

Real Life™

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AAWG Recommendations for the
Patient Support Services Program

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CIRM
CALIFORNIA'S STEM CELL AGENCY

OUR MISSION

Accelerating world class science to deliver transformative regenerative medicine treatments in an equitable manner to a diverse California and world





CIRM has funded 103 clinical trials to date, over half are still active



200 patients were enrolled in CIRM funded trials in
FY2022-2023



Treatment sites report 30-50% of patients require support services

Patent Royalties and License Revenues Paid to the State of California

*All royalty revenues received through the intellectual property agreements shall be deposited into an interest-bearing account in the General Fund, ...for the purpose of **offsetting the costs of providing treatments and cures** arising from institute-funded research to California patients who have **insufficient means** to purchase such treatment or cure, including the reimbursement of **patient-qualified costs for research participants**.*

Identified barriers to clinical trial participation:

1 INFORMATIONAL

- Patients or providers do not know a trial may exist for the patient's condition
- Patient may not know how to connect to trial site

2 LOGISTICAL COORDINATION

- Consent, screening, enrollment, and follow up can require multiple steps or visits; coordination can increase successful enrollment

3 FINANCIAL

- Travel expenses, meals, accommodations, childcare and other out of pocket expenses (“patient-qualified costs”) can fall on patients
- Financial needs of underserved population tend to be more significant as they are less likely to be able to assume costs (even if they are reimbursable)

Overall program financing is supported by two distinct sources:

CIRM grant to PSP awardee

- Supported by CIRM program budget only
- Funds are for program design and planning, operational expenses

Patient Support Program (PSP)
\$2.5M

Patient Assistance Fund (PAF)
\$15.6M

Funds to directly cover patient costs

- Serves eligible participants in CIRM-funded trials
- Dedicated to patient-qualified costs
- Fund may be supplemented by future CIRM royalty streams

This program will address the financial and logistical bottlenecks often experienced by patients and their family members enrolling in or participating in CIRM-funded cell and gene therapy trials.

PSP Awardee will coordinate with CIRM on the program activities described below.

1 INFORMATIONAL

- Maintain a Patient Support Center to direct patients to clinical trials
- Coordinate with sponsors to verify authorization of participation
- Determine if patient is eligible for financial support

2 LOGISTICAL COORDINATION

- Manage referrals
- Coordinate visits on behalf of patients

3 FINANCIAL

- Administer PAF funds to cover travel expenses, meals, accommodations, childcare and other out of pocket expenses
- Develop accounting system to facilitate disbursements reporting to CIRM and to ensure non-duplication of costs or expenses

The INFR7 Awardee will implement the Patient Support Program as part of a three-stage project plan



Startup

- Program planning
- Development of operational systems
- Establishment of business rules, SOPs and process flows
- Testing of program services with Alpha Clinics



Phase 1 Implementation

- Launch of Patient Support Program
- Metrics and gap-analysis reporting to CIRM
- Reporting program performance to AAWG

