programs and able to devote at least 75 percent effort to the project. This requirement may be satisfied through a contract with CIRM's Stem Cell Center to provide project management services.

(5) Co-funding requirements

CIRM will require for-profit applicants to co-fund at least 20% of the total allowable costs of the project. Non-profit applicants may provide co-funding but it is not required. The co-funding may come from any funding source arranged by the applicant. Documentation demonstrating the commitment of funds to cover the proposed co-funding amount must be provided by the application deadline (e.g., copy of executed term sheet showing amount of co-funding, conditions, and source).

(6) For-profit organizations must demonstrate solvency

For-profit organizations must provide documentation that shows 180 days cash on hand from date of application submission and the financial ability to meet the co-funding requirements for the term of the project. The determination of solvency will be made at CIRM's sole discretion.

(7) CIRM applicant must be the IND/IDE sponsor

The intended IND/IDE sponsor (i.e., the entity to be named as the sponsor on the IND or IDE application to the FDA) must be the CIRM applicant organization if an organization-sponsored IND/IDE or the CIRM PI if an investigator-sponsored IND/IDE.

(8) Application must be accurate and complete

All required components of the application must be completed and may not contain false or inaccurate information.

(9) Applicant must be in "good standing"

In order to be eligible to apply for CIRM funding, an applicant must certify that it is in good standing, as follows:

a. For-Profit and Non-Profit (in existence for less than five years):
(i) The applicant's Chief Executive Officer, Chief Financial Officer, and Principal Investigator must not have been convicted of, or currently under investigation for, crimes involving fraud/misappropriation; and
(ii) The applicant must have accounting systems in place that are capable of tracking CIRM funds.

b. All Applicants:
The Principal Investigator must not be currently under investigation for research misconduct by the applicant institution or a funding agency, and must not be currently debarred by HHS Office of Research Integrity.

Who can apply?

California Research Organizations

California Organizations (for-profit and non-profit) may use CIRM funds for eligible project costs incurred both in California and outside California. To qualify as a California organization, the organization must have >50% of its employees located in, and paid in, the state of California, and must direct and control~~conduct~~ the award activities from the California location.

Non-California Research Organizations

Non-California organizations may also apply; however, CIRM funding can be used only for allowable expenditures incurred within California, including the costs of a contract with CIRM's Stem Cell Center. The applicant must demonstrate by the application deadline a commitment of funds from other sources for project activities outside of California.

Who can serve as the Principal Investigator (PI)?

To be eligible, the PI must satisfy the following requirements:

- Must be an employee of the applicant organization or be accountable for the conduct of the proposed project to the applicant organization through a formal contract
- Must propose a level of effort on the project consistent with achieving the project's aims and not less than 15% on average over the project period~~commit at least 30 percent effort to working on the project~~ (note: "project" includes both the CIRM-funded and applicant co-funded components). Any effort for which salary from CIRM is claimed must be expended in California
- Must be authorized by the applicant organization to conduct the research and assume the responsibilities of the PI
- Must not currently have another application pending review or approval under this funding opportunity

SCHEDULE AND DEADLINES

Applications Due	5:00 pm (PDT/PST) on the last business day of each month
Grants Working Group (GWG) Review	Approximately 60 days post submission
ICOC Review and Approval	Approximately 90 days post submission

Award Start	Must start within 45 days of award approval (i.e., approximately 130 days post submission)

CLIN 2: FUNDING OPPORTUNITY for CLINICAL TRIAL STAGE PROJECTS

OBJECTIVE

The objective of this funding opportunity is to complete a clinical trial for a stem cell-based therapy that addresses an unmet medical need.

AWARD INFORMATION

What activities will CIRM fund?

