Children's Hospital LOS ANGELES®

Core Pilot Program Resource Kit

Purpose

The purpose of the CHLA Core Pilot Program (CCPP) is to provide funding support for investigators to acquire preliminary data to provide a competitive edge for securing extramural grant funding. This program is one of a number of institutional investments to grow the research portfolio of the CHLA research enterprise.

Definition

A core pilot project is defined as a short-term project to develop an applicable preliminary data set to be used in the process of developing an extramural grant proposal for submission. Pilot data also is useful for determining sample power and demonstrating data quality. Pilot project funding is not to be used for full-scale research projects or to supplement existing funded awards.

Eligibility

This expanded pilot program is open to the following investigators:

- Faculty of any rank at CHLA for the purposes of collecting new data that will support submission of a new, revised or competing renewal extramural grant. Clinical research projects whose expenses are not covered in standard of care are eligible. USC investigators collaborating with a CHLA faculty member who is serving as PI or Co-PI are also eligible for applying to the pilot program for support.
- Non-Faculty Principal Investigators, who have received extramural funding within the last three years, for the purposes of collecting data that are not included in the budget of a funded grant and will be included as preliminary data in a future grant application.
- Graduate students and postdoctoral fellows, applying under the supervision of a research faculty member for the purpose of collecting data that are not included in the budget of a funded grant, and that will be included as preliminary studies in a future grant or fellowship application.

Application Guidelines

Proposals for pilot research should be submitted using a fillable form that is available online via the link found on www.chla.org/content/chla-core-pilot-program-application. Each proposal will be reviewed by the Core to assess its scientific merit and to ensure that the proposed use of core resources meets the goals of the CCPP. **Please note that the scheduling of fee-for-use studies by CHLA investigators or USC faculty who do not have access to specific core services or equipment at HSC or UPC will take priority over unfunded ones.**

The proposal application should be brief and must contain the following information:

1. Specific aims of the pilot proposal and statement of scientific significance of the overall planned research program (300 word limit)
2. Rationale for requesting support for the specific pilot project, including how the data are essential for the overall planned research program that will be the focus of an extramural grant application (100 word limit)
3. Pilot study design, including proposed measures (600 word limit)
4. Assurance from the applicant of resource availability (identifying account number and source) to support the non-core portions that are necessary to perform the pilot study (e.g. coordinator or technical personnel, trainees, materials and supplies, subjects (animal or human)
5. A detailed budget for pilot project that includes the normal charges of the core.
    a. Pilot budgets may include core materials, instrument/equipment utilization fees, and service charges. Pilot budgets must only be comprised of a Core's fee for service charges and may **not** include percent effort by the Core Director. Any cost **not** directly associated with a standard core charge, including but not limited to, travel, participant payments, gift cards, lab and/or faculty personnel or office supplies, is not allowable on a core pilot project budget.
    b. Core pilot grants must stay within the designated Core(s) outlined in the application. Core cross collaboration is allowed, but only if it is approved during the application process. The pilot budget needs to account for each Core being used and all applicable Core directors must review and approve the application and budget.
    c. It is the responsibility of the PI to ensure that the pilot project stays within budget. Any budget overage must be covered by the PI's additional funding source and is not the responsibility of the participating Core or Research Operations.
6. Pilot project timeline, including start and end date
7. A description of a plan for submitting an extramural application (including applicant organization and PA or RFA, if any) for supporting the proposed research program, including estimated time of submission (100 word limit)
8. A list of prior pilot project funding during the past 3 years, and a brief description of outcomes in terms of extramural grant applications, review score, if available, and funding status.

Please note that if funds are required for reagents, antibodies, or other materials needed for use of core instrumentation, this should be detailed for review in the initial proposal. Inclusion will be at the discretion of the Core Director based on availability of funds. The demonstration of financial need will be a foremost consideration in review of this component of the application.

If pilot project requires IACUC or IRB approval, this must be discussed with the Core Director during feasibility discussions and the project cannot begin without obtaining proper institutional approvals.

CHLA Core Pilot Program Process

STEP 1: Investigator will review Core Pilot Program Guidelines available at www.chla.org/research/ccpp to ensure compliance.

STEP 2: Investigator will set up a meeting with the applicable Core Director or Core Manager to discuss the feasibility of the pilot project idea and its timeline. Any institutional study approvals required to begin the pilot study must be discussed with the Core Director. If the Core Director agrees that the project is feasible, investigator will proceed to steps listed below.

In addition to meeting with the Core Director, the investigator is encouraged to have a short meeting with the Biostatistics Core to ensure the proposed pilot will capture the best data for planned proposals.

A list of participating Cores can be found on pages *5-7* in this toolkit.

STEP 3: Investigator will submit a completed proposal application via the link at www.chla.org/content/chla-core-pilot-program-application

STEP 4: Research Operations will send the completed proposal application to the respective Core Director, who will oversee the review process for the Core.

STEP 5: After review, the Core Director will notify Research Operations of their decision. If approved, Research Operations will assign a Project ID and budget to the pilot project.

STEP 6: Core Director and Research Operations will notify investigator if pilot project is approved or denied. If funded, investigator will work directly with the Core Director throughout the duration of the pilot project.

