

**Chronic Renal Insufficiency Cohort Study Opportunity Pool Program
Funding Opportunity Announcement: Winter 2021**

**National Institute of Diabetes and Digestive and Kidney Diseases
and the University of Pennsylvania**

<p>Background</p>	<p>The Chronic Renal Insufficiency Cohort (CRIC, http://www.cristudy.org) Study is a longitudinal cohort study of patients with chronic kidney disease. CRIC was established by the National Institute of Diabetes and Digestive and Kidney Diseases in 2001 to promote advancement in our understanding of chronic kidney diseases. The study has enrolled more than 5,625 participants with chronic kidney disease, who are engaged in ongoing central and ancillary research activities. The overarching goal of the CRIC Opportunity Pool Program (CRIC OPP) is to engage the broader research community, including investigators who have not previously worked on CKD epidemiology as well as those from outside of the field of nephrology, in novel investigations involving CRIC participant data.</p>
<p>Overview</p>	<p>We are accepting applications to fund highly innovative studies using CRIC participant data, led by investigators in any scientific or clinical discipline. The CRIC Scientific and Data Coordinating Center (SDCC) at the University of Pennsylvania administers this program. A total of \$1,000,000 are available for applications funded under this announcement. During this funding cycle, we anticipate that there will be 6-7 awards (up to \$200,000 total costs for the entire project period).</p> <p>Applications for studies addressing topic areas not fully explored in prior CRIC investigations and that promise significant potential health impact are encouraged. Applications may address a broad array of topics, but those focused on the following areas/approaches are particularly encouraged:</p> <ul style="list-style-type: none"> • Innovative studies utilizing existing multi-omics data such as genomics, metabolomics and proteomics, to help identify disease subgroups or pathways associated with CKD progression and/or CVD outcomes are highly encouraged (see appendix with list of available genomics, metabolomics and proteomics data) • Innovative measures and analytic approaches to allow for sub-phenotyping of CKD subgroups. Can be based on either existing or newly collected data including the laboratory analysis of existing biospecimens. • Broadening the range of scientific approaches through novel reanalysis of complex imaging data such as echocardiogram measures, CT, MRI. (see appendix with list of available imaging data) <p>Applications focused on biomarker research will not be accepted.</p>
<p>Eligibility and Scope of Applications</p>	<p>Individuals eligible to apply for CRIC OPP funding are faculty members at higher education institutions and members of organizations other than institutions of higher education.</p> <p>This funding announcement is intended to support research utilizing CRIC Study participants, their samples, and their data. Applications focused exclusively on individuals not enrolled in the CRIC Study will be considered non-responsive to this announcement and will not be reviewed.</p> <p>Studies that fully overlap with ongoing or approved CRIC ancillary studies (i.e., overlapping simultaneously on outcomes, variables and analytic approach) will typically not be</p>

	<p>reviewed. Please contact the SDCC with any questions related to overlap with existing studies (contact information at the end of this announcement).</p> <p>Existing publications and funded ancillary studies can be found at http://www.cristudy.org/Chronic-Kidney-Disease/Chronic-Renal-Insufficiency-Cohort-Study/collaborate-with-cric-study.</p> <p>Existing data and resources can be found at http://www.cristudy.org/Chronic-Kidney-Disease/Chronic-Renal-Insufficiency-Cohort-Study/research-data.</p>
<p>Application Instructions: Letter of Intent</p>	<p>A letter of intent must be submitted no later than March 29, 2021. It should be a maximum of one page in length (no smaller than 11 pt Times New Roman font, single line-spacing) and include:</p> <ol style="list-style-type: none"> 1. The study question, justification of its importance, and brief rationale 2. A brief description of intended methods/study design and key measurements 3. Indication of whether the study will require collection of new data or use of existing data and resources in CRIC 4. An explanation of the novelty/innovation and potential public health impact of the proposed approach or topic area 5. Separate from the letter of intent, please identify all members of the study team and their anticipated roles. Please include an NIH biosketch for each team member.
<p>Application Instructions: Full Application</p>	<p>Letters of intent will be reviewed, and selected applicants will be invited to submit a full application that will include the following elements: Abstract, Research Plan, Reference List, Protection of Human Subjects, NIH Biosketches, and Budget and Justification.</p> <p>The Abstract should be a succinct summary of the project that includes the significance of the proposed study, the hypothesis, and the innovative potential of the study. The Abstract should not exceed 200 words in length.</p> <p>The Research Plan should not exceed four pages (no smaller than 11 pt Times New Roman font, single line-spacing, with 0.5" margins). Other aspects of the Full Application (i.e. Abstract, Reference List, Protection of Human Subjects, NIH Biosketches, and Budget and Justification) are not included within these page limitations. No appendices may be submitted. The research plan will include:</p> <ol style="list-style-type: none"> 1. Specific Aims 2. Background and Justification 3. Novelty and Innovation 4. A detailed description of intended Methods/Study Design, Plans for Implementation, and Logistical Considerations 5. Key Measurements and Data to be used and collected, including, where relevant, indication of whether the study will require collection of new data or use of existing data and resources in CRIC and a quality assurance plan for any new data collection. 6. A Statistical Analysis Plan including assessment of study power