CIRM funds will support the following activities under this opportunity:

- All activities necessary for the conduct and completion of a Phase 1, Phase 2 (limited to cell therapies), or Phase 3 (limited to cell therapies for pediatric or rare indications, e.g., FDA orphan drug designation) clinical trial with a single therapeutic candidate
- Manufacturing of product to supply the proposed clinical trial, including a follow on clinical trial, where practical
- Exploratory biomarker testing of samples from the clinical trial
- ~~Assay development (e.g. potency assay)~~In vivo or in vitro assays (e.g. assay development/ parallel in vivo product characterization or potency assays) to support the clinical trial or ongoing product development (as long as it is a component of the trial)
- Commercial development activities

CIRM funds cannot be used to support the following activities under this opportunity:

- Early research and translation for candidate discovery/selection
- ~~Formal comparability studies~~
- ~~Manufacturing or process development activities to support clinical trials other than the trial proposed in the application~~
- Studies to remove a clinical hold by the FDA

How will funds be awarded?

Funds will be disbursed pursuant to a Notice of Award. Awardees may elect, upon completion of their award, to treat their award as a loan pursuant to CIRM's award conversion policy. (See CLIN Grants Administration Policy, Ch. IV(C).) Except for the

first payment issued upon initiation of an award, payments will be disbursed upon completion of specific operational milestones.

Award Caps

CLIN 2 awards are capped at a maximum per award amount as follows:

(1) Phase 1 trial[2]: $5 million (for profits) and $9 million (non-profits)

(2) Phase 2 trial: $12 million[3]

(3) Phase 3 trial: $15 million

ELIGIBILITY

What types of projects are eligible for funding?

To be eligible, the proposed project must satisfy the following requirements:

(1) Must be ready to initiate work on the funded project within 45 days of approval

Given the urgency of CIRM's mission, all approved awardees must initiate work on the funded project within 45 days of approval and authorization for funding by the Application Review Subcommittee of the Independent Citizens' Oversight Committee.

Because of the open and ongoing nature of this Program Announcement, investigators should only apply when their program has reached the stage where all eligibility criteria are met.

(2) Must propose a single clinical trial using a stem cell-based therapy

CIRM will support the completion of a single clinical ~~Phase 1, Phase 2, or Phase 3~~ trial per award to~~. The trial must~~ test the safety and/or efficacy of a therapeutic candidate, as follows ~~that is either~~:

Phase 1 trial:

- A cell therapy where stem or progenitor cells either ~~comprise~~ compose the therapy or are used to manufacture the cell therapy. Minimally manipulated bone marrow, minimally manipulated cord blood or unmodified hematopoietic stem cells (HSCs),

[2] For purposes of a CLIN 2 award, a Phase 1 trial includes a Phase 1/2 trial, as described in the protocol agreed to by the Food and Drug Administration. Representations to the public concerning the trial, including the description of the trial on clinicaltrials.gov, must be consistent with the description of the trial included in the protocol and in the CIRM application .

[3] An applicant for funding for a phase 2 trial which FDA has indicated could be used as the basis for marketing approval may elect to apply as a phase 3 applicant for purposes of the award caps and co-funding requirements.

are eligible **only if** being developed as a novel method of addressing a rare or unmet need unlikely to receive funding from other sources.

- A small molecule or biologic ~~that~~ **(i)** that acts on or is dependent on ~~that stimulates/recruits~~ endogenous stem cells for its therapeutic effect~~as the primary MOA for repair/regeneration~~, that ~~OR~~ is dependent on ~~specifically~~ target~~ings~~ cancer stem cells for its therapeutic effect~~as the primary MOA~~, that modifies a stem cell product, OR where a stem cell is necessary to manufacture the therapy, and **(ii)** is being developed for a rare or unmet need unlikely to receive funding from other sources.

Phase 2 trial:

- A cell therapy where stem or progenitor cells either compose the therapy or are used to manufacture the cell therapy.

Phase 3 trial:

- A cell therapy where stem or progenitor cells either compose the therapy or are used to manufacture the cell therapy and where the therapy is for pediatric or rare indications (e.g., FDA orphan drug designation).

