INFR5: California Cell and Gene Therapy Manufacturing Network

Phase One Awards

Applicant FAQ

Project Scope

1. **Are applicants expected to address all the bullet points listed in the RFA for each category of allowable activities?**

   No. The bullet points are non-limiting examples of activities that are responsive to each of the three categories of allowable activities. Applications are expected to be responsive to all three categories of activities but the scope of proposed activities in each category and the respective budget allocations are at the discretion of the applicant.

2. **Are applicants expected to only propose activities that will be completed within the 2-year award period?**

   The Phase One Awards are intended for the awardee to make progress in quality-driven facility enhancements that de-risk manufacturing of cell and gene therapy projects, in building areas of specialization and in developing inclusive manufacturing workforce development programs. The applicant is advised to provide its overall objective for each of these categories and define what activities will be completed under the Phase One award to demonstrate progress toward the respective objectives.

3. **Are collaborations required? What is expected of the collaborators?**

   While collaborations are not required for this INFR5 Phase One Awards RFA, they're strongly encouraged where appropriate. The nature of a collaborator's contribution (whether financial, resource or otherwise) should align with the needs of the project and is not limited or prescribed by the INFR5 Phase One Awards RFA.

Eligibility

1. **If a California non-profit organization has a cell and gene therapy GMP manufacturing facility that has only recently become operational, does it meet the eligibility requirements of having a California operating location?**

   At the time of application submission, the applicant organization's cell and gene therapy GMP manufacturing facility must be fully constructed, adequately equipped and staffed, and capable of operating in compliance with cGMP to be considered eligible for the INFR5 Phase One Awards RFA. Applicants are advised to contact CIRM for eligibility questions.

2. **If a California non-profit organization has a cell and gene therapy GMP manufacturing facility that has only recently become operational, how can the applicant organization demonstrate a track record of performing GMP manufacturing activities for cell and gene therapy candidates?**

   The applicant organization may provide examples of having conducted such GMP manufacturing activity at its facilities other than the recently operational GMP facility. The applicant organization may also provide information on newly contracted projects and how they will utilize the recently operational GMP cell and gene therapy manufacturing facility. A description of the applicant team's experience should also be considered.

Program Director

1. **Does the program director need to be a faculty member (i.e. clinical director)?**

   No. Please refer to the eligibility requirements for Program Director on Page 7 of the INFR5 Phase One Awards RFA.

2. **Can the application propose co-Program Directors?**

   Only one Program Director is allowed.

Budget & Co-Funding

1. **Are there are limits to how much funding can be requested for subcontracts?**

There are no limits to subcontract amounts for this INFR5 Phase One Funding Opportunity. Refer to the INFR5 Phase One RFA for allowable subcontract costs.

2. **Can the applicant institution's salary support of any listed project team members count toward the 20% co-funding requirement?**

   The salary support could be acceptable toward meeting the co-funding requirement if it is specifically for the activities performed under the INFR5 Phase One Award.

3. **Are travel costs for conferences allowable in this RFA?**

   Yes, if the conference travel is relevant to the activities proposed in the project and/or to the objectives of this RFA. Applicants may also request funding for in-state travel to an annual INFR5 Symposium.

4. **Can an applicant propose the required personnel effort without requesting the requisite salary amount in the application budget?**

   Yes. CIRM does not require applicants to request salary support to match the proposed personnel effort.

Intellectual Property

1. **What CIRM Intellectual Property (IP) regulations apply to this RFA?**

   CIRM's current Intellectual Property regulations apply to this RFA. The current CIRM IP Regulations can be found at this link. A CIRM IP FAQ can be found at this link.

2. **Are INFR5 Phase One awardees required to share any IP developed with CIRM funding?**

   This INFR5 Phase One RFA does not impose any specific IP sharing requirements. Applicants may propose appropriate management and sharing of IP as may be necessary to achieve the activities described in the project.

3. **What licenses and materials transfer agreements should be included in the application?**

   Applicants should include only licenses or materials transfer agreements that are necessary to conduct the proposed CIRM-funded project activities described in the application.