DISC5 Awards Informational Webinar: Frequently Asked Questions (FAQ)

ADDITIONAL RESOURCES FOR APPLICANTS

- **The application form is available in the CIRM Grants Management Portal**
- **DISC5 Program Announcement (PA)**
- **Grants Administration Policy for Discovery, Translation, and Education Projects**
- **DISC5 Webinar can be found on our website**
- **Guide for AOOs**
- **CIRM's Our Review Process webpage**

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CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

PROGRAM SCOPE AND PROJECT ELIGIBILITY

Program scope and project eligibility are described in the 'Scope and Structure' and 'Eligibility' sections of the DISC5 PA. Eligibility is determined at CIRM staff's sole discretion.

For questions related to your specific project please reach out to discovery@cirm.ca.gov to arrange a consult with CIRM Science Officers. Note that a consult does not guarantee your submitted application will meet eligibility requirements, succeed in Merit Review, or be approved for funding.

1. What percentage of a DISC5 project must use stem cells, if any?

There is no specific percentage requirement for how much of a DISC5 proposal should use stem cells. However, purely genetic research unrelated to stem cell biology is **not in scope** unless it addresses a regenerative medicine bottleneck.

To be in scope (and therefore eligible for) DISC5, the project must

- Address a fundamental knowledge gap or bottleneck in stem cell biology and/or regenerative medicine;
- Meet one or more of the outcomes defined in the 'Scope of Structure' section of the PA (p 4-5); and
- Employ human stem cells and/or genetic research as part of the central approach or hypothesis (PA, p 6).

A consultation with CIRM Science Officers is strongly encouraged to align with the DISC5 scope.

2. Can a DISC5 application be focused on a specific disease/disorder?

Yes. While CIRM encourages submission of proposals that may lead to foundational insights applicable across multiple biological systems or indications, proposals can be focused on a single disease or disorder.

However, to meet eligibility requirements, disease-focused proposals must address **a knowledge gap or bottleneck in stem cell biology or regenerative medicine**, not solely disease mechanism. It's also important that your project focus on stem cell and/or genetic research and foundational discovery (not therapeutic development).

3. Does the DISC5 opportunity allow for discovery work using mouse models?

DISC5 awards should be centered on human biology and employ human-derived cells, tissue or data where possible. However, this requirement does not entirely preclude the use of animal models and/or systems as part of the project.

Importantly: if the plan involves studies using non stem cells or animal models, applicants must provide clear justification for any proposed use of non-human models; and include plans to validate such studies with a relevant human cell equivalent where possible.

Please note that studies involving human cells transplanted into animal models are considered to be studies of human cells/biology.

4. Are projects investigating cancer stem cells eligible?

Cancer stem cells are an eligible topic under DISC5. The definition of 'cancer stem cell' can vary widely and it is up to applicant to make the case to the reviewers that the cells under study indeed qualify as cancer stem cells.

5. Are mechanistic clinical trials, and/or prospective observational clinical studies, and/or biomarker studies allowable activities under the DISC5 mechanism?

The DISC5 program supports foundational disease biology research that may include reverse translational studies, including those using clinical samples or data, and basic research involving human subjects, provided the study is not subject to FDA oversight or regulation. Observational clinical studies or biomarker studies may be allowable as a component of a project if they are aimed at achieving the expected outcomes of a DISC5 award and all necessary consents and institutional approvals are obtained.

DISC5 **will NOT support** the conduct of clinical trials, whether interventional or mechanistic, that involve drugs, products, devices or other interventions subject to FDA oversight or regulation. Use of biosamples or data derived from such trials, however, would be allowable if all consents and approvals are in place.

6. Is gene therapy platform technology development eligible under DISC5?

Yes. DISC5 can support the development of gene therapy platform technology, provided:

- Studies are basic/discovery work on a scientific or technical bottleneck in gene therapy, not validation or optimization of a specific product.
- Human stem cells and/or genetic research are part of the central approach.
- The project does not include preclinical or clinical development activities that fall in the remit of CIRM's Preclinical Development (PDEV) program such as lead optimization, manufacturing, pre-clinical toxicology or pharmacology studies.