	<p>Protection of Human Subjects should be addressed in a separate document. Indicate whether or not the project involves human subjects research. If yes, please include the following sections with a brief statement on each:</p> <ol style="list-style-type: none"> 1. Protection of Human Subjects 2. Inclusion of Women and Minorities 3. Inclusion of Children <p>Please identify all members of the study team and their anticipated roles. Please include an NIH Biosketch for each team member.</p> <p>Please also include a detailed Budget and Justification using the NIH SF424 (R&R) Budget form.</p>
Key Dates	<p>Letter of intent due date: March 29, 2021 (by 5:00pm local time of the applicant's organization)</p> <p>Applicants will be notified of invitation to submit a full application on or about April 30, 2021.</p> <p>Full applications will be due six weeks after receipt of the invitation for submission.</p> <p>Notifications to awardees will be distributed in winter 2021.</p>
Budget	<p>Budgets will typically be approximately \$100,000 (total costs- direct and indirect costs) for the entire project period to be budgeted over one year. When extremely well justified, budgets up to \$200,000 (total costs) will be considered.</p> <p>Budgets should be well-justified and account for all study costs, including costs to CRIC Study centers if any new data collection is required. Please contact the CRIC SDCC for information on how to account for these factors in the budget.</p> <p>Additional information regarding budget preparation is available at http://www.cristudy.org/Chronic-Kidney-Disease/Chronic-Renal-Insufficiency-Cohort-Study/opportunity-pool</p>
Application Submission Instructions	<p>Letters of Intent must be submitted electronically through the CRIC Study website. http://www.cristudy.org/Chronic-Kidney-Disease/Chronic-Renal-Insufficiency-Cohort-Study/opportunity-pool</p> <p>Invited applicants should submit full applications per the instructions which will be provided by email from the CRIC Opportunity Pool Program.</p>
Requirements of Awardees	<p>Awardees are required to submit a progress report twelve months after receiving funding.</p> <p>Awardees will present their findings to the CRIC Steering Committee at the conclusion of the study. It is expected that each study will culminate in publication(s).</p>
Contact Information	<p>For questions, please contact: Chronic Renal Insufficiency Cohort Study Scientific and Data Coordinating Center The University of Pennsylvania cricprog@pennmedicine.upenn.edu</p>

Appendix

Selected data resources

The following types of data are expected to be available to successful Opportunity Pool awardees for use in analyses. Most of these data are not available in all CRIC participants. Raw image data will be more limited than summary data from the images. Please contact the CRIC Scientific and Data Coordinating Center for additional information about availability of data.

Omics data

- Plasma proteomics (SomaLogic)- n= 3,547 (Phase I cohort)
- Plasma metabolomics (The Broad Institute)-n=1800 (random selection from Phase I cohort)
- Urine metabolomics (non-commercial platform)- n=1000 diabetic participants
- Plasma metabolomics (non-commercial platform)- n=400 participants (case-cohort design)
- Genomics
 - o GWAS- Illumina HumanOmni 1-Quad Array Platform- n=3,527 (Phase I cohort)
 - o DNA methylation – n=500 diabetic participants
 - o whole exome sequencing- n=600 diabetic participants

Imaging data

- Echocardiograms
- EBCT
- MRI
- Retinal images

Other data

- Pulse wave velocity
- Ambulatory blood pressure monitoring
- Electrocardiograms

The above lists are not comprehensive of all data resources. Additional descriptions of data resources can be found on the CRIC Study website:

- *Case Report Forms:*
- <http://www.cristudy.org/Chronic-Kidney-Disease/Chronic-Renal-Insufficiency-Cohort-Study/research-data>
- *CRIC DataView:*
- <http://cristudy.org/Chronic-Kidney-Disease/Chronic-Renal-Insufficiency-Cohort-Study/CRIC-DataView>