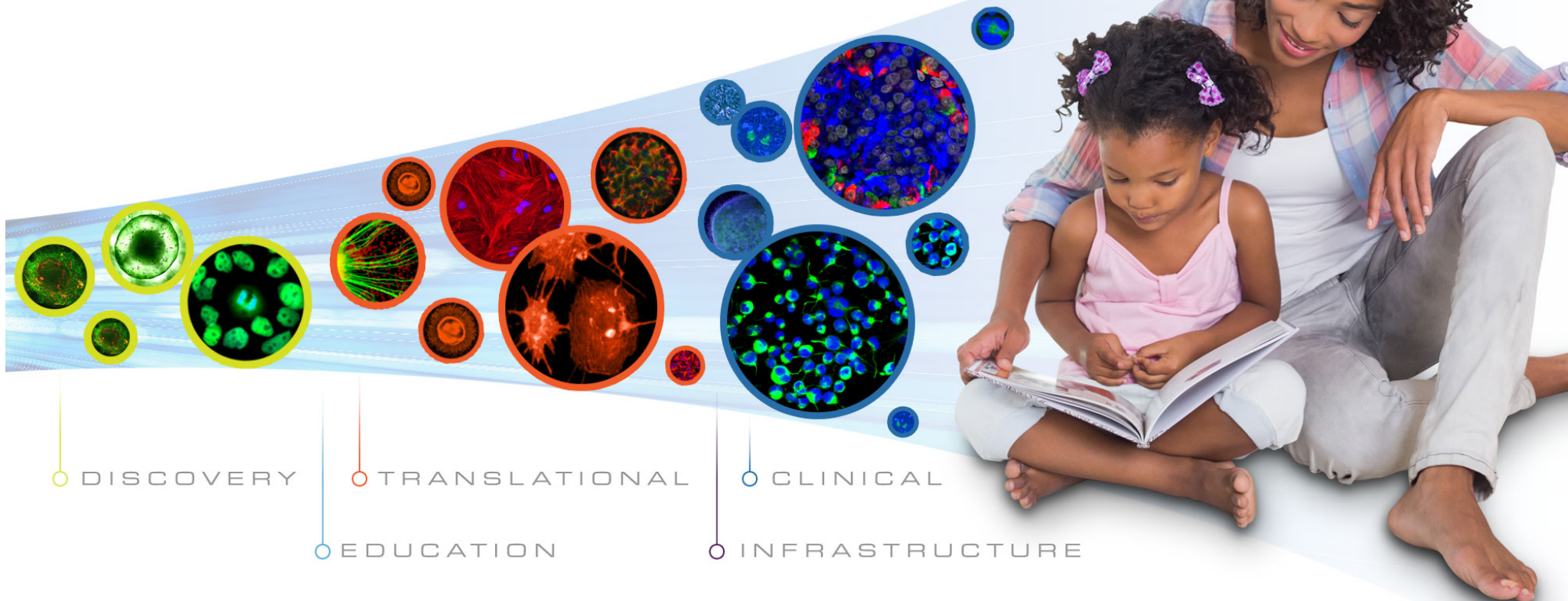


# CIRM

CALIFORNIA'S STEM CELL AGENCY



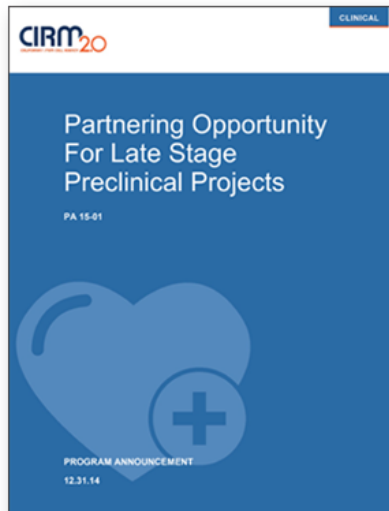
## GWG Review of Clinical Program Applications

**Gil Sambrano**

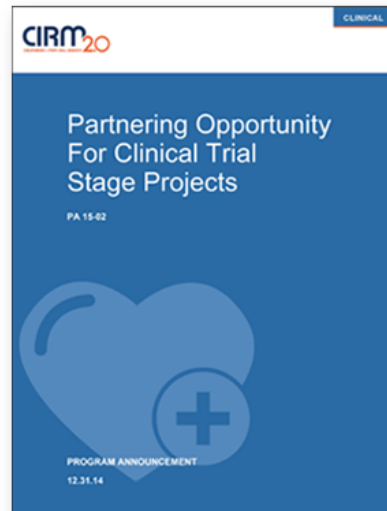
Director of Portfolio Development and  
Review

# Clinical Stage Programs

**CLINICAL STAGE**



**PA15-01**



**PA15-02**



**PA15-03**

# Scoring System for 2.0 Applications

- Score of “1”  
*Exceptional merit and warrants funding.*
- Score of “2”  
*Needs improvement and does not warrant funding at this time but could be resubmitted to address areas for improvement.*
- Score of “3”  
*Sufficiently flawed that it does not warrant funding and the same project should not be resubmitted.*

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

# CTS1-08280: Phase 3 Clinical Trial for Glioblastoma

**Therapy:** Autologous dendritic cells pulsed with HLA-specific peptides derived from tumor-associated antigens.

**Indication:** Newly diagnosed glioblastoma

**Goal:** Complete a Phase 3 clinical trial under an SPA to demonstrate safety and efficacy of the therapy for newly diagnosed glioblastoma.

## **Major Proposed Activities:**

- Clinical site initiation and patient enrollment.
- Manufacture autologous therapeutic product for each patient in the Phase 3 trial.
- Conduct multi-center trial and perform data analysis.

**Funds Requested:** \$19,919,449 (\$35,412,355 Co-funding)

# CTS1-08280: Phase 3 Clinical Trial for Glioblastoma

**Budget Review:** Pass

**GWG Score:** 1\* exceptional merit and warrants funding

- Votes for score of 1: **9**
- Votes for score of 2: **0**
- Votes for score of 3: **0**

**CIRM Team Recommendation:** Fund (concur with GWG recommendation)

**Award Amount:** \$19,919,449

\*Revised application score - originally scored 2 (1-9-2)