PKD Foundation 2024 Research Request For Applications (RFA)

Overview of Program Goals and Scope

The PKD Foundation's principal mission is to support basic, translational, and clinical research that will benefit patients with autosomal dominant and autosomal recessive polycystic kidney disease (ADPKD and ARPKD).

Under this RFA, the PKD Foundation solicits research grant applications in the following areas:

- Basic research to enhance understanding of molecular bases of PKD and its pathobiology
- Translational research to accelerate development of predictive and therapeutic strategies for PKD
- Clinical research such as small pilot studies
- Epidemiology/data analysis research to conduct secondary data analyses utilizing existing database resources, or to develop new statistical methodologies or test hypotheses <u>using</u> <u>existing data</u>

Special consideration will be given to proposed research in the following areas:

- Autosomal <u>Recessive</u> PKD (ARPKD)
- ADPKD in children
- Biomarker discovery and validation
- Innovative approaches to machine learning
- Lifestyle interventions (e.g., in dietary habits)
- Epidemiology/ data analysis (e.g., using existing datasets)
- Extra-renal manifestations of PKD, including but not limited to congenital hepatic fibrosis, polycystic liver disease and intracranial aneurysms
- Clinical care disparities (e.g., race, ethnicity, socioeconomic status, rural versus urban)
- Diabetes and PKD

Thanks to international PKD Foundation alliances, special consideration will also be given to grant applications for research conducted in:

- Canada (made possible by a collaboration with the PKD Foundation of Canada)
- Australia (made possible by a collaboration with the PKD Australia)

Applicants must submit a pre-application to be considered for funding and will be notified by October as to whether they are invited to submit a full grant proposal. Full applications will not be accepted unless notification of invitation has been received from PKDF.

PRE-APPLICATION SITE OPENS	June 2023			
PRE-APPLICATION DEADLINE	August 14, 2023 @ 5 PM CST			
REVIEW PERIOD	August-October 2023			
INVITATIONS TO SUBMIT FULL APPLICATIONS	October 2023			
FULL APPLICATION DEADLINE	January 15, 2023 @ 5 PM CST			
REVIEW PERIOD	January – May 2024			
APPLICANT NOTIFICATION	May 2024			
FUNDING CYCLE	July 1, 2024 – June 30, 2026			

Eligibility Criteria

Applicants must have an M.D., Ph.D. or equivalent degree and hold a faculty appointment at the institution where the research will be conducted at the time of award. Applicants do not need to be United States citizens. No fellowships will be awarded under this RFA, although salary support for personnel working on the project may be requested. Applicants may only submit one grant proposal per funding cycle.

Application Review Procedures

The PKD Foundation strives to be transparent in relation to our decision-making processes. We rely on our grant review committees, who develop recommendations for funding, as well as the process we use as a Foundation to make funding decisions. Learn more <u>here</u>.

Funding

Award amounts will equal **\$80,000** direct costs per year for two years, for a total grant award of **\$160,000** (or \$240,000 for a three-year Young Investigator Award). Future year funding is dependent upon the availability of funds and interim research progress. The funds awarded must be used solely for the purposes specified in the proposal submitted to and approved by the PKD Foundation as executed by the investigator and institution in strict compliance with the budget attached to the application. Please note the following restrictions on salary, travel, and indirect costs:

- No Indirect Costs are paid on this award.
- No more than 50% of the Direct Costs (\$40,000) may be used for the applicant's or other personnel's salary. Any use of the award for salary support must be justified in the application.
 - Salary and equipment cost limitations may be waived on research involving epidemiology/data analysis research or other proposals requiring heavy personnel support. Please contact <u>vanessah@pkdcure.org</u> with details of your project to be considered.
- Consultant costs cannot exceed \$10,000; equipment costs cannot exceed \$12,000.
- No more than \$1500 per year may be used for travel. More funds can be requested if intended to apply to PKDConnect Conference attendance.
- Successful applicants may not hold any other research funding from the PKD Foundation at the time funding of this grant begins.
- Applicants with existing funding from other sources will be eligible to apply for this award if there is no scientific overlap between the new application and existing or anticipated funding.
- All current or potential funding must be disclosed at the time of application.

Young Investigator Award (YIA)

An optional third year of support will be available to a young investigator(s) to support the transition of a junior scientist to an independent investigator.

