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 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?