

## Request for Applications 2021-2022 UCDC Pilot/Feasibility Core (PFC)

### **Key Dates**

Date of RFA:	December 21, 2020
½ Page Letter of Intent:	January 22, 2021
Full Submission Due:	March 15, 2021
Award Announced By:	April 15, 2021
Funding Begins:	August 1, 2021
Funding Ends:	July 31, 2022 (applicants may apply for a 2 <sup>nd</sup> year of funding during the next RFA from the UCDC PFC; funding decisions for second year of support will be made based on the progress made with the project during year 1 and scientific merits of the proposal)

**Mission:** The primary mission of this program is to provide funding for pilot projects or feasibility projects that take maximum advantage of new clinical research opportunities in UCDCs. Pilot/feasibility projects that will generate feasibility data and will lead to new UCDC clinical protocols are highly encouraged. Pilot/feasibility studies may include development of novel laboratory assays and clinical instruments, development of tools for drug discovery (e.g. development of bioassays for screening compounds), development of strategies for assessing current therapeutic interventions, conducting phase I or II clinical trials (under current regulations, NCATS does not support phase IIb and IIb/III trials), analysis of biomarkers of disease and/or response to therapeutics, or retrospective chart review from different study sites that can add to the analyses being conducted within the UCDC LS. ***The use of animal models is not permitted by the parent RFA (<https://grants.nih.gov/grants/guide/rfa-files/RFA-TR-18-020.html>).*** Pilot/feasibility projects are encouraged to be collaborative and include multiple investigators both within and outside of the UCDC.

A plan for a clinical trial must include provisions for rigorous data management, quality assurance, and safety monitoring. These monitoring activities are distinct from the requirement for study review and approval by an Institutional Review Board (IRB). For details about the Policy of the NIH for Data Safety Monitoring of Clinical Trials, see the PHS 398 Instructions (Rev. 09/2004; Part II, page 34). A general description of the data and safety monitoring plans should be included in the application. The NIH also requires that all investigators proposing research involving human subjects are educated on the protection of human research participants

**Mechanism:** Funding will be provided for **one year**. Annual funding of up to \$50,000 direct costs is available for one project. Indirect costs, capped at \$19,625 (39.2%), are allowed for Institutions within the U.S.; foreign institutions are capped at 8% (\$4,000) for indirect costs. Applications from sites that will not accept the lower indirect rate may adjust their direct costs accordingly as long as the total requested does not exceed \$69,625. Application for a successive 12-month period of support is possible, but this will be on a competitive basis. Pilot projects may receive a second year of funding based on the progress, productivity, scientific merit, and availability of funding. If your application is for a second year of support, please contact Jennifer Seminara and/or Sandesh Nagamani regarding indirect rates for the second year of funding. ***The budget section of the application does not need to be approved and signed off by the applicant's Institution at the time of the initial submission of the application by March 15, 2021.*** The PI of the project that is selected to receive funding will be requested to submit an official budget signed off by the Institution after the funding decision has been made in April. **Only one application can be submitted from each UCDC site/institution.** Funds can be used for salary support, technical support, clinical care costs, and/or supplies.

**Application Process:** A letter-of-intent (half-page abstract) from the applicant formally requesting support and showing relevance to UCDC mission (one-page limit) should be submitted by January 22, 2021. The UCDC Chair of the PFC PI will review the letters-of-intent and invite appropriate applicants to submit a full proposal. If an application is requested, the full application should be submitted as a PDF document (11 pt. Arial font, half inch margins) and transmitted via email by

11:59 PM EST on March 15, 2021. The application should use the attached template. If applicant is not a UCDC site PI, include a letter of recommendation/support from the sponsoring UCDC site PI (one-page limit). If the applicant is not part of a UCDC site, at the time of a full application, a sponsor from a UCDC will be required. We can assist with identifying that sponsor, if needed.

**Review criteria:** The “study section” for the applications will consist of UCDC site PIs and NIH colleagues who will be recruited by the Chair of the PFC. The site PIs from applicant sites will not be asked to be part of the review committee. External Ad Hoc reviewers may be called as needed. NIH scale scores will be used for reviewing applications. The Chair of PFC (Sandesh Nagamani, M.D.) will forward averaged scores and recommendation for funding to the PI of the UCDC. Each applicant will be reviewed based on the following criteria:

- Does the application describe the plan for ensuring that the proposed project is related to UCDCs, promotes clinical trial readiness and has the potential to move the field forward?
- Does the application adequately address how the pilot/feasibility project leverages existing resources and infrastructure?
- Does the application adequately address pilot/feasibility project milestones and deliverables?
- Does the application adequately address how the pilot/feasibility projects will be evaluated and managed at the end of the first year?
- Quality of science - overall impact, innovation, significance and approach

The Selection Committee will announce the award by April 15, 2021 and funding will begin on August 1, 2021.

**Submission:**

The complete application should be submitted as a single PDF document and transmitted via email to Chair of the PFC, Sandesh Nagamani [nagamani@bcm.edu](mailto:nagamani@bcm.edu) and UCDC program manager, Jennifer Seminara [jseminar@childrensnational.org](mailto:jseminar@childrensnational.org).

Please contact Dr. Nagamani or Ms. Seminara with any questions you may have about the application process:

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