Specific eligibility criteria not necessary at the time of application, but required by start of funding include:

- Primary faculty appointments are not required at time of application but must be held by start of funding
- No other career development award may currently be held (e.g., NIH K-award or equivalent)
- No major research award may currently be held (in the role of lead investigator) (e.g., NIH R01 or equivalent)
- No more than 5* years from completing post-doctoral or clinical fellowship training *Does not include maternity leave or FMLA

Interested applicants will need to clearly outline their interest, eligibility, and scope of research for this third year of funding. Grant applications should be written for the standard two-year proposal; a section will be provided for those applying to the YIA to provide an additional page justification.

Application Resubmissions

Applicants are restricted to one application resubmission and will be asked to provide a one-page response to reviewer comments. Thereafter, the application must be submitted as a new application.

Reporting Requirements

Grantees must submit an annual Progress Report to be submitted along with a Financial Report. As part of these reports, a brief (one or two paragraph) summary written for the lay public must be included. Although Research Grant and Fellowship Awards are for a two-year period, the PKD Foundation reserves the right to terminate any grant if there has been inadequate research progress during the first year of the award.

Download the PKDF Report Requirements.

Attribution

A stipulation to all awards is appropriate attribution of the PKD Foundation in any publication, news release, presentation, etc. that results from work funded by the award. The PKD Foundation must also receive a copy of the publication and/or news release. This responsibility extends beyond the interval of provided funding.

Grantees are asked to please use language similar to the following: *This research was funded by a grant from the Polycystic Kidney Disease Foundation, pkdcure.org. The Foundation had no role in study design, data collection and interpretation, or the decision to submit the work for publication.*

Intellectual Property Policy

All research projects funded by the PKD Foundation are subject to its intellectual property policy. Details can be found <u>here</u>. By accepting a PKD Foundation award for a research project, the Principal Investigator or other personnel contributing to and working on the project, as well as the Institution(s) with which they are affiliated, agree to be bound by the terms and conditions of this policy.

Liability Policy & Reporting Responsibilities

The PKD Foundation serves as a grantor not a sponsor for research grant projects. For those involving human subjects, the responsibility for liability issues and all reporting requirements including local, state, and federal regulations and requirements including those of the FDA, will reside with the sponsoring institution, not the PKD Foundation.

Conflict of Interest

Any relationship between the investigators and any industrial collaborator must be disclosed in the application.

Grants Policy Statement Regarding Sexual Harassment in the Workplace

Prior to releasing funding, the PKD Foundation will require an Authorized Organizational Representative to certify by means of a signed letter on institutional letterhead, institutional commitment to ensuring:

- 1. Proper policies, procedures and oversight are in place to prevent discriminatory harassment and other discriminatory practices, and
- 2. Commitment to respond promptly and appropriately to allegations of discriminatory practices.

Failure to provide the signed letter will result in withdrawal of the application/funding. The full Foundation policy can be found <u>here</u>.

Pre-Application Instructions

Applicants must submit a pre-application to be considered for funding and will be notified by October as to whether or not they are invited to submit a full grant proposal. Full applications will not be accepted unless notification of invitation has been received from PKDF.

Pre-application requirements:

- 1. Letter of Intent
 - a. Abstract (3,500 characters with spaces)
 - b. Significance, Innovation, Specific aims and approach, Scientific team and environment (4,500 characters w/ spaces)
 - c. Tables and Figures (one page limit, PDF upload)
- 2. References (*one-page limit*)
- 3. Biosketch (*five-page limit*): new style NIH Biosketch <u>format</u>. Include relevant details of applicant's career trajectory as related to this proposal.
 - *Also include a Biosketch for all key personnel.

Full Application Instructions

Applicants must submit a pre-application in order to be considered for funding and will be notified by October as to whether or not they are invited to submit full grant proposals. Full applications will not be accepted unless notification of invitation has been received from PKDF.

