NephCure Kidney International-
CureGN Ancillary Studies Grant Program

Objectives

NephCure Kidney International (NKI), in cooperation with the NIH-sponsored Cure Glomerulonephropathy Network (CureGN), announces a research grant program to support investigator-initiated studies that employ CureGN resources to advance clinical and translational research in glomerular disease. The program is open to all scientists, within or outside the CureGN Consortium. Proposed projects can include but are not limited to those that generate feasibility data to support advancement of promising future studies and projects to develop clinical assays, or protocols, or early phase clinical trials. NephCure funds one project for up to $100,000 direct cost per project after a competitive process to select the most meritorious project. Wherever possible, proposals should adhere to the guiding principles of the CureGN:

1. Collaboration among participants within the CureGN, and between CureGN and external investigators conducting pilot or ancillary studies using Consortium resources, is essential to the success of the program.
2. Integration: NephCure and CureGN understand—and will take advantage of—the dramatic benefits to advancing glomerular disease science inherent in employing a multi-disciplinary approach.
3. Sharing: CureGN will serve as a resource to the community of scientists and lay persons interested in studying FSGS, MN, MCD, or IgAN. CureGN's ability to share its systematically collected data, biospecimens, and infrastructure for ancillary studies is as important to advancing this field as studies conducted directly by CureGN.
4. Networking: The existence and experience of maintaining a network of investigators and clinical study sites with experience in glomerular disease research will dramatically facilitate organizing and conducting future clinical studies by investigators in the public and private sectors.

Meritorious Characteristics

Pilot project proposals will be evaluated for their compliance with the guiding principles described above. The following project characteristics will be considered meritorious if:

1. The project utilizes the unique CureGN clinical data, biomaterials, infrastructure, and/or contributes by adding to these resources in a collaborative manner for the advancement of the work of others within the Consortium.
2. The project requires and benefits from the collaboration of individuals within CureGN and or members of the Consortium and external investigators.
3. The project integrates scientific disciplines in order to advance glomerular disease research.
4. The project shares new data, biological specimens, and/or infrastructure that may result from the project with the Consortium and its collaborating investigators.

Eligibility

CureGN investigators and their collaborators **OR** scientists presently unaffiliated with CureGN. Applicants are required to leverage the resources provided by CureGN (infrastructure, accumulated human subjects and their associated data and materials) by bringing additional resources to conducting proposed investigations.

Funding

1. **One project will be funded directly by NephCure Kidney International to the recipient institutions.**
2. A maximum of **$100,000 per project direct costs only.**
3. **No indirect costs.** NephCure Kidney International has a long standing policy to support direct costs only.
4. Projects are funded for 12 months, with a start date of January, 2023.

Application/Review Process

The process of submitting applications to NephCure for this grant program occurs in 3 steps. No application can be submitted to NephCure before approval of the CureGN Ancillary Studies Committee, which assesses proposals for scientific burden to the CureGN consortium, CureGN subjects, and their biosamples.

1. Submit a Letter of Intent.

   First step is for the investigator to submit a short, one-page description of the proposed study (the LOI Form is posted on the CureGN website). A Review committee comprised of members from NephCure and CureGN will select the top 50% or top 10 proposals and invite the investigators to apply for the program.

2. CureGN Ancillary Studies Committee Approval

   Next, the investigator submits an ancillary studies proposal to the CureGN Consortium. CureGN will treat these proposals in a fashion identical to any CureGN ancillary study. As such, these proposals will be reviewed by the Data Analysis Coordinating Center (DCC) for feasibility and then by the CureGN Ancillary Studies Committee (ASC) for the purpose of determining whether the project is compliant with the goals of the NKI-CureGN ancillary studies grant program and whether the project represents an acceptable burden to CureGN subjects, its dataset, and its infrastructure. Final approval for all CureGN ancillary studies resides with the Steering Committee prior to submission for external funding.

3. Grant Submission to NephCure Kidney International (NKI)

   Once the CureGN consortium approves the ancillary study, the investigator submits a formal grant proposal to NephCure. NephCure is responsible for funding decisions. They will assemble a formal peer-review committee (with no more than two CureGN investigator participants), evaluate proposals, and assign a priority score that will be used by the NephCure Research Committee in reaching funding decisions. The goal of this process is to identify the most meritorious ancillary study proposals prioritized based on**:**

   - The potential value of the project to the collective mission of nephcure and curegn
   - The scientific significance and/or novelty of the proposed hypothesis
   - The feasibility of the project
   - The impact of the project to the care of glomerular disease patients

Approval by Applicant's IRB is required (funding will be provided when IRB approval is in place, or when IRB approval is granted pending funding). CureGN recognizes that projects will vary in the fashion in which they utilize or add to consortium resources and infrastructure. The resources of the CureGN consortium will mature and grow over time. Working with the CureGN DCC, applicants should understand the scope and scale of the CureGN dataset to establish study feasibility.

