

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 here.. The Core will review each proposal to assess its scientific merit and to ensure that the proposed use of core resources meets the goals of the CCPP. Pilot applications are accepted on a rolling basis from July 1st to December 31st. All pilot applications must end within the same fiscal year in which they were awarded. If pilot applications are submitted following the December 31st deadline, the application must be placed on hold until the next fiscal year. Core Directors will have up to 10 business days to approve a Pilot Project following the submission.

Certain exemptions may occur allowing an investigator to be considered for funding outside of the December 31st application deadline. The exemptions will be granted by the Core Director, Chief Scientific Officer, and Core Program Administrators if the proposed timeline, budget, and goals are feasible.

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 the Health Sciences Campus (HSC) or University Park Campus (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 <u>not</u> include percent effort by the Core Director. Any cost <u>not</u> 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 (May not exceed 12 months and must be within the same fiscal year).
- 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.

Awarded pilot projects with limited progress and minimal funds used will not carry over to the next fiscal year. Funds will not roll over if the pilot is incomplete. In such cases, the investigator will be able to reapply for pilot voucher funding and will become part of consideration for the next fiscal year.

If a 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.

Terms of Award

Once the Pilot Award is granted, the awarded Investigator agrees to abide by the Terms of Award: <u>Core Use Policy:</u> When utilizing Core services, the awarded investigator and research team agrees to follow all institutional lab safety and compliance policies as well as <u>Core User policies</u>.

<u>Duration:</u> The effective award start and date is outlined within the award letter and may not be extended.

Use of Funds: Funds must be expended in accordance with approved budget.

- Allowable costs: Core services as listed on the Core Pilot Application Proposed Budget.
- Unallowable costs: Any costs that are not directly associated with the Core's service fees and outside of the Core Pilot Application Proposed Budget.

<u>Unspent Funds</u>: Funds awarded from the Core Pilot Program that remain unspent upon the end date of the award will be forfeited and shall not cross-fiscal years.

CHLA Core Pilot Program Process



Funding	Request for	Application Due	Review	Award
Opportunity	Application			Announcement
Core Pilot Program	June 1	Between July 1 –	Within 10 business	10 business days
		December 31	days of receipt of	after receipt of
			application	application

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 <u>Biostatistics and Data Management Core</u> to ensure the proposed pilot will capture the best data for planned proposals.

A list of participating Cores can be found in pages 7-9 of this Toolkit.

STEP 3: Investigator will submit a completed proposal application via the link at Core Pilot Application Link

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, the 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 <u>outcomes report</u> must be submitted to Research Operations 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 and Data Management Core

The Biostatistics and Data Management 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 and Data Management Core offers two types of pilot funding: (1) a *traditional pilot grant* (for up to 25 hours of biostatistics support) or (2) 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 and Data Management Core services, please first complete the <u>Biostatistics and Data</u> Management 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 | 0: 323-361-8564

Flow Cytometry Core

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

Faculty Director: Chintan Parkeh, MD
Core Manager: Annie Luong, MB (ASCP)
CParekh@chla.usc.edu | O: 323-361-5142
aluong@chla.usc.edu | O: 323-361-5935

Human Imaging Core



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

Faculty Directors: Chia-Shang Jason Liu, MD, PhD

<u>cjliu@chla.usc.edu</u> | O: 323-361-5628 <u>rcir@chla.usc.edu</u> | 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 | 0: 323-361-2501

Nutrition and Metabolic Core

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

Core Director: Michael Goran, PhD

Associate Core Director of Animal Research: Anna Kamitakahara, PhD

akamitakahara@chla.usc.edu | mgoran@chla.usc.edu

Spatial Biology and Genomics (SBG) Core

The SBG 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

<u>SBGCore@chla.usc.edu</u> | 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 Core

The Stem Cell 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



Technical Director: Narine Harutyunyan

stemcellcore@chla.usc.edu | O: 323-361-3665

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