Device Trial:

Under an IDE, CIRM will support a feasibility trial of a medical device (including a diagnostic device), as follows:

- A device where human stem or progenitor cells are a necessary component of the device or are used to manufacture the device.
- A device intended for clinical use with human stem or progenitor cells where the stem or progenitor cell contributes to the therapeutic MOA of the combination product.
- A device intended to address a critical bottleneck to clinical development or use of a stem cell treatment AND where testing with a human stem or progenitor cell confirms the clinical safety and efficacy of the device.
- A device where the therapeutic MOA requires the recruitment or incorporation of an endogenous stem or progenitor cell.

(3) Must have regulatory approval to proceed with proposed trial

- ***All applicants*** must have an active IND/IDE for the proposed candidate in the proposed indication before applying (i.e. the IND/IDE has been filed with FDA for >30 days and ~~is not on clinical hold~~has approval to proceed with the proposed clinical protocol) . ~~Applicants for funding for a clinical trial to test a device must have an active Investigational Device Exemption (IDE).~~

- ***Phase 2 trial applicants*** must have Phase 1 safety data ~~supporting progression to Phase 2~~, obtained with the proposed candidate in an appropriate indication.
- ***Phase 3 trial applicants*** must have ~~compelling~~ Phase 2 data for the ~~same~~ proposed indication(s)~~., completed an End-of-Phase 2 meeting, and obtained FDA agreement on the trial design for Phase 3.~~

(4) Must include a project manager

The project team must include a Project Manager with experience in managing clinical development programs and able to devote at least 75 percent effort to the project. This requirement may be satisfied through a contract with CIRM's Stem Cell Center to provide project management services.

(5) Co-funding requirements

CIRM will require co-funding from the applicant as indicated below. The co-funding may come from any funding source arranged by the applicant. Applicants must commit at least the percentage of total project costs indicated below. Documentation demonstrating the commitment of funds to cover the proposed co-funding amount must be provided by the application deadline (e.g., copy of executed term sheet showing amount of co-funding, conditions, and source).

Minimum Percentage of Total Allowable Project Costs the Applicant Must Provide

Applicant Type	Phase 1	Phase 2	Phase 3
Non-profit	None	40%	50% ~~with CIRM contribution not to exceed $20M~~
For-profit	30%	40%	50% ~~with CIRM contribution not to exceed $20M~~

(6) Must adhere to requirements for clinical trial sites in California

Applicant organizations located outside of California must have at least one clinical site in California ~~and CIRM funding can only be used for costs incurred within the State~~.

California applicant organizations are expected to have clinical trial sites in California and must provide justification for inclusion of any sites located outside the State.

(7) For-profit organizations must demonstrate solvency

For-profit organizations must provide documentation that shows 180 days cash on hand from date of application submission and the financial ability to meet the co-funding requirements for the term of the project. The determination of solvency will be made at CIRM's sole discretion.

(8) CIRM applicant must be the IND/IDE sponsor

The IND/IDE sponsor (i.e., the entity named as the sponsor on the IND or IDE application to the FDA) must be the CIRM applicant organization if an organization-sponsored IND/IDE or the CIRM PI if an investigator-sponsored IND/IDE.

(9) Application must be accurate and complete

All required components of the application must be completed and may not contain false or inaccurate information.

(10) Applicant must be in "good standing"

In order to be eligible to apply for CIRM funding, an applicant must certify that it is in good standing, as follows:

a. For-Profit and Non-Profit (in existence for less than five years):

(i) The applicant's Chief Executive Officer, Chief Financial Officer, and Principal Investigator must not have been convicted of, or currently under investigation for, crimes involving fraud/misappropriation; and

(ii) The applicant must have accounting systems in place that are capable of tracking CIRM funds.

b. All Applicants:

The Principal Investigator must not be currently under investigation for research misconduct by the applicant institution or a funding agency, and must not be currently debarred by NIH Office of Research Integrity.