7. What is an acceptable level of risk ("blue-sky" research) that is practical for a DISC5 application?

The level of acceptable risk can vary, as reviewers evaluate both the potential impact and the feasibility of the proposal. Their assessment will depend on how they weigh these factors. Generally, reviewers may be open to higher-risk approaches when the potential impact is significant.

8. How much preliminary data are required for this type of proposal?

A specific amount of preliminary data is not prescribed, and the DISC5 Review criteria include Innovation and other elements to encourage Reviewers to support meritorious proposals that are "high risk high reward". Generally, reviewers will assess the extent to which the rationale and feasibility are supported by the body of available data (including published and any preliminary data) and incorporate this into their scoring (see Review Criterion 3, Rationale, pg. 12 of the PA). Where preliminary data are limited, reviewers will assess whether the knowledge to be gained justifies the investment of resources.

The strongest types of preliminary data tend to support the rationale for the project and/or the feasibility of executing the project in the three-year timeframe—including the qualifications of the applicant team to do so.

9. How is the scope of DISC5 different from Preclinical Development (PDEV) awards?

Preclinical Development (PDEV) awards fund preclinical studies for progressing a development candidate to an IND. To be eligible for funding, a PDEV project must have an identified candidate that is demonstrated to have disease-modifying activity.

A DISC5 project must address knowledge gaps or bottlenecks in the field of stem cell biology or regenerative medicine and achieve one of more of the four outcomes described in the 'Scope and Structure' section of the DISC5 PA. Whether a therapy or therapeutic approach will work for a disease indication is **not** a suitable research question for DISC5.

DISC5 **cannot** be used for demonstration of disease modifying activity, e.g., for the purpose of establishing eligibility for future PDEV funding. However, limited proof of concept studies may be included in order to validate new disease targets or biomarkers that have been identified through the funded project.

10. How is the scope of DISC5 different from CIRM's prior DISC0 and DISC2 programs?

DISC5 is similar to DISC0 (now closed) but structured and focused to meet the goals of CIRM's Strategic Allocation Framework (SAF).

- Both DISC0 and DISC5 projects must define and address a knowledge gap in stem cell biology or regenerative medicine; centrally employ stem cell or genetic research; and focus on human cells or tissues.
- DISC5 funds must be awarded to pairs of investigators – one PI and one Co-I – from different laboratories.
- The DISC5 PA more explicitly excludes projects that are directed towards a single therapy or therapeutic approach.
- Like CIRM's Preclinical (PDEV) and Clinical (CLIN) programs, the DISC5 Notice of Award (NOA) will establish clear aims/milestones, success criteria, and timelines for the project.

Demonstration of disease modifying activity was the remit of CIRM's DISC2 program (now closed), and may be incorporated into a separate, future program.

INDIVIDUAL,TEAM, AND ORGANIZATION ELIGIBILITY

11. Can a postdoc in a collaborating lab serve as Co-I?

This is institution-dependent and uncommon.

Co-I's must be accountable for the conduct of their portion of the proposed project to their organization and meet their organization's expectations for a PI (i.e., same level of authority and independence the organization requires to support an investigator as a PI).

See CIRM's Common Definitions and Requirements for more information CIRM's requirements for PIs and Co-Is.

12. Is a team comprising a PI and Co-I from two different departments at the same company eligible for DISC5 funding?

This is possible. We recommend including brief information describing the distinct departmental homes when consulting with CIRM staff for guidance prior to applying and within the Key Personnel section of the application. The departments should be distinct in expertise and approach.

13. Are there any citizenship requirements for applicants?

CIRM does not have any citizenship requirements for applicants, but we recommend checking with your institution(s) to confirm if they have any specific eligibility criteria of their own.

14. Can all team members be from industry, or are academic partners required?

All team members can be from for-profit organizations (industry). There is no requirement for the team to include academic team members.

15. What are the IP obligations if a California-based start-up company receives part of a grant?

All collaborators (including start-up companies) that receive CIRM funds and obtain ownership rights to inventions or data are subject to the CIRM IP Regulations, including revenue sharing obligations. Please see CIRM Regulations, *Chapter 6: Intellectual Property and Revenue Sharing Requirements for Non-Profit and For-Profit Grantees,* for more information. Email questions to legal@cirm.ca.gov.

