OSARM/PKD Center Clinical Research Pilot and Feasibility Award FY2019
Request for Applications

The Office of Scholarly, Academic and Research Mentoring (OSARM) and the Kansas Polycystic Kidney Disease (PKD) Research and Translation Core Center announce the availability of funds to support one pilot grant of $50,000 for clinical research in PKD. This award is intended for junior medical faculty in the Department of Internal Medicine who wish to pursue a specific research project in order to gain research skills, develop methods, and obtain pilot data which may then become the basis for future larger proposals. The pilot project will be funded for one year beginning July 1st, 2019, and is potentially renewable for a second year, contingent on progress. The deadline for applications is April 17th, 2019.

Scope of program: Autosomal dominant polycystic kidney disease (PKD) is the most common life-threatening genetic disorder in adults with a prevalence of >1 in 1000. The pathogenesis of kidney cysts involves abnormal proliferation of cyst-lining epithelial cells mimicking a neoplastic disorder, and many drugs developed for cancer are effective in preclinical PKD models. PKD is also a multi-system disease. In addition to affecting the kidney, PKD complications can include hypertension, left ventricular hypertrophy, mitral valve prolapse, liver and pancreatic cysts, and cerebral aneurysms. Tolvaptan has recently been approved by the FDA for treatment of PKD but there is a need for the development of new therapies. The goal of this pilot and feasibility program is to stimulate clinical research in PKD by supporting the careers of junior faculty interesting in pursuing research in this disease. Faculty in any of the medicine subspecialties, including but not limited to cardiology, hematology/oncology, gastroenterology and nephrology, are encouraged to submit proposals and to apply their expertise to the study of PKD. Types of research supported by this program include:

- Preclinical studies that are directly relevant to human health and use human cells or other human biological materials, with the endpoint of identifying new therapies or biomarkers
- Early bench to bedside research leading up to and including first-in-human and/or clinical proof of concept trials evaluating new drug treatments
- Community-based clinical research studies using human subjects, families, and/or communities for testing new treatments or interventions, assessing new health outcomes, etc.
- Outcomes and comparative effectiveness studies

In vivo preclinical studies and ex vivo studies using animal models and tissues will be considered only if results lead directly to clinical research. Specific questions regarding the scope of this program can be directed to James Calvet, Ph.D. and John Chen, Ph.D.

Eligibility: Faculty with an M.D., D.O., or Ph.D. degree that have a primary appointment in the Department of Internal Medicine at the level of Assistant or Associate Professor at the time of award are eligible to be the principal investigator (PI). The PI must be able to devote a percentage of their time to the project. A letter from the Division Director confirming that support will be provided to protect the faculty member’s research time will be required.

Budget: The maximum annual award is $50,000 for research costs, salary and fringe benefits for the PI and personnel, and limited career development expenses.
**Core support:** The pilot project should make use of at least one of the following two clinically-based research cores of the PKD Center.

**Biomarkers & Biomaterials Core** (Core Director: Darren Wallace)
The Biomarkers & Biomaterials Core supports the discovery, validation and development of biomarkers for early PKD and provides human primary cells and other reagents. The Core is enrolling a longitudinal cohort of PKD patients and normal individuals, so as to establish and maintain a repository of PKD biospecimens including blood, urine, and urinary exosomes. Subject-level data including BUN, serum creatinine and total kidney volume from MRI is also being collected.

**Clinical Research Core** (Core Director: Alan Yu)
The Clinical Research Core facilitates clinical and translational research in PKD through the provision of consultative advice on drug development, a patient registry network for clinical trials recruitment, resources and services for conducting clinical trials, and a searchable integrated clinical data repository for observational research.

Applicants should contact the appropriate Core Director(s) to discuss their project prior to submitting an application. Pilot projects will be eligible for discounted or waived fees for Core resources and services.

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**APPLICATION INSTRUCTIONS**

**General instructions**
Applications must be in Arial font, size 11 point or larger, with margins of at least 0.5 inch.

1. **Cover page**
The cover page form attached must be filled out and attached to the front of the application.