Who can apply?

California Research Organizations

California Organizations (for-profit and non-profit) may use CIRM funds for eligible project costs incurred both in California and outside California. To qualify as a California organization, the organization must have >50% of its employees located in, and paid in, the state of California, and must direct and control~~conduct~~ the award activities from the California location.

Non-California Research Organizations

Non-California organizations may also apply; however, CIRM funding can be used only for allowable expenditures incurred within California, including the pro rata share of costs incurred out-of-state to treat California clinical trial subjects. The applicant is expected to demonstrate by the application deadline a commitment of funds from other sources for project activities outside of California.

Who can serve as the Principal Investigator (PI)?

To be eligible, the PI must satisfy the following requirements:

- Must be an employee of the applicant organization or be accountable for the conduct of the proposed project to the applicant organization through a formal contract
- Must propose a percent effort consistent with achieving the project's aims and not less than 15% on average over the project period ~~commit at least 30 percent effort to working on the project~~ (note: "project" includes both the CIRM-funded and applicant co-funded components). Any effort for which salary from CIRM is claimed must be expended in California
- Must be authorized by the applicant organization to conduct the research and assume the responsibilities of the PI
- Must not currently have another application pending review or approval under this funding opportunity

SCHEDULE AND DEADLINES

Applications Due	5:00 pm (PDT/PST) on the last business day of each month
Grants Working Group (GWG) Review	Approximately 60 days post submission
ICOC Review and Approval	Approximately 90 days post submission
Award Start	Must start within 45 days of award approval (i.e., approximately 130 days post submission)

CLIN 3: PARTNERING OPPORTUNITY FOR A STEM CELL THERAPY REGISTRATION CLINICAL TRIAL~~FUNDING OPPORTUNITY for SUPPLEMENTAL ACCELERATING ACTIVITIES~~

OBJECTIVE

The objective of this funding opportunity is to- support new activities on active CIRM-funded projects that will, if successful, enable a sponsor to attain marketing approval of the proposed stem cell treatment with the Food and Drug Administration (FDA)~~support new activities on active CIRM-funded development projects that will significantly accelerate or increase the likelihood of success of the proposed therapy~~.

AWARD INFORMATION

What activities will CIRM fund?

CIRM funds will support the following activities under this opportunity:

- ~~Activities related to a single project objective~~ necessary to enable the non-registration trial covered by the parent award to directly to registration~~to accelerate an ongoing clinical trial that is currently funded by CIRM – NOTE: the application will only be considered for activities resulting in the trial being completed sooner than proposed under the original parent award.~~
- ~~Manufacturing improvements and optimization, or scale up to support later stage development~~
- ~~Nonclinical bridging studies to demonstrate comparability of product produced with an improved manufacturing process~~
- ~~Exploratory biomarker validation~~
- ~~Assay development (e.g. potency assay)~~
- New activities not ~~currently~~ being funded under a parent award (see below) that would enable the sponsor to conduct clinical activities that ~~would support~~are necessary for registration.

CIRM funds cannot be used to support the following activities under this opportunity:

- ~~The conduct of a new clinical trial~~
- Studies for therapeutic candidate discovery
- Specific activities already funded under the parent award
- Activities not necessary to obtain FDA marketing approval

- Activities occurring after attaining marketing approval

- ~~Activities approved for funding under the parent award~~

How will funds be awarded?

Funds will be disbursed pursuant to a Notice of Award. Awardees may elect to treat their award as a loan pursuant to CIRM's award conversion policy. (See CLIN Grants Administration Policy, Ch. IV(C).) Except for the first payment issued upon initiation of an award, payments will be disbursed upon completion of specific operational milestones.

Award Cap

CLIN 3 awards are capped at a maximum amount of $15 million per award.

ELIGIBILITY

What types of projects are eligible for funding?

