EMORY

We are pleased to announce the launch of the Clinical Trials in Organ Transplantation in Children and Adults (CTOT-CA) (U01 Clinical Trial Optional) competition. Click on the link below to view more information. Thank you!

- Internal Submission Deadline: Monday, July 20, 2020
- Funding Organization's Deadline: Friday, October 9, 2020
- Award Cycle: FY2021
- **Discipline/Subject Area:** clinical studies/clinical trials to improve outcomes of recipients of thoracic or abdominal organ transplants, vascularized composite allografts (VCA), or cell replacement allografts (e.g., pancreatic islet or hepatocyte transplants)
- Description:

This announces the internal process for selecting Emory University's candidate for the NIH/NIAID Trials in Organ Transplantation in Children and Adults (CTOT-CA) (U01 Clinical Trial Optional). Emory as an institution may submit up to two (2) applications for this program, provided that the trials or studies described in the applications are independent of each other and target different, non-overlapping patient populations. Website: https://grants.nih.gov/grants/guide/rfa-files/RFA-Al-20-029.html

PURPOSE: The purpose of this FOA is to solicit applications to participate in a clinical studies program to improve the long-term outcome of adult and pediatric transplant recipients (thoracic organ, abdominal organ, vascular composite tissue, and cellular replacement). The Clinical Trials in Organ Transplantation in Children and Adults (CTOT-CA) program will support cooperative, multiinstitutional consortia for the conduct of interventional trials (Phase 1, 2, or 3) or observational clinical studies in organ, vascularized composite tissue, or cellular replacement allotransplantation. Each applicant institution must represent a consortium of 2 or more clinical sites. Each clinical study must include associated mechanistic studies that focus on immune-mediated processes that are relevant to the proposed clinical study. The goals of this research will be to further our understanding of and

ultimately reduce immune- and infection-mediated morbidity and mortality of allotransplantation. **AWARD BUDGET AND PROJECT PERIOD:** Application budgets are not limited but need to reflect the actual needs of the proposed project. NIAID anticipates that the yearly direct costs per award for clinical trials and/or studies will be approximately \$2 million. This amount does not include the Ancillary Studies Fund (ASF). The budget for the ASF is limited to \$4 million direct costs/year. The project period must be 7 years.

Agency Deadline: September 9, 2020 (Letter of Intent); October 9, 2020 (Full Applications)

Instructions for submitting internal applications: To apply, click on "<u>View competition</u>" and follow the directions to submit your internal application.

Internal applications are due by July 20, 2020 and must include the following (in a single pdf file with the abstract first):

- 1. an abstract of proposed project (not to exceed 2 pages), and
- 2. an NIH-style biosketch

Please note that written reviews or summary statements from the internal review and selection process will not be available.

Questions: Holly Sommers — hsomme2@emory.edu

View competition