

Are You an Early-Stage Investigator Interested in PKD Research?

About The Polycystic Kidney Disease Research Resource Consortium (PKD RRC)

The goal of the PKD RRC is to accelerate discovery in the field of polycystic kidney disease by promoting innovation and resource sharing.

The PKD RRC Pilot and Feasibility Program

The PKD RRC Pilot and Feasibility (P&F) program will provide funds for a maximum of two years to eligible investigators for the development of innovative and high impact projects broadly related to the study of polycystic kidney and liver disease. Projects focusing on the following areas of emphasis are encouraged:

- Use of existing data sets (For example “omics” or EHR databases) to address basic and clinical questions in PKD.
- Use of PKD RRC pre-clinical models to: a) decipher the early events/pathways involved in cyst initiation/formation or b) to test therapeutic strategies
- Human biomarker studies utilizing the PKD RRC biorepository.
- Studies focused on understanding the role of polycystins in the cardiovascular system.
- Studies aimed at understanding the functional domains of polycystin-1 and -2, fibrocystin and other cysto-proteins.
- Studies utilizing Human iPSC-derived organoid or tubuloid models of PKD to understand cystogenesis.
- Projects investigating PKD progression in underrepresented communities.

Proposals outside of these areas of emphasis that involve discovery (hypothesis-generating) and/or innovative (high-risk/high-reward) research will also be considered. Research involving human subjects is limited to observational studies with non-invasive or minimally invasive testing. Clinical trials, as defined by the NIH (<https://grants.nih.gov/policy/clinical-trials/definition.htm>), are beyond the scope of this program. Awards are expected to prepare the applicant(s) to submit a future investigator-initiated project (eg. NIH R01). Applicants are encouraged, but not obligated, to make use of PKD RRC resources and expertise (www.pkd-rcc.org).

Eligibility

- Early-stage investigators (ESI), as defined by the NIH (<https://grants.nih.gov/policy/early-investigators/index.htm>)
- Applicants must have an independent faculty position at the time of the application.
- Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are encouraged to apply.
- Investigators at non-domestic (non-U.S.) entities (foreign institutions) are not eligible to apply.
- PKD RRC key personnel are not eligible to apply.
- The PKD RRC Coordinating Site will confirm the applicant’s ESI status. Applications that are non-compliant will be administratively withdrawn.
- Higher priority will be given to investigators who have not held a pilot award during this U24 funding cycle.

Full Application: Deadline 5 PM EST December 18, 2023

- The application must be typed in Arial font, 11 point or larger with single spacing and margins of at least ½ inch on all sides. Page numbers should be included. Appendices are not allowed. All tables, graphics, and

supporting documentation must be contained within the proposal itself. No additional materials may be submitted after the receipt date.

- Email a single PDF containing the Application to info@pkd-rrc.org. **The deadline for submitting the proposal is 5 PM EST on December 18, 2023.** An email confirming receipt will be sent to the applicant.
- The Application should include the following sections:
 - 1. NIH PHS 398 face page**
 - 2. Abstract** (250 words or less)
 - 3. Detailed Budget Form and Justification** as described below.
 - 4. Biographical Sketches**

An NIH biographical sketch with other support (current and pending) is required for the PI and any key personnel.
 - 5. Research Plan** (Up to 4 pages total)
 - A. Specific Aims
 - B. Research Strategy
 1. **Background and Significance:** Discuss the scientific problem or challenge that will be addressed, and why it is important to the field of PKD. State the premise of the research project, including any strengths and weaknesses of prevailing relevant theories.
 2. **Innovation:** Briefly discuss any pioneering and possibly high-risk approaches that, if successful, will lead to groundbreaking or paradigm-shifting results.
 3. **Research Approach:** Describe preliminary data and the scientific plan and explain how anticipated results will lead to future funding. If applicable, describe the proposed use of PKD RRC cores, resources, and expertise.
 - 6. Literature Cited** (no limit)
 - 7. Vertebrate Animals and/or Human Subjects** (no limit)
 - 8. Resource Sharing Plan** (no limit)
 - 9. Institutional Letter of Support**

Early-stage investigators must include **one** letter of institutional support to describe the applicant's level of independence. The letter should address the following points: 1) institutional commitment 2) protected time for research 3) academic title and whether the applicant is on the tenure track and 4) will the applicant have dedicated lab space or additional start-up funds?

Budget

Applicants may request up to \$63,500 (direct + indirect costs) each year for two years, with no more than \$50,000 in direct costs. A maximum of \$10,000 may be used to support the principal investigator's salary and fringe. A narrative justification should be provided for key personnel and any major equipment (cost greater than \$5,000) deemed to be necessary for the proposed project. Funding for Year 2 will be contingent on progress made in Year 1. This is a federal grant, so federally negotiated F&A rates apply.

Application Review

The PKD RRC Central Coordinating Site will review applications that are submitted for completeness and compliance with this funding opportunity announcement. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed. Higher priority will be given to investigators who have not held a pilot award during this U24 funding cycle. Applications will be reviewed by at least three subject matter experts and will be given scores for Significance, Investigator, Innovation, Approach, Environment, and an Overall Score based on the NIH Scoring System for Research Applications (1-9). Reviewers will strongly consider the goals of the program regarding areas of emphasis, to support discovery (hypothesis generating) or innovative (high-

risk/high-reward) research. All decisions are final, and appeals will not be accepted for applications submitted in response to this solicitation. Funding for Year 2 will be contingent on progress made during year one. Unfunded applications can be submitted as an amended application in subsequent cycles, but there will not be an option to respond to reviewers' critiques. Funding is expected to begin by Early 2024.

Expectations of Awardees Receiving Pilot Funding from the PKD RRC

- Awardees are expected to join the PKD RRC as external members and take advantage of the research collaboration framework offered by the consortium.
- Awardees may be asked to participate in future grant reviews for the pilot program.
- Awardees are expected to present their research at the PKD RRC annual symposium and/or educational activities organized by the PKD RRC.
- Investigators are expected cite support from the PKD RRC in all related publications and presentations.

Mentoring Option

P&F grant awardees will be offered access to mentoring by subject matter experts within the PKD RRC consortium. Mentors will provide feedback on the project and assist in networking with established investigators in the PKD field. This is an optional service to assist early- stage investigators to develop competitive research programs and apply for additional NIH funding.

If you have any questions about the PKD RRC Pilot and Feasibility Program, your eligibility, or the application process, please contact us at info@pkd-rrc.org.

The Pilot and Feasibility program is supported by the NIDDK Grant U24DK126110