16. Are there alternatives to a W-2 to demonstrate that the applicant organization is domiciled in California?

To qualify as a California organization, the company must employ and pay more than 50% of its employees in California. CIRM relies on W2s for verification. If you believe you meet CIRM's definition of CA organization but are unable to provide W2s, please contact legal@cirm.ca.gov for guidance. If your organization has no CA employees, you are not eligible for an award.

17. Can the project team include investigators outside of CA, or outside of the US?

Non-CA-based investigators are **not** eligible to serve as PIs or Co-Is on DISC5 awards, but can be Key Personnel. DISC5 applicants are allowed to budget grant funds to support a non-CA-based collaborator through a grant subcontract, provided the out-of-state organization **does not** retain the intellectual property or independent publication rights of any intellectual property (e.g., invention, technology, data) arising out of the CIRM-funded project.

BUDGET AND APPLICATION

18. Can I submit more than one application?

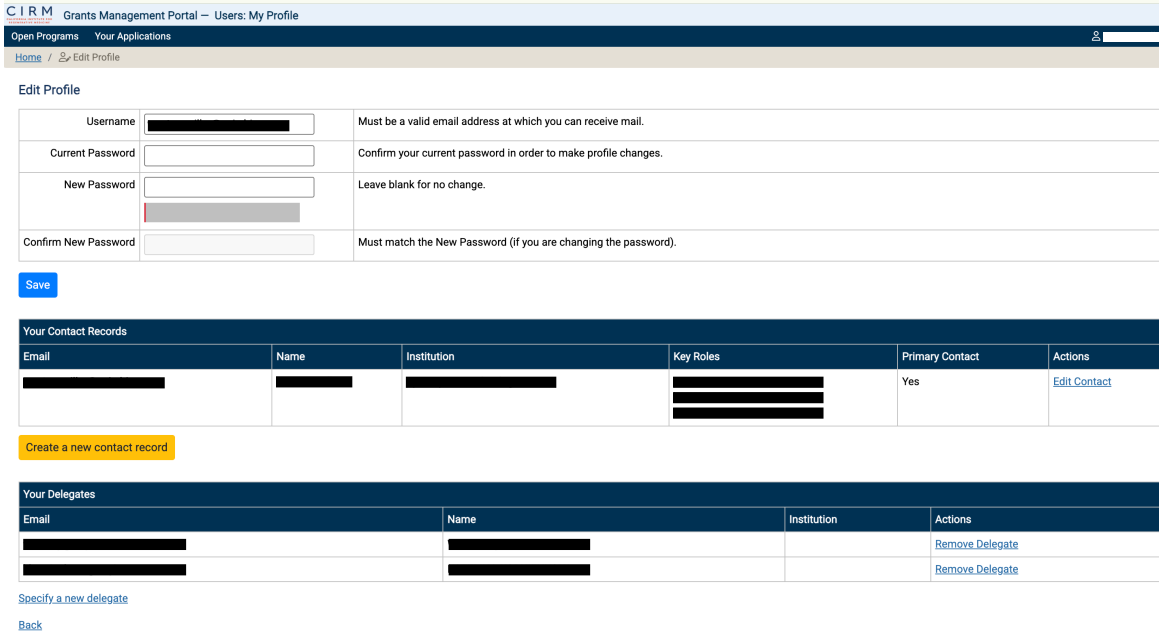
You may only submit one application as the Principal Investigator (PI) under the DISC5 funding opportunity.

An individual serving as the PI on one (1) DISC5 application may be a Co-I on **only one (1)** additional DISC5 application. An individual serving as a Co-I on one (1) DISC5 application may serve as a PI or Co-I on **only one (1)** additional DISC5 application.

In other words, an individual can be a core team member (PI or Co-I) on up to two (2) applications (up to 1 as PI).

19. Can I invite my Co-I and/or Project Manager into the Grants Management Portal to help complete the online sections? Or can only the PI enter information into the portal?

The applicant PI can delegate authority in the Grants Management Portal (including edit, complete, and submit privileges) to another user who has an account in the system. Once the new user's account is set up, the PI can delegate via their own "Edit Profile" link in the dropdown menu on the top right of their User Profile page. At the very bottom, "Specify a new delegate" and select the delegate by their name and email address.



