

Label	Value
Core Facility Name	SKCCC Analytical Pharmacology Core
Last Name	Rudek
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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:</p> <ol style="list-style-type: none"> 1) Preclinical study and clinical trial design with a focus on critical pharmacological endpoints. 2) State-of-the-art, Good Laboratory Practice (GLP)-quality, cost-effective services to quantitate drugs and metabolites in biological fluids: <ol style="list-style-type: none"> a. Analytical method development and validation that is needed for both preclinical and clinical specimens, b. Quantitation of anticancer drugs and metabolites in biological fluids, c. Elucidation of in vitro metabolic stability, ex vivo plasma stability, metabolite phenotyping, and metabolite identification, d. Characterization of plasma protein binding 3) Pharmacokinetic/pharmacodynamics data analysis and interpretation.
What specific services do you plan to offer as part of this RFA?	<p>We plan to offer quantitation of drugs and metabolites in biological fluids utilizing any of four chromatographic (UPLC or UHPLC) instruments with a UV/Vis detector (1), triple stage quadrupole mass spectrometer (3), and a QTrap system with ion trap capabilities (1). As noted in the Core services, the quantitation can be applied to preclinical or clinical projects or various stability projects.</p>
How do these services address the goals of the pilot program?	<p>The SKCCC Analytical Pharmacology Shared Resource Core offers services as a fee-for-service. The cost of experiments is often a major barrier to investigators needing these services but not currently funded or with insufficient funds request them. 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.</p> <p>The services that we intend to offer as part of the address two different goals:</p> <ol style="list-style-type: none"> 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. <p>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 benefit from interactions with researchers, some of whom may not have realized the benefit of incorporating drug quantitation into their experiments to provide further insight into mechanisms of action or pharmacodynamic variability.</p>
How would you select recipients to receive core services? Please describe the process and criteria you might use.	<p>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 FY17, 12 junior faculty (of 30 total users) were supported; 10 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</p>

	<p>addition, Dr. Rudek participated as a co-investigator on 16 grant submissions (ranging from Foundation grants to NIH R01s or P01s). In general, the Core typically has ~15-20 ongoing clinical trial projects and ~30 ongoing preclinical projects per year. The Core has over 70 methods developed and validated for clinical use and 130 methods developed for preclinical experiments. Of note, each users tends to bring more than one project to the Core. The CORE COINS will help offset the expense issue for a project that meets our criteria.</p> <p>The Core plans to advertise the services (i.e., quantitation of drugs and metabolites 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). 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 two goals (junior faculty and preliminary data for grants with preference to junior faculty). Additionally, the Core Director and the Analytical Chemist will generate an estimated budget. From these criteria, the projects will be ranked from highest priority to lowest priority with preference given to new collaborators and junior investigators.</p>
<p>How do you plan to allocate the amounts available to individual investigators?</p>	<p>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. Typical initial preclinical experiments for a new drug costs \$3000 for method development and ~\$1500 for a comprehensive pharmacokinetic assessment. For clinical trials, it would be anticipated that support would be only for the initial method development (\$7000). If the Core already has a method developed, then only per sample charges will apply. Per sample costs range from \$45 for simple preclinical projects to \$91 for complex clinical projects with a minimum batch cost of \$1000 (i.e., >22 preclinical samples or >11 clinical samples). A similar approach was utilized for an older grant (FAMRI Center of Excellence) where the Core had funding to be able to support ~5 preclinical projects and one clinical project per year with similar funding.</p> <p>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).</p>