To be eligible, the proposed project must satisfy the following requirements:

(1) Must be ready to initiate work on the new activities within 45 days of approval

Given the urgency of CIRM's mission, all approved awardees must initiate work on the funded new activities within 45 days of approval and authorization for funding by Application Review Subcommittee of the Independent Citizens' Oversight Committee.

Because of the open and ongoing nature of this Program Announcement, investigators should only apply when their program has reached the stage where all eligibility criteria are met.

(2) Must supplement an active, development, CIRM-funded project

The applicant must currently have an active CIRM-funded clinical trial award (such as a Disease Team Award, Strategic Partnership Award, or Clinical Trial Stage Award [CLIN2]).

(3) Must use the same therapeutic candidate as the parent CIRM-funded project

The new activities proposed must use the same stem cell therapeutic candidate as in the parent award and any process development or product improvements must be under the same IND.

(4) Co-funding requirements

CIRM will require all applicants to co-fund at the same level required for ~~the parent award~~a Phase 3 trial. The co-funding may come from any funding source arranged by the applicant. Documentation demonstrating the commitment of funds to cover the proposed co-funding amount must be provided by the application deadline (e.g., copy of executed term sheet showing amount of co-funding, conditions, and source).

(5) CIRM applicant must be the IND~~/IDE~~ sponsor

The IND~~/IDE~~ sponsor (i.e., the entity named as the sponsor on the IND ~~or IDE~~ application to the FDA) must be the CIRM applicant organization if an organization-sponsored IND~~/IDE~~ or the CIRM PI if an investigator-sponsored IND~~/IDE~~.

(6) Application must be accurate and complete

All required components of the application must be completed and may not contain false or inaccurate information.

(7) Limit to One CLIN3 Award Per Parent Award

An applicant is only eligible for a single CLIN3 award per parent award.

(8) FDA Concurrence

The applicant must present correspondence with the Food and Drug Administration confirming that the activities would ~~be appropriate for~~support registration.

(9) Applicant must be in "good standing"

In order to be eligible to apply for CIRM funding, an applicant must certify that it is in good standing, as follows:

a. For-Profit and Non-Profit (in existence for less than five years):

(i) The applicant's Chief Executive Officer, Chief Financial Officer, and Principal Investigator must not have been convicted of, or currently under investigation for, crimes involving fraud/misappropriation; and

(ii) The applicant must have accounting systems in place that are capable of tracking CIRM funds.

b. All Applicants:

The Principal Investigator must not be currently under investigation for research misconduct by the applicant institution or a funding agency, and must not be currently debarred by NIH Office of Research Integrity.

Who can apply?

Only CIRM grantees with an active CIRM-funded ~~development~~ clinical trial award (such as a Disease Team Award, Strategic Partnership Award, ~~Late Stage Preclinical Award [PA 15-01],~~ or Clinical Trial Stage Award [~~PA 15-0~~CLIN2]) can apply.

California Research Organizations

California Organizations (for-profit and non-profit) may use CIRM funds for eligible project costs incurred both in California and outside California. To qualify as a California organization, the organization must have >50% of its employees located in, and paid in, the state of California, and conduct the award activities from the California location.

Non-California Research Organizations

For non-California organizations, CIRM funding can be used only for allowable expenditures incurred within California, including the pro rata share of costs incurred out-of-state to treat California clinical trial subjects. The applicant is expected to demonstrate by the application deadline a commitment of funds from other sources for project activities outside of California.

Who can serve as the Principal Investigator (PI)?

To be eligible, the PI must satisfy the following requirements:

- Must be the same PI as the parent award
- Must not currently have another application pending review or approval under this funding opportunity

SCHEDULE AND DEADLINES

Applications Due	5:00 pm (PDT/PST) on the last business day of each month
Grants Working Group (GWG) Review	Approximately 60 days post submission
ICOC Review and Approval	Approximately 90 days post submission

Award Start	Must start within 45 days of award approval (i.e., approximately 130 days post submission)