INTRODUCTION: The mission of our PKD Center is to promote research leading to a better understanding of PKD through the discovery of therapy targets and development of clinical trials to improve patient outcomes. The Pilot and Feasibility Core of our NIH funded P30 center grant is seeking applications with the intent to fund up to three proposals in the amount of $50,000 each, for a duration of 1-2 years of funding.

PROGRAM: The purpose of the pilot program is to provide modest support that will allow an investigator the opportunity to develop sufficient preliminary data as a basis for an application for independent research support. It is not intended to support or supplement ongoing research of an established investigator. A proposed pilot and feasibility study should present a testable hypothesis and clearly delineate the question being asked, detail the procedures to be followed, and discuss how the data will be analyzed. Projects should be focused, since funding for these studies is modest and is limited to two years or less. The pilot project should make use of at least one of the following Kansas PKD Center research cores:

Gene Targeting Core – (Core Director: Chris Ward)
The Gene Targeting Core provides expert CRISPR/TALEN gene-editing for the generation of unique PKD animal models and cell lines for the identification of new targets for drug development. The goal of the Core is to assist PKD investigators in the generation of unique animal models and cell lines using TALENS or CRISPRs to help them solve complex PC1/PC2 signaling questions.

Genomics & Epigenetics Core – (Core Directors: Ken Peterson and Robin Maser)
The Genomics & Epigenetics Core provides services and reagents to facilitate the efforts of PKD investigators in this new and exciting frontier in PKD science. The goal of the Core is to help PKD researchers understand and investigate the mechanisms by which transcriptional and epigenetic regulation are disrupted in PKD, and to use this information to develop specific and effective therapeutic strategies.

Biomarkers & Biomaterials Core – (Core Director: Darren Wallace)
The Biomarkers & Biomaterials Core supports the discovery, validation and development of biomarkers for early PKD and reagents for studying primary cyst cells. 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 will also be 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.
ELIGIBILITY:

Faculty-level investigators at U.S. institutions who fall into any one of the following categories are eligible to apply:
1. New investigators without significant peer-reviewed support.
2. Established investigators with no previous work in PKD, requiring seed funds to apply their expertise to a problem in this area.
3. Established investigators who propose testing innovative ideas that represent a clear departure from ongoing research interests.

Each pilot and feasibility study proposal should state clearly the justification for eligibility of the investigator under one of the above three criteria. Past recipients of Kansas PKD Center pilot grants and KUMC Kidney Institute pilot grants are not eligible to apply.

ALLOWABLE COSTS:

- The maximum annual award is $50,000 in direct costs. No F&A costs will be awarded.
- Research materials and supplies
- Small equipment (≤ $5,000) required for the proposed research
- Salary support and fringe benefits for the PI up to a maximum of $5,000.
- Salary support and fringe benefits for research assistants/associates, postdoctoral fellows, or students.
- Travel and registration for conferences or training courses (≤ $1,500).

Awardees have discretion in the budgeting of funds to meet their research needs within the general guidelines of the budget and the terms of the proposal; however, funds may not be transferred to another project.

REVIEW AND AWARD:

Research proposals will be initially reviewed by an external review committee, who will consider the significance and relevance of the proposed research, the validity and feasibility of the approach, the innovativeness of the project, the expertise of the investigator(s), and the likelihood that it will lead to an extramurally funded research project. Final review and approval will be made by the PI of the Kansas PKD Center, Dr. James Calvet. Applicants will be notified of the amount and conditions of the award in mid-June 2019 and funding will begin on July 1st, 2019.

REPORTING:

Awardees will submit a brief report, including research progress, budget expenditures, publications, and new external support within 30 days of the termination of the grant year. In addition, awardees will be asked to provide an oral report at the annual EAC meeting and at the conclusion of their project as part of the Jared Grantham Symposium in Kansas City, which typically occurs in early-mid June. Travel to Kansas City will be reimbursed by the Kansas PKD Center and should not be included in the pilot grant budget.

ACKNOWLEDGEMENT OF SUPPORT:

Any publication arising from work supported by the grant should acknowledge the Kansas PKD Research and Translation Core Center, P30 DK106912.
APPLICATION INSTRUCTIONS
General instructions:
Applications must be in Arial font, size 11 point or larger, with margins of at least 0.5 inch.

1. **Letter of Intent (LOI)**
   A non-binding letter of intent is required by March 15th (5:00pm CST). The LOI should briefly (200 words or less) but adequately describe the research project to facilitate identifying expertise needed for the review of your application. Please submit the LOI as a .pdf file via e-mail to Lyn Harris, lharris3@kumc.edu

2. **Cover Page**
   The cover page form must be filled out, scanned, and attached to the front of the application.

3. **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.

4. **Budget**
   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.

5. **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.

6. **Biographical Sketch**
   Provide a biographical sketch for the PI in the latest NIH format.

7. **Progress Report (for renewal applications only, one-half 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 Strategy.

8. **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 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.

9. 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.

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

11. Letter(s) from the Director or Department Head
This should indicate support 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.

12. 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.

13. Bibliography (not to exceed 2 pages)

APPLICATION SUBMISSION

The Letter of Intent (LOI) deadline is March 15th, 2019 at 5:00pm CST.
The full proposal must be submitted on or before April 17th, 2019 at 5:00pm CST.

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

Pre-submission inquiries should be directed to:
Lyn Harris
Administrative Director
Kansas PKD Center
University of Kansas Medical Center
Tel: (913) 588 6075
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.

__________________________________________  _________________________
Applicant’s Signature                        Date