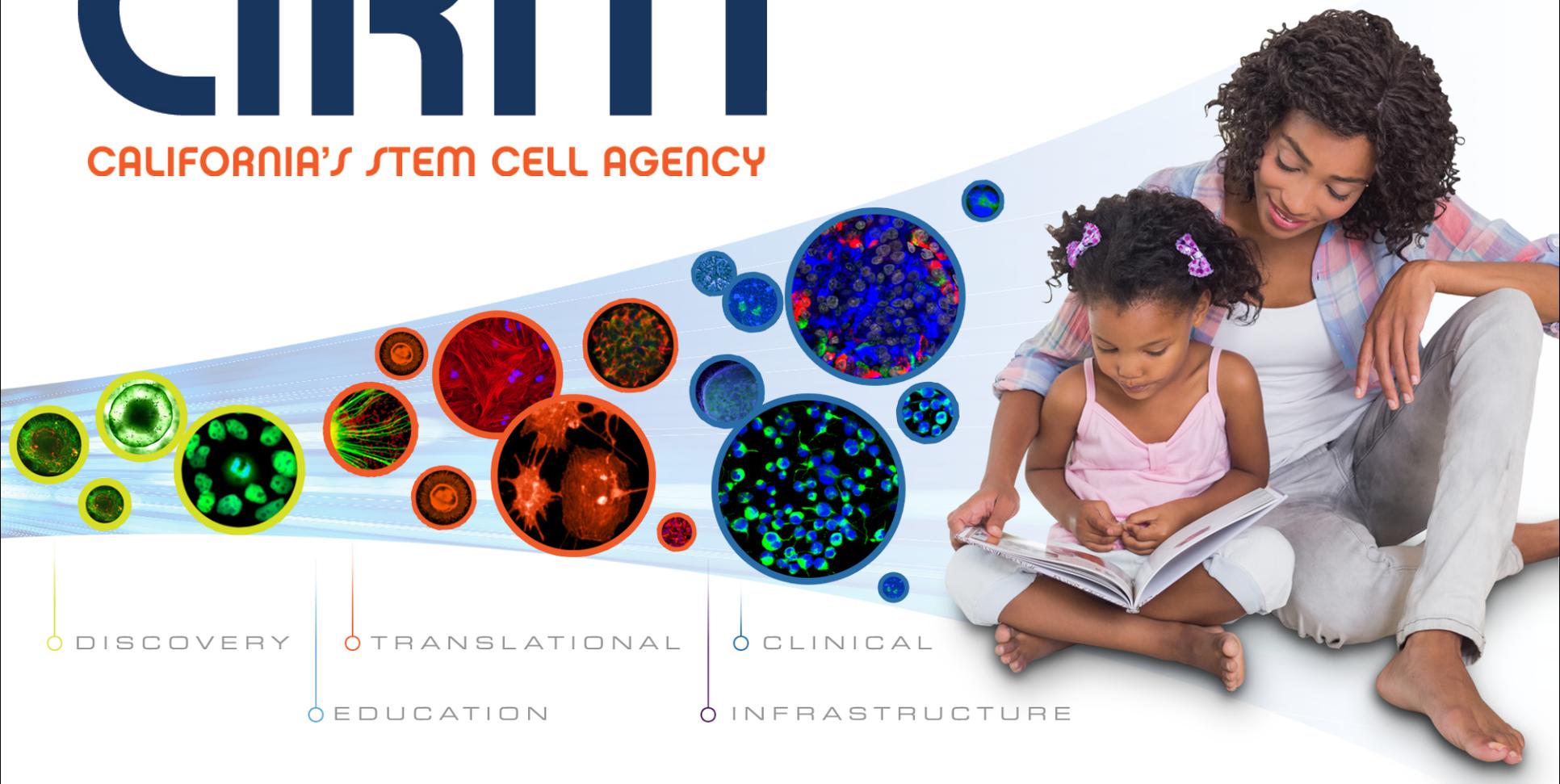


CIRM

CALIFORNIA'S STEM CELL AGENCY



○ DISCOVERY

○ TRANSLATIONAL

○ CLINICAL

○ EDUCATION

○ INFRASTRUCTURE

Proposed IP Regulations

Our Mission

To accelerate stem cell treatments to patients with unmet medical needs.

I. Goals for IP Revisions

- Ensure regulations are clear and self-executing
- Fundamental components should be objective instead of subjective
- Revenue sharing should be easy to calculate so that awardees have certainty about their obligations
- Administrative efforts should support CIRM's strategic mission, not interpreting and enforcing rules

II. Solution: 2.0 our IP Regulations

These revisions:

- Reconnect regulatory scheme to fundamental tenets
- Strike Prop 71's balance to share revenue but not hinder research/commercialization
- Optimize CIRM's resources = focus on strategic plan goals
- Simplify revenue sharing = easier to understand, explain, and apply
- Focus revenue sharing on market successes

III. Public Comment Feedback

Substantive feedback was provided by the University of California Office of the President and Stanford University. Major concerns included:

- How to ensure the proposed policy doesn't reach beyond technology funded by CIRM.
- Making sure the proposed policy does not capture routine non-profit activities.
- Burdening the ability to negotiate deals for the IP and technology.

IV. CIRM Response to Public Comments

- How to ensure the proposed policy doesn't reach beyond technology funded by CIRM.

The term Targeted CIRM-Funded Technology will be used to define the scope of a CIRM Award in the Notice of Award and amended as necessary. This will inform the Awardee of the scope of its licensing obligations as to data.

- Making sure the proposed policy does not capture routine non-profit activities.

This public comment assumed CIRM's royalties would extend to sales beyond the first sale of a Drug. This is not the case and clarification language has been added.

IV. CIRM Response to Public Comments (continued)

- **Burdening the ability to negotiate deals for the IP and technology. The royalty rate is in the current CIRM regulations for for-profits. In addition, it seems to be a lower amount than other non-profit institutions are requesting for their funding. CIRM has decided to retain the current royalty rate.**

V. Conclusion

- **CIRM has undergone three rounds of Public Comments on the proposed IP Regulations.**
- **The commentators have had their issues addressed.**
- **CIRM is requesting that the IP Subcommittee recommends approval of the proposed IP Regulations to the whole ICOC Board.**

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Accelerating stem cell treatments to patients with unmet medical needs.