

# CIRM 2.0

## Clinical Stage Programs

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In January 2015 CIRM launched “CIRM 2.0”:  
*....a radical overhaul of the way we do business,  
one that introduces more efficient systems and  
programs and that places added emphasis on  
speed, partnerships, and patients.*

The first initiative is **Clinical Stage Programs**  
which are intended to speed up support for  
projects through any stage of clinical trial activity.

# CIRM 2.0 – Clinical Stage Programs

- 3 new program announcements
- Rolling deadline
  - applications accepted on an ongoing basis
  - PI's submit applications when ready to start project
  - CIRM review time is less than 90 days from review to JIT
  - significant departure from prior review time (6-18 months)

# Awards Characteristics

- Work must start date 45 days after JIT
- Must include a project manager with clinical development experience
- After first payment (initiated upon award), payments will be disbursed upon completion of Operational Milestones

# Awards Characteristics

## Contingency Plan

- project must identify potential risks and have a financial contingency plan which identifies other funding sources in the event costs exceed amount of award
- Costs resulting from a delay or failure to meet an Operational Milestone will be the sole responsibility of the recipient

# Awards Characteristics

## Contingency Plan

- Must reporting suspension events to CIRM, i.e. FDA hold – only able to spend funds for 30 days; after 30 days, PI must use contingency plan

# Awards Characteristics

Clinical Advisory Panel -CAP (CIRM science officer, external advisor, patient rep)

- CIRM will appoint a CAP to partner with the Awardee
- CAP will meet with awardee regularly to provide guidance to achieve operational goals
- CAP will follow project through completion

# What does this mean to UCLA

## Timely compliance

- Approvals and compliance (IRB, Coverage Analysis, etc.) should be obtained prior to application submission
  - Project may be refused for subsequent consideration by CIRM



# What does this mean to UCLA

Additional reporting requirements

- Ongoing and regular communication with CAP
- Must be listed on [clinicaltrials.gov](https://clinicaltrials.gov) and submit results

# What does this mean to UCLA

## Financial impacts

- mandatory cost sharing
- Funding holds
  - Suspension events
  - Failure to complete Operational Milestone
  - Additional time to complete Operational Milestone

# For additional information

## CIRM 2.0 FAQ:

- <https://www.cirm.ca.gov/about-cirm/cirm-20-faq>

## CIRM 2.0 1/21/15 Presentation:

- <https://www.cirm.ca.gov/agendas/01152015/cirm-20-we-are-changing-way-we-work-presentation-dr-randy-mills-cirm-president>

# Questions?

