

Agenda Item #7: Consideration of proposal to approve increase in the amount of funding for Early Translational Research Award No. TR1-01267.

The Early Translation Research Award Application TR1-01267 entitled "Developmental Candidates for Cell-Based Therapies for Parkinson's Disease" was approved by the ICOC at its April 2009 meeting. One key consideration that required resolution before CIRM could issue the Notice of Grant Award for this program was that significant CIRM-funded research was going to be conducted outside of California. The PI was notified of this issue and asked to address it on May 1 and again on June 16.

In August, the PI proposed to CIRM to utilize personnel at the grantee organization to conduct the research activities originally proposed to be conducted outside the state. The PI indicated that the proposed changes would increase the cost of the research. CIRM requested current Curriculum Vitae (CV) for the new key personnel, an updated budget and any proposed changes to the project scope and timeline. In November, after receipt and an internal review of the CVs and supporting documents, CIRM's President, Dr. Trounson, requested an external expert assessment of the proposed changes in research activities and the qualifications/expertise of the proposed investigators at the grantee institution as compared to the original personnel. In addition, Dr. Trounson requested a site visit to the grantee institution to meet with the PI to address the proposed changes and to address the ability of the PI to commit the required effort.

The consultant noted that the proposal was to replace senior out-of-state investigators with the grantee institution's junior staff, who would put increased effort into the project compared to the out-of-state senior investigators. The consultant provided specific items to address with the PI, which CIRM did at the site visit in December.

The site visit was successful and informative. CIRM staff was assured that the core facilities at the grantee institution were adequate and could replace all the research activities critical to this project. To address the ability of junior staff to substitute for experienced senior out-of state investigators, CIRM was reassured that, in addition to the expertise of the PI, there is an established collaborative, integrated multi-institutional network that will be actively engaged in the project and can provide scientific and technical expertise to complement the newly hired and more junior staff. CIRM also received adequate assurances with regard to the ability of the PI to commit adequate time to the project.

The impact on the budget is highlighted in the table below. The cost increase is a combination of increased personnel percent effort on the project and the higher overhead of the grantee organization.

CIRM is satisfied that the research can be conducted to achieve the goals as proposed in the original application, albeit at higher cost. CIRM requests that the ICOC approve the amended budget.

