

Label	Value
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Phone	443-287-6476
Amount of Funding Requested	25000
Briefly describe the core services you offer:	<p>The Sidney Kimmel Comprehensive Cancer Center (SKCCC) Analytical Pharmacology Shared Resource Core provides the following services in a Good Laboratory Practice (GLP) environment:</p> <ol style="list-style-type: none"> <li>1) Preclinical study and clinical trial design with a focus on critical pharmacological endpoints.</li> <li>2) State-of-the-art and cost-effective services to quantitate drugs and metabolites in biological fluids: <ol style="list-style-type: none"> <li>a. Analytical method development and validation that is needed for both preclinical and clinical specimens,</li> <li>b. Quantitation of anticancer drugs and metabolites in biological fluids,</li> <li>c. Elucidation of in vitro metabolic stability, ex vivo plasma stability, metabolite phenotyping, and metabolite identification,</li> <li>d. Characterization of plasma protein binding</li> </ol> </li> <li>3) Pharmacokinetic/pharmacodynamics data analysis and interpretation.</li> </ol>
Briefly describe your current user base and how the current proposal will expand that base?	<p>The Analytical Pharmacology Shared Resource Core currently provides service to any investigator interested in the services provided by the Core. Over the past 5 years, the Core typically has provided support to ~60 clinical trial projects and ~80 preclinical projects involving ~80 collaborators (~25% being junior investigators). Of note, each users tends to bring more than one project to the Core. In total, the Core has over 90 methods developed and validated for clinical use and 150 methods developed for preclinical experiments.</p>
What specific services do you plan to offer as part of this RFA?	<p>We plan to offer quantitation of small molecules (i.e., drugs and metabolites) in biological fluids utilizing any of four chromatographic (UPLC or UHPLC) instruments with a UV/Vis detector (1), triple stage quadruple mass spectrometer (3), and a QTrap system with ion trap capabilities (1). The services can be applied to preclinical or clinical projects or various stability projects. The base rate cost for these services range from \$3850-\$2200 to develop an analytical method; \$49.50-77.50 per sample for preclinical/non-GLP projects; \$73.50-\$106.00 per sample for clinical/GLP projects.</p>

The SKCCC Analytical Pharmacology Shared Resource Core offers quantitation of small molecules as a fee-for-service with a range of prices depending on the nature of the project (i.e., GLP vs. non-GLP, simple vs. complex methodology). A major barrier to investigators needing these services is the cost. Thus, the Core Coins will provide these investigators a rapid, targeted funding mechanism to be able to incorporate critical pharmacology endpoints into their preclinical studies and clinical trials.

How do these services address the goals of the pilot program?

The services that we intend to offer address three different goals:

- 1) To provide services to junior faculty who have not yet established a significant funding base.
- 2) To generate preliminary data to strengthen a grant application.
- 3) To attract new users to the Core who were not aware of our services nor capabilities.

This award would enable the Core to give users access to state-of-the-art services who may not be able to afford them otherwise. The Core will also benefit from interactions with researchers. The goal will be to generate results to provide further insight into mechanisms of action or exposure-response variability.

Since the Analytical Pharmacology Shared Resource Core is a Sidney Kimmel Comprehensive Cancer Center (SKCCC) and Institute for Clinical and Translational Research Core, the Core receives approximately 10 new queries for projects/month. Of these, the bulk do not come to fruition due to either the scope of the project not matching the Core's capabilities based on the instrumentation or the estimated cost being higher than budgeted for the project. In FY18, 8 junior faculty (of 24 total users) were supported; 11 projects were focused on generating preliminary data for a grant application; and at least 5 investigators had stated that they could not proceed due to funding issues while several others recent inquiries are pending decisions. In addition, Dr. Rudek participated as a co-investigator on 17 grant submissions (ranging from Foundation grants to NIH R01s or P01s). The CORE COINS will help offset the expense issue for a project that meets our criteria.

How would you select recipients to receive core services? Please describe the process and criteria you might use.

The Core plans to advertise the services (i.e., quantitation of small molecules in biological fluids) in a broadcast email to solicit projects. Applicants will be asked to submit a one page proposal describing their research question, how quantitation of a drug (and metabolites) will advance their research by providing data for a publication or to secure grant funding, and initial description of the proposed experimental plan (i.e., develop a method to quantitate a drug and measure X samples). Based on the proposal, the Core Director and the Analytical Chemist will generate an estimated budget. The

investigator's NIH biosketch should accompany the application. The Core will work directly with junior investigators who have on-going or planned projects to place an application in the system. The Core's Steering Committee (members plus the Core Director and the Analytical Chemist) will review and rank the proposals within two weeks from the application due date. Proposals will be ranked based on novelty, relevance, feasibility with the Core's instrumentation, potential for impact, established vs. new collaborations, and adhere to at least one of the goals (junior faculty, new users, and preliminary data for grants with preference to junior faculty). From these criteria, the projects will be ranked from highest priority to lowest priority with preference given to new collaborators and junior investigators.

The Analytical Pharmacology Shared Resource Core is a fee for service Core. Based on the initial solicitation, projects will be prioritized based on the clear need and adherence of the project to the two goals (junior faculty and preliminary data for grants). A preliminary assessment of cost will be made for the top projects to ensure equitable allocations. The fee for service ranges depending on whether method development and validation is required or sample analysis. If a project is preclinical or non-GLP, a subsidy of up to \$2500 will be provided. If a project is clinical or GLP, a subsidy of up to \$5000 will be provided. In 2017, the Analytical Pharmacology Shared Resource Core was able to provide 8 CORE COINS allocations: 5 preclinical/non-GLP and 3 clinical/GLP projects; 5 junior investigators; with all 8 being new users of the Core.

How do you plan to allocate the amounts available to individual investigators?

Start and end dates of the award will be monitored to ensure timely use of funds. One year after receiving these Core Coins the investigators will be surveyed to determine their satisfaction working with the Core and the impact of the data generated in this Core Coins program (i.e., publications (planned or accepted) and grant applications submitted).