STEP 7: Once the pilot project is completed, an outcomes progress report of the pilot study, including a list of grant proposals must be submitted to the Core Director within three months of the pilot project end date. Should the pilot study require an extension past the end of the fiscal year in which it was funded, a new application must be submitted to the PI, and include an explanation for requesting the extension of support to complete the pilot study. All grant submissions that result from the use of the CHLA

Core Pilot Program must include the following acknowledgement statement: ***"We acknowledge support of The Saban Research Institute at CHLA and its Core Pilot Program for the use of [Core name]."***

STEP 8: Research Operations and the Core Director will work together to ensure that any grant funding that results from their Core pilot program is confirmed and tracked. This return on investment information is important to support the continuation of funding for this program.

STEP 9: Once the pilot project is completed, the outcomes report must be submitted to the Core Pilot Project within three months of the pilot project end date. Failure to submit the outcomes report will exclude the user from participation in the Core Pilot Program for three years.

Review Process

Pilot research applications are evaluated based on the quality of pilot study design, how well the data will support the development of the PI-initiated full research project, and the likelihood that the data collected will enhance the quality and likelihood of submission of extramural grant applications.

CHLA Cores may utilize one of the following review processes:

1) Review by a committee established by the Core Director, who receives a recommendation from the committee in order to make a final decision

2) Review by the Core Director

3) Review by the Chief Scientific Officer when the PI or Co-PI of the pilot research application is a CHLA Core Director or Co-Director.

Brief feedback will be provided to applicants by the Core Director, with suggestions for improving the pilot study if the initial decision was not to fund the application.

Participating CHLA Cores

A listing of participating Cores and Directors, as well as their contact information can be found at: www.chla.org/research/core-facilities

Biostatistics Core

The Biostatistics Core supports efficient and accurate data collection and analysis by providing a variety of consultation services, including research design, grant planning, data collection, data analysis, and consultation for presentations and publications.

The Biostatistics Core offers two types of pilot funding: a traditional pilot grant (for up to 25 hours of biostatistics support) or a grant proposal pilot (for up to 12-15 hours of grant proposal writing/analysis), which requires the PI to include a minimum 10% effort for the faculty director in their proposal.

To request Biostatistics Core services, please first complete the Biostatistics Service Request Form and someone will be in touch within two business days.

Cellular Imaging Core

The Cellular Imaging Core provides expert consultation on the design, execution and analysis of imaging experiments for both fixed and live experiments.

Technical Director: Esteban Fernandez, PhD
gefernandez@chla.usc.edu | O: 323-361-2548

ExtraCellular Vesicle Core

The ExtraCellular Vesicle Core provides expertise, optimized tools and emerging technologies to support research in the fields of ExtraCellular Vesicle and nanoparticles research.

Technical Director: Paolo Neviani, PhD
pneviani@chla.usc.edu | O: 323-361-8564

FACS Core

The FACS Core provides consultation, sorting, specialized pre-sort setup, data acquisition, training, image streaming and data analysis.

Faculty Director: Chintan Parkeh, MD
CParekh@chla.usc.edu| O: 323-361-5142

Human MRI Core
The Human MRI Core provides unique access to 3.0T system, giving PIs the opportunity to develop, refine, test and implement novel MR protocols.

Faculty Directors: Marvin Nelson, MD
mdnelson@chla.usc.edu | O: 323-361-4572

Neuropsychology Core
The Neuropsychology Core provides various assessment techniques to ascertain central nervous system function and dysfunction.

Faculty Director: Sharon O'Neil, PhD
shoneil@chla.usc.edu | O: 323-361-2501

Rodent Metabolic Core
The Rodent Metabolic Core provides access to the most current metabolic phenotyping technologies as well as standardized in vivo metabolic assays.

Interim Faculty Director: Rohit Kohli, MBBS, MS
Core Co-liaisons: Anna Kamitakahara, PhD & Soyoung Park, PhD
akamitakahara@chla.usc.edu | soypark@chla.usc.edu

Single Cell, Sequencing & CyTOF Core
The SC2 Core provides personalized expertise in scientific design, conduct and analyses of experiments utilizing state of the art technologies with high dimensional data.

Faculty Directors: Shahab Asgharzadeh, MD & Jeffrey M. Bender, MD
Technical Director: Long Hung
sc2core@chla.usc.edu | O: 323-361-8502

Small Animal Imaging Core
The Small Animal Imaging Core provides MRI, x-ray, bioluminescence, fluorescent, SPECT and in vivo and ex vivo uCT as well as analysis and quantification of data.

Faculty Director: Rex Moats, PhD
Technical Director: Gevorg Karapetyan
SAIC@chla.usc.edu | O: 323-361-4578

Stem Cell Analytics Core

The Stem Cell Analytics Core is a centralized support facility with a well-equipped and well-maintained space providing tissue culture and other equipment support for pluripotent stem cell research.

Faculty Director: David Cobrinik, MD, PhD
Faculty Co-Director: Jennifer Aparicio, PhD
Technical Director: Narine Harutyunyan
stemcellcore@chla.usc.edu | O: 323-361-3665

For more information about the CHLA Core Pilot Program, please contact: Cores@chla.usc.edu