20. Can a proposal have 2 subawards — one to the co-PI and one to a Key Person at a third Californian lab?

There is no limit to the amount of subawards (subcontracts) that can be included in a DISC5 award.

21. How do I determine whether CIRM considers a cost allowable?

When not otherwise specified by CIRM regulations, CIRM applies the Office of Management and Budget cost allocation principles including the determination of whether costs are 1) reasonable, 2) allocable, 3) consistently treated, and 4) adhering to any other limitations set forth by the PA/RFA or Notice of Grant Award. For more information, see the NIH Cost Principles. CIRM encourages grantees to use these cost principles to make their own determinations on cost allowability as CIRM cannot make a judgment on every cost scenario.

Allowable project expenses include, but are not restricted to: personnel salaries, fringe benefits, specified supplies, tuition and fees, research animal expenditures, consulting fees, itemized clinical study outlays (encompassing research patient care costs) subject to the Program Announcement limitation noted in Question 5, travel-related disbursements, project-related equipment, publication expenses, service agreements, subcontracts, and delineated administrative costs necessary for executing the endorsed project.

Please see the Grants Administration Policy and FAQ on Allowable Project Costs for more information.

22. How are indirect costs of subawards handled?

As stated in the PA, this CIRM Award is subject to a total award cost cap of allowable project costs, rather than a cap on direct costs. DISC5 proposal budgets should not exceed the maximum award amount, inclusive of direct and indirect costs.

Subawardees' (subcontractors') indirect costs must be included in the primary institution's direct cost budget.

23. Does the subcontractor need to follow CIRM's facility cost / indirect cost policy, or can they apply their own indirect cost rate?

Your subcontractor would include the full amount of overhead they are eligible for under CIRM regulations as part of their subcontract budget. The full cost of the subcontract budget (direct+ indirect) is entered in the primary budget as a direct cost. Our funding calculator will automatically exclude the amount of any subcontract over $25,000 from generating F&A to the primary applicant.

24. Do Key Personnel need to be listed if they will not receive CIRM grant salary?

Yes. If they are Key Personnel for the project per CIRM's definition, they must be listed in the Key Personnel section of the application even if they will not receive salary from the CIRM grant. Please see the definition of Key Personnel on pg. 6 of CIRM's Common Definitions and Requirements.Key Personnel can include trainees (graduate students, post docs), even if they are supported by an external fellowship or funding source.

25. How do early-stage startups with limited funding show solvency?

Historical cash flow records from the last 180 days need to be described and justified with verifiable proof (bank statements). If this is not possible, reach out to discovery@cirm.ca.gov and grantsmanagement@cirm.ca.gov for additional guidance as this may raise questions around overall institutional eligibility.

26. Will CIRM support funding if the project has already commenced?

For an ongoing project, you may only include costs incurred **after** the date of the CIRM board's approval of your application (approximately 150 days post application due date).

All approved awardees must initiate work on the funded project within 90 days of approval and authorization for funding by the board. The proposed project period must not exceed three (3) years from the award start date.

REVIEW PROCESS

27. Are applications unsolicited (is pre-approval required for submission)?

There is no pre-submission or pre-approval required or provided for submission of a DISC5 application.

28. What is the percentage of applications that go to the Merit Review? What is the funding success rate for applications that undergo Merit Review?

These percentages depend heavily on the number of applications submitted.

Based on historical data from all DISC reviews from 2017-2025, about 55% of applications undergo full Merit Review by the GWG and 12% (overall) are funded.

However, looking specifically at the most recent DISC0 Review (325 eligible applications), 24% of applications were fully reviewed by the GWG and 7% (overall) were funded. We expect the upcoming DISC5 competition to have a similarly large number of submissions and similar outcomes.

Note that these numbers are descriptive, not policy.

29. Are there any preference topics or preferred research areas for DISC5?

There are no specific topic or disease area preferences for DISC5. Proposals are evaluated based on their significance, innovation, project plan and design, and population impact (the five review criteria on pg. 12 of the PA). The review will be competitive as a high volume of diverse projects is expected.

30. Are matching funds, a collaboration, or other support from a non-profit patient organization considered an advantage for DISC5?

Relationships with patient organizations that support or inform the integration of patient perspectives into the development of the project are encouraged under DISC5. Reviewers consider the benefits of such partnerships as part of review criterion 5, Population Impact (see pg. 12 in the PA).

