NephCure Pilot Grant

Objectives:

NephCure announces a research grant program to support investigator-initiated studies that employ CureGN and or NEPTUNE resources to advance clinical and translational research in glomerular disease. The program is open to all scientists, including those within and outside of the CureGN or NEPTUNE Consortia. Proposed projects can include, but are not limited to, those that can be used to generate feasibility data to support advancement of promising future studies and projects to develop clinical assays, or protocols, or early phase clinical trials. NephCure will provide funding of up to $250,000 direct cost per project ($125,000 per year per project over a two-year time period, for two total projects) after a competitive process to select the most meritorious projects. Wherever possible, proposals should adhere to the guiding principles of NEPTUNE and CureGN:

1. Collaboration: among participants within the Consortia and between the Consortia and external investigators conducting a pilot or ancillary studies using Consortium resources, is essential to the success of the program.
2. Integration: NephCure and the NEPTUNE and CureGN Consortia understand--and will take advantage of--the dramatic benefits to advancing glomerular disease science inherent in employing a multi-disciplinary approach.
3. Sharing: NEPTUNE and CureGN will serve as a resource to the community of scientists and lay persons interested in studying glomerular disease. NEPTUNE and CureGN's ability to share systematically collected data, biospecimens, and infrastructure for future ancillary studies is as important to advancing this field as studies conducted directly by the Consortia.
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 sector.

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 or NEPTUNE clinical data, biomaterials, infrastructure, resources and/or contributes by adding to these resources in a collaborative manner for the advancement of the work of others within the Consortia.
2. The project requires and benefits from the collaboration of individuals within CureGN or NEPTUNE Consortia and external investigators.
3. The project integrates scientific disciplines 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 and/or NEPTUNE participant investigators and their collaborators **OR** scientists presently unaffiliated with CureGN or NEPTUNE. We are accepting applications from national and international institutions.
- Applicants are required to leverage the resources provided by CureGN/NEPTUNE (infrastructure, accumulated human subjects and their associated data and materials) by bringing additional resources to conducting proposed investigations.
- NephCure maintains pilot project grant programs that require the use of either CureGN or NEPTUNE or both consortium resources.

Funding

- **Projects will be funded directly by NephCure to the recipient institutions.**
- Applicants may request up to **$250,000 per project in direct costs only, paid over a 2-year period or $125,000 per year.**
- **No indirect costs allowed**. NephCure has a long-standing policy to support direct costs only.
- Projects are funded for 24 months, with a start date no earlier than January 2028.
- This program offers up to $500,000 in FY2028 for this grant program, to be paid out over two years. The number of projects funded will be dictated by the size of project budgets requested and awarded. NephCure makes this determination at the time of review.

Application/Review Process:

The process of submitting applications to NephCure for this pilot grant program will occur following the deadlines listed below. Pilot project applications must propose using resources from either NEPTUNE, CureGN or both consortia. For this reason, no application can be submitted to NephCure before approval of a joint CureGN or NEPTUNE Ancillary Study Review Committee and the CureGN and/or NEPTUNE Steering Committees. This process helps evaluate proposals for burden to NEPTUNE and/or CureGN Consortia, their study subjects, and their biosamples.

Please follow the following process in submitting applications:

1. Applicants are encouraged to discuss study feasibility and impact of the proposed study on the consortium with consortia investigators or support staff. Prospective applicants may contact the project management team at – **NephCurePilotGrant@med.umich.edu** for referral to individuals who can help. This contact email should be used by those using both CureGN and/or NEPTUNE applications. Working with the DCC and prior to submission of ancillary study applications, applicants should understand the scope and scale of the datasets to establish study feasibility.
2. Submit a Letter of Intent: Applicants must submit a short, one-page description of the proposed study using the template attached by the deadline below. An ad hoc review committee comprised of NEPTUNE and CureGN investigators will evaluate and prioritize Letters of Intent and will invite a maximum of 12 applicants to continue the application process.
3. Invited CureGN/NEPTUNE Ancillary Study Proposal: Those invited will be asked to submit a formal NEPTUNE/CureGN ancillary study proposal by the deadline below (see attachment below). These proposals will be reviewed by the Consortia Ancillary Studies Committee (ASC) for the purpose of determining whether the project represents an acceptable burden to NEPTUNE/CureGN subjects, its dataset, and its infrastructure. Final approval for all Consortia ancillary studies resides with the Steering Committee prior to submission for external funding.
4. Grant Application Submission to NephCure: Applicants will be informed once NEPTUNE/CureGN ancillary study approval is obtained, and will be invited to complete formal proposal applications that will be submitted to NephCure for competitive review. NephCure is responsible for funding decisions. NephCure will assemble a formal peer-review committee (with no more than two CureGN or NEPTUNE 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 scientific impact of the project consistent with the collective mission of NephCure, CureGN, and/or NEPTUNE;
    - Scientific significance and/or novelty of the proposed hypothesis;
    - Feasibility of the project;
    - Impact of the project to the care of glomerular disease patients.
5. Just in Time Approval by Applicant's IRB – if required by the nature of the project, funding will be provided when IRB approval is in place, or when IRB approval is granted pending funding. IRB approval is not necessary prior to application.

Review Timeline:

Deadline for submission of Letter of Intent to apply: January 15, 2027. Please contact, Project Management, at **NephCurePilotGrant@med.umich.edu** for details. The CureGN and NEPTUNE websites can also be helpful as you begin thinking about this project. [CureGN.org and NEPTUNE-study.org] We strongly recommend commencing this discussion as soon as possible.

Important Dates:

- Deadline for Letter of Intent/Concept Sheet: **January 15, 2027**
- Deadline for receipt of final Ancillary Study Application: **March 19, 2027**
- **Deadline for application to NephCure: July 16, 2027, 8 PM Eastern Time (no exceptions)**
- **Announcement of preliminary intent to award project: October, 2027**
- Completion of Just-In-Time process (necessary IRB approval/amendment): **December, 2027**
- Project Start Date: **January, 2028**

Final NephCure 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 a description of how additional resources obtained outside this grant, if any, will be used to leverage 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 and/or NEPTUNE 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.
- 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 Consortia Policy
- Letters of Support – from co-investigators and/or 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 ½-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 to Rebecca "Birdie" Cook at **rcook@nephcure.org**. Please place "NephCure-Pilot grant applic/Your last name" in the subject line. If you are preparing a project using CureGN and NEPTUNE data, please edit the name of your saved grant application to reflect this. If you are using just one data/sample set, please use that name. 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 that 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 first and second year of funding 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 policies of CureGN and NEPTUNE.
6. It is expected that publications will be submitted in compliance with the publications policies of CureGN and/or NEPTUNE.
7. NephCure and NIH support of ancillary studies will be acknowledged by grantees in publications, presentations, abstracts and other relevant press releases and on associated websites.
8. CureGN, NEPTUNE, and associated investigators do not discriminate based on race, gender, religious, or ethnic group; applicants should assure compliance with this policy in designing and executing their studies.