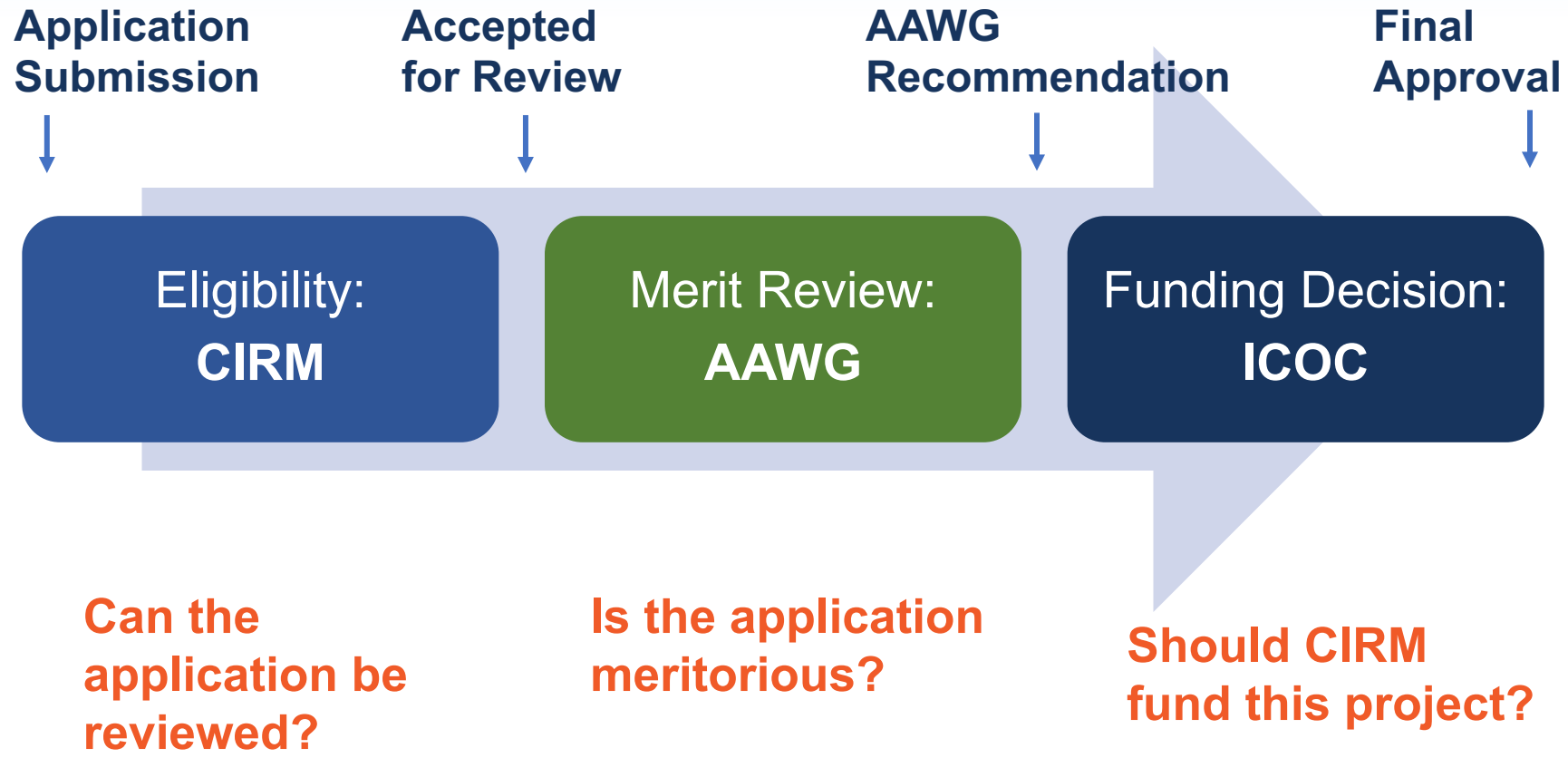


Phase 2 Expansion

- Expansion of patient financial and logistical support services based on guidance from CIRM and AAWG

Who Can Apply?

- For-profit and not-for-profit organizations with at least 5 years of experience in patient support programs
- Applicant must be able to initiate services within 120 days of the final contract.
- Applicant must have a California location
- Applicant must provide evidence of adhering to best practices for patient support programs





- **Score of “1”**

Exceptional merit and warrants funding.

May have minor recommendations and adjustments that do not require further review by the AAWG

- **Score of “2”**

Needs improvement and does not warrant funding at this time but, at the applicant's option, may be resubmitted to address areas for improvement if the Application Review Subcommittee has not approved an application for funding following the Working Group's review.

AAWG should provide recommendations that are achievable (i.e., “fixable changes”) or request clarification/information on key concerns.

- **Score of “3”**

Sufficiently flawed that it does not warrant funding.

Applications are scored by all members of the AAWG with no conflict.

Review Criteria

Basis for Score

1. Does the application offer a meaningful value proposition to improve access and retention to CIRM-funded clinical trials through its proposed patient support services?
2. Is the project well planned and designed?
3. Is the project feasible?
4. Does the project uphold principles of diversity, equity, and inclusion (DEI)?

Scoring Diversity, Equity, and Inclusion – Prop 209

- While reviewers should feel free to evaluate almost any aspect of DEI you find pertinent, under CA's Prop 209 you must refrain from considering the race, ethnicity, national origin, or gender of applicant team personnel.
- If an applicant references these demographic characteristics in describing hiring efforts or current team members, please ignore these statements.
- Other characteristics of team members can be considered *if you feel they are pertinent* – e.g., first to college, rural setting, adversity, disability...

AAWG Recommendations

| APP # | TOTAL BUDGET REQ | AAWG SCORE | 1 | 2 | 3 | CIRM Recommendation |
|--------------------|--------------------|------------|---|---|---|---------------------|
| INFR7-15912 | \$2,485,000 | 1 | 7 | 6 | 0 | FUND |
| INFR7-15523 | \$2,485,303 | 2 | 0 | 9 | 3 | Do not fund |
| INFR7-15628 | \$2,430,472 | 2 | 0 | 7 | 5 | Do not fund |
| INFR7-15487 | \$2,500,000 | 2 | 0 | 7 | 6 | Do not fund |

For each award, the final award amount shall not exceed the amount approved by the ICOC and may be reduced contingent on CIRM's assessment of allowable costs and activities.