- 1. <u>Grant resubmission response to reviewer comments (6000 characters with spaces)</u>: must describe nature and impact of the revision and summarize the changes made to the application since the last submission.
- 2. <u>Proposal Summary/Abstract</u> (6000 characters with spaces) and its relevance to PKD research. Describe project in a scientific abstract that is understandable to a multidisciplinary group of scientific reviewers.
- 3. <u>Impact statement (6000 characters with spaces)</u> written for the lay audience that addresses relevance to the stakeholder/ patient community. See our <u>Guidance for Reviewers</u> with more details on how the Stakeholder Reviewers will be asked to score your application.
- 4. <u>Resources and environment</u> (4000 characters with spaces): Include brief description of laboratory space, equipment, clinical facilities (if relevant), access to patient populations (if relevant) and other resources necessary for the project.
- 5. <u>Research Plan</u>:
 - a. Section 1 (*one single page*):
 - i. Specific aims and rationale

- b. Section 2: (*up to 8 pages*)
 - i. Significance
 - ii. Innovation
 - iii. Approach (including Rationale, Background and Preliminary studies, Research design, Expected outcomes, Concerns and Alternative strategies)
 - iv. Statistical analyses
 - v. Rigor, Reproducibility and Transparency (including Scientific premise/Quality of prior research, and Scientific rigor/Strategies for unbiased experimental design)
- 6. <u>Young Investigator Award Justification (if applicable, one-page limit)</u>: outline the applicant's interest, eligibility, and scope of research for the potential third year of funding.
- 7. <u>References</u> (*no page limit*): citations of relevant publications
- 8. <u>Budget and Justification</u> in United States dollars (see Funding section for details)
- 9. <u>Biosketch</u> (*five-page limit*): new style NIH Biosketch format. Must include a Biosketch for any key personnel and co-investigators.
- 10. <u>Letters of Support</u> from Collaborators, Contributors, and Consultants (not required; quantity not limited). *Those qualifying for the Young Investigators Award may also want to provide a professional reference letter speaking toward the researcher's individual quality as a scientist (maximum of 2 reference letters).*
- 11. <u>Other support</u> (*no page limit*): new style NIH format including current funding, pending funding for all key personnel. More information <u>here</u>.
- 12. <u>Signed IRB approval</u> and summary of clinical protocol (or letter confirming that IRB approval will be obtained before start of project/funds are awarded), if applicable
- 13. <u>Signed IACUC approval of animal use protocol</u> (or letter confirming that IACUC approval will be obtained before start of project/funds are awarded), if applicable

Formatting Requirements

Font size and types, margins and line spacing requirements are necessary to ensure readability. Applications that do not strictly adhere to the following guidelines will be administratively withdrawn.

- Font size: Must be 11 points or larger. Smaller text in figures, graphs, diagrams, and charts is acceptable, if it is clearly legible when the page is viewed at 100%.
 - Some PDF conversion software reduces the font size. It is important to confirm that the final PDF document complies with the font requirements.
- **Text fonts:** please use one of the following:
 - \circ Arial
 - Georgia
 - o Helvetica
- **Page margins:** 1-inch margins from top, bottom, left and right aspects of each page.
- Line spacing: No more than six lines per vertical inch (e.g., text using Arial font size 11 would need to be at least single (1.0) spaced).

- **Text color:** No restriction. Though not required, black or other high-contrast text colors are recommended since they print well and are legible to the largest audience.
- *All images, graphs, charts, etc. should be included in the Project Plan section of the application.

For general guidance how to structure and write a grant application consider NIH resources (e.g., <u>Format</u> and <u>Write Applications</u>, or <u>Research Forms</u>)

If you have any questions, please contact <u>research@pkdcure.org</u>.

SAMPLE BUDGET PAGE

DETAILED BUDGET FOR TWO	YEAR PERIOD				FROM	
PERSONNEL (Salary plus fringe benefits				TOTAL SALARY		TOTAL
cannot exceed 50% of total/y				YE	EAR 1	SALARY
NAME	ROLE ON PROJECT	SALARY	FRINGE	Y	ear 1	Year 2
SUBTOTALS						
CONSULTANT COSTS (Cannot	CONSULTANT COSTS (Cannot exceed \$10,000 total)					
EQUIPMENT (Itemize; cannot exceed \$10,000 total)						
SUPPLIES (Itemize by category	y; no limit)					
TRAVEL (Cannot exceed \$150	0 total)					
OTHER EXPENSES (Itemize by	category)					
SUBTOTAL DIRECT COSTS FO	R BUDGET PER	IOD				
NO INDIRECT COSTS WILL BE PAID ON THIS AWARD				0	0	
TOTAL COSTS FOR INITIAL BU	JDGET PERIOD					

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