Center for Pediatric Cellular Therapies Clinical Trial Launch Grant Request for Applications

The newly established Center for Pediatric Cellular Therapies is accepting Clinical Trial Launch Grant applications. The Center's mission is to operate at the forefront of novel cell-based therapeutics to develop new paradigms for the treatment of human diseases. The Center will foster multidisciplinary scientific collaboration towards development of novel cellular therapies and will facilitate the rapid translation of new discoveries into clinical trials through provision of targeted infrastructure and expertise to meet these objectives. This includes supporting investigators through all stages of the Investigational New Drug (IND) application.

To support this mission, a two level award is available:

- Planning grant
 - o Emphasis on IND-enabling studies
 - o An eventual IND submission to the FDA is an expected main outcome
 - o Expected timeline of 6-12 months
 - Budget should be commensurate with project need, expected to be \$40,000-\$60,000
 - o Expect to be able to transition to implementation grant if milestones are met
- Implementation grant
 - o To implement the studies for moving novel cellular therapies to clinical use
 - o Expected timeline of 2-3 years
 - Budget should be commensurate with project need, expected to be ~\$200,000 total

Applicants should submit two page a letter of intent (LOI) detailing:

- Project title
- List PI and key personnel, indicating who is/will be the IND sponsor
- Summary of project and methods (include hypotheses, aims/objectives)
- Timeline of milestones, key for planning grant if wish to move to implementation grant
- Simple budget and budget justification
- If applying for planning grant, please include timeline for transition to implementation grant, milestones for the implementation grant will be requested at the transition
- Due June 3 at 5 pm, check center website on <u>www.pedsresearch.org</u> for application portal link, or click here to start a new application.

The Center's advisory board will review the LOIs and on June 10 invite promising projects to submit a full proposal, due July 8. Pilot start date of September 1, 2019.

To discuss potential projects and appropriateness, please contact center directors:

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- Ed Horwitz, MD, PhD, edwin.horwitz@emory.edu