Reviewers may also consider whether the patient organization's involvement brings other added value to the project by, for example, increasing the potential for impact (review criterion 1) or improving the project plan or feasibility (review criterion 4).

DATA SHARING AND MANAGEMENT

31. When are project data expected to be shared and how are proprietary/IP aspects protected for biotech companies?

All applicable data generated under CIRM DISC awards must be shared no later than the time of publication or by the end of the award period, whichever comes first. Applicant organizations are free to file for IP protection.

32. Does DISC5 support efforts for system digitalization and/or AI/ML collaborations?

Yes, AI/ML approaches or other computational components of projects are allowable, and requesting funds to support activities associated with these aims is allowed, including local data management, digitalization, and computing resources directly allocable to the project. You may also budget for funds to enable data sharing and collaboration.

Please note that institutional computing resources that are typically covered under indirect costs (e.g., university-wide servers, shared computing infrastructure) should not be included in the direct cost budget. However, project-specific computing needs, such as dedicated hardware, software licenses, or cloud services directly supporting the proposed work, may be budgeted as direct costs.

33. Does GEO suffice for data sharing requirements?

If data are appropriate for GEO, then yes. That's a great example of a database for sharing data with the scientific community.

But if sequence data need to be deposited in a restricted access database, or if data types not accepted by GEO are generated, different databases need to be selected.

CONTACT AND OTHER RESOURCES

34. How can we get in touch with the Shared Resource Labs?

To find information about CIRM Shared Resources Labs for Stem Cell-based Modeling, go to the CIRM website, and navigate –> For Researchers -> Shared Resources Laboratories. There, you will find links to SRL websites (which include contact information) and a link to SRL catalogs (SRL Research Offerings, CIRM-Supported Courses) with relevant links to SRL websites.

You can also contact ugrieshammer@cirm.ca.gov if you have questions.

35. What do new applicants need to know about the CIRM application process?

First, read through the resources at the top of this FAQ.

Next, familiarize yourself with CIRM's process for the Authorized Institutional Officials (AOO), the individual with the signature authority for an institution that is submitting a full application **(not required at pre-submission**). Please see "Guide for AOOs" linked at the top of this FAQ. The AOO must be "cleared" by our Grants Management Team before the final application is considered submitted, which can take up to a week. Application requires that both the PI and AOO submit (PI first, then AOO). The approved AOO must log in and submit through their own interface.

Finally, know that there are significant differences in application form and templates between CIRM programs and NIH or other funding agencies. First time applicants are advised to familiarize themselves with the Grants Management Portal (https://grants.cirm.ca.gov), DISC5 application online components, document upload templates, and other material well ahead of the deadline.

36. What do new applicants need to know about the CIRM review process?

The DISC5 review process comprises (1) eligibility assessment by CIRM staff, (2) Merit Review of eligibility by CIRM's Grants Working Group (GWG), and (3) funding approvals by the

Application Review Subcommittee (ARS) of CIRM's board. These three, independent phases are described here: Our Review Process. An application must be successful in all three phases to be funded by CIRM.

Applications that are deemed ineligible (i.e., disqualified) by CIRM staff are not reviewed by the GWG. Scope misunderstandings are the #1 reason for ineligibility. CIRM staff will read your full application, as needed, to determine whether the project is within DISC5's scope.

To ensure your application is eligible for review and funding under the DISC5 program,

- Carefully read the 'Scope and Structure' and 'Eligibility' sections of the PA.
- Watch the webinar, and see the responses to questions 1 through 6 of this FAQ.
- Schedule a consult with a CIRM science officer and come to the consult with proposed aims and major activities prepared.
- Remember that DISC5 is not a therapeutic development award or early translational mechanisms and will **NOT support** activities that focus on preclinical or clinical development of therapeutic candidates. Applicants seeking support for such activities may choose to explore CIRM's Preclinical Development (PDEV) and Clinical (CLIN2) programs, which may be a better fit.

Finally, DISC5 Merit Review by the GWG is competitive and multidisciplinary; therefore, the scoring review panel has board expertise rather than subfield specialists. Proposals should clearly articulate the scientific question, the knowledge gap addressed, and the feasibility and innovation of the approach in the context of the subfield.