2. **Summary** (*one-half page or less*)
Describe the primary objective of the proposed research, the key components of the research design, and its significance in general terms.

3. **Budget for 1-year period**
Provide a budget using NIH style budget form page 4. Provide an explanation on a separate page, to clarify the role of individuals for whom salary support is requested. Explain how travel funds will be used to conduct the research. Equipment, if included, must be well justified.

4. **Other Support**
On a separate page, list all other sources of active or pending internal and external support for the PI and other key personnel. For each, give the title, sponsor, role of the PI on the project, funding period, annual direct costs, percent effort by the PI, and the goals of the project. Describe the relationship of each to the current proposal. In cases in which existing funds appear to be similar to the proposed project, take special care to explain the differences.

5. **Biographical Sketch** (*not to exceed 5 pages*)
Provide a biographical sketch for the PI in the latest NIH format.
6. **Research Strategy** *(Up to 5 single-spaced pages for Items A.-D. Proposals may not exceed that length)*

**A. Specific Aims** *(one-half page recommended)*  
List the broad, long-term objectives and what the specific research proposed in this application is intended to accomplish.

**B. Significance**  
State the importance and relevance of the research project for advancing our understanding and treatment of polycystic kidney disease or its complications.

**C. Innovation**  
Explain how the application challenges current research or clinical practice paradigms. Describe any novel concepts, approaches, instrumentation or intervention(s) to be developed or used.

**D. Approach**  
Describe the research activities to be carried out under the award. State your research design, and explain how it will allow you to address the question(s) and hypotheses of the project. Explain potential pitfalls you might encounter and how you plan to overcome them. Preliminary studies can be included but are not required.

Describe how you will make use of the PKD Center clinical core(s) in your research. State succinctly how completion of this study will facilitate the submission of a future proposal for extramural funding and identify any potential funding sources.

7. **Appendix**  
Include surveys, other measurement instruments and similar items. The Appendix may not be used to provide additional data or information that should be part of the 5 page proposal.

8. **Letter(s) of Collaboration**  
While not required, we encourage collaborative interactions with members of the PKD Center.

9. **Letter(s) from the Division Director**  
This should indicate support for protected time for the PI to do the research. Indicate any commitment of matching or contributed funds to support the research project including supplements to the PI's salary needed to support this level of effort/time commitment.
10. **Status of IRB or IACUC submission**
Please provide updated documentation on where the proposal is in the approval process. If approval has been granted, include confirming documentation. If approval is not complete, indicate whether or not it is currently in process and if so submit documentation and a draft of the IRB application. If not yet approved, indicate if there are any specific foreseeable challenges in obtaining approval.

11. **Bibliography (not to exceed 2 pages)**

**PROGRESS REPORT (1 page)**
Applicants requesting a second year of funding are required to describe the progress made on the research project proposed in the original pilot grant. List any new grants funded, submitted grant applications and research manuscripts that were supported by the pilot grant. Describe the primary objective of the application and justify why a second-year of funding is necessary. Please include a detailed plan, including timeline, for how the proposed work will be used to obtain extramural funding. This is not included within page limitations of the Research plan.

**APPLICATION SUBMISSION**

All proposals must be submitted on or before **April 17, 2019**.

All materials must be submitted electronically as a single document in Acrobat (.pdf) format to lharris3@kumc.edu.

**Presubmission** inquiries and submission of a non-binding letter of intent are encouraged. These should be directed to:

Lyn Harris  
Administrative Director  
Kansas PKD Center  
University of Kansas Medical Center  
3901 Rainbow Blvd  
6020A WHE  
Kansas City, KS 66160-3018  
Tel: (913) 588 9252  
Email: lharris3@kumc.edu
1. **Applicant:**
   
   Name: ____________________________
   
   Title/Rank: ____________________________
   
   Department/School: ____________________________
   
   University Address:
   
   E-Mail: ____________________________
   
   Tel:

2. **Title of Proposal:** ____________________________

3. **Amount Requested:** $ ________________

**Applicant Agreement:**

I agree to abide by the conditions and reporting requirements of the Kansas PKD P30 Pilot Research Grant guidelines.

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Applicant's Signature  Date