Applicants may discuss project application process with appropriate CureGN investigators and support staff N (contact: CureGN-AncillaryReview@arborresearch.org) prior to making application, or to discuss study feasibility and impact of the proposed study on the consortium with appropriate CureGN investigators and support staff.

Application Format

Except where noted, applicants should use the NIH Form 398 application form and complete all items on indicated forms following 398 form instructions. (http://grants1.nih.gov/grants/funding/phs398/phs398.html)

Please use the following checklist:

____ Face Page (signature from institutional representative required)

____ Abstract (398 Form Page 2)

____ Budget (398 Form Page 4—a modular budget should **not** be used)

____ Include description of how additional resources obtained outside the NKI-CureGN grant, if any, will be used to leverage CureGN support (if appropriate, attach support documentation)

____ Biographical Sketch – PI and key personnel (398 Format; please employ newly revised NIH format)

____ Resources (398 Format)

Research Plan – The following format should be employed:

____ Specific Aims

____ Background and Significance

____ Preliminary Data, if any

____ Research Design

- Include description of how resources of CureGN will be leveraged in completing the proposed studies
- Include a discussion of how the project or the data generated might be employed/shared by other consortium investigators or how the consortium or its participating investigators might benefit from this project
- Include description of how this "pilot" project will be parlayed into a complete project
- If an interventional trial is being proposed, the application should discuss how the proposed trial will be integrated into the existing observational protocol
- Include timeline
- Include Literature Cited
- Include one paragraph summary describing how the research design employs the "meritorious characteristics" described above
- **Page limit:** 5 pages for entire Research Plan. This page limit includes figures and tables. Literature Cited is not included in these limits.

____ Human Studies:
Follow Form 398 instructions for human studies (provide evidence of IRB approval as necessary; may be provided just prior to issuance of notice of award)

____ Sharing Plan:
Please provide a statement that you will impose no restrictions in sharing data or reagents generated by this project in accordance with the NephCure and CureGN Ancillary Studies Policy.

____ Letters of Support:

- From co-investigators
- Committing to additional support (institutional or other), if any

____ Study protocol may be included with initial application or may be provided after announcement of intent to fund and before vetting by the Ancillary Studies Committee and IRB

____ No other appendix of any type permitted

____ **Formatting requirements:**
Applicants must use an 11 pt Arial font and 1/2 inch margins and cannot exceed length restrictions described above; this will be strictly enforced; must be written in English language. Applications that fail to comply with this format will be returned to the applicant without review.

____ **Grant submission:**
All applications should be compiled into a single pdf format document that can be read using the Adobe Reader or Acrobat application. Formal grant applications should be emailed Rebecca Cook, NephCure Grants Administration at rcook@nephcure.org. Please place "NKI-CureGN grant applic/Your last name" in the subject line. A receipt will be provided on the following day.

Terms of Support

1. Funds (direct costs only) are provided to investigator's institution for use by the applicant; it is the applicant institution's obligation to ensure proper use of funds and timely submission of progress reports.
2. Disbursal of grant funds will be made in quarter-annual payments at the end of each fiscal quarter. Final payments will be made only after receipt of a final progress report which is due no later than 30 days following the last day of the project. NephCure does not support no-cost extensions.
3. Principal investigators must comply with human institutional review board requirements and demonstrate current approval of these committees.
4. Reporting requirements: Principal investigators must provide an annual report due no later than 30 days after the grant termination date describing progress made during the previous year. Failure to provide this report in a timely manner may result in reduction in payment.
5. It is expected that results obtained will be shared with the consortium in a manner consistent with the ancillary studies policy of CureGN.
6. It is expected that publications will be submitted in compliance with the publications policies of CureGN.
7. NephCure and NIH support of CureGN ancillary studies will be acknowledged by grantees in publications, presentations, abstracts and other relevant press releases and on associated websites.
8. CureGN and its associated investigators do not discriminate on the basis of race, gender, religious, or ethnic group; applicants should assure compliance with this policy in designing and executing their studies.