UNIVERSITY of MARYLAND BALTIMORE
INSTITUTE FOR CLINICAL & TRANSLATIONAL RESEARCH

UMB ICTR 2022 Nephrotic Syndrome Research Program (NSRP)
Pilot Grant Funding Opportunity Announcement (FOA)

Contents

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Deadlines:	**Application – Friday, September 2, 2022, 5:00 PM (Eastern Time)**
Eligibility:	Faculty at the level of Assistant Professor, Associate Professor, or Professor from the University of Maryland, Baltimore (UMB), University of Maryland, Baltimore County (UMBC), or University of Maryland, College Park (UMCP)
Budget:	Up to $65,000 in direct costs per year for 2 years
Grant period:	December 1, 2022 – November 30, 2024
Application:	Form templates and electronic submission instructions are available https://www.umaryland.edu/ictr/funding/nephrotic-syndrome-pilot-grant-foa/

NSRP PILOT GRANT FUNDING OPPORTUNITY DESCRIPTION

The University of Maryland, Baltimore (UMB) Institute for Clinical and Translational Research (ICTR) invites innovative, translational research applications that timely address prominent issues directly relevant to Nephrotic Syndrome (NS).

NS is a rare but important manifestation of kidney diseases caused by increased glomerular permeability and defined by massive proteinuria, hypoalbuminemia, and edema. The disorder may be caused by a disease specific to the kidneys (primary cause) or secondary to a systemic disorder such as diabetes, lupus, infections, or genetic disorders. NS can affect children and adults of all ages and is often associated with various complications such as hyperlipidemia, thromboembolism, increased risk of infection and, in some cases, end stage renal failure.

The Nephrotic Syndrome Research Program (NSRP) pilot grant award aims to accomplish the following objectives:

- Attract new scientific expertise and promote innovative research in the field of human kidney physiology, development, and disorders by providing funds to support projects specifically focused on the translation of laboratory and/or clinical research into new interventions that improve clinical outcomes (e.g., new diagnostics or approaches to prevention/treatment).
- Utilize a milestone-driven approach for proposed projects that will ensure timely generation of tangible products and outcomes within the funding period and final, approved budget.
- Promote cross-disciplinary, collaborative research across or within UMB Schools.
- Support investigators in the effective attainment of their milestones by providing guidance and access to ICTR resources.
- To generate pilot data for innovative research projects that will foster or support subsequent major external funding applications.

To be considered for the UMB ICTR NSRP pilot grant award, proposals must be received by the application deadline. Incomplete applications will not be reviewed.

For questions regarding application guidelines, please email the ICTR Navigator at ICTR-Navigator@umaryland.edu. Further details are on the following pages.

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NSRP PILOT GRANT GUIDELINES

A. UMB ICTR NSRP Pilot Grant Funding Opportunity Categories

This request for proposals offers funding for research along the translational continuum that will provide critical new information on NS and will accelerate development of treatment strategies and improve prognosis for NS. High impact, collaborative research performed by an interdisciplinary team in the following areas will be considered:

- ***Basic Research***
  Aims to support new or existing collaborations among faculty at UMB to enhance the understanding of molecular basis and pathobiology of NS.

- ***Clinical Research***
  Aims to support new or existing clinical research collaborations among faculty at UMB that will explore a novel intervention or an innovative application of an intervention for the prevention or the treatment of NS.

- ***Epidemiology/Data Analysis Research***
  Aims to support new or existing collaborations among UMB faculty to conduct secondary data analyses utilizing existing database resources, or to develop new statistical methodologies or test hypotheses.

B. Eligibility

- Any faculty member at the level of Assistant Professor, Associate Professor, or Professor from the UMB Schools of Medicine, Pharmacy, Dentistry, Nursing, Law, Social Work, Graduate School, or UMBC, or UMCP is eligible to apply as a Lead Principal Investigator (PI) for the ICTR NSRP Grant. The **UMBC or UMCP Lead Principal Investigators (PIs) must name a UMB Co-PI.** Adjunct or Visiting faculty are not eligible to apply.
- Multiple PI applications are allowed but is restricted to 1 Lead PI (the applicant) and 1 Co-PI. If a Co-PI is included in the application, a Multiple PI Leadership Plan, describing the respective roles, must be included with the application. In multi-PI applications, the Lead PI will serve as the point of contact for all communications.
- New or junior investigators are encouraged to apply.
- An investigator may submit only one proposal in response to this funding opportunity announcement. The Lead PI or the Co-PI (if applicable) cannot serve as a PI on another application. However, the PI may serve as a non-PI collaborator on other proposals
- Undergraduates, graduate students, postdoctoral fellows, and Research Associates/Instructors are **not eligible** to apply and cannot be listed as Co-PIs or Co-Investigators. However, they may be listed as in other roles in the proposal.
- We will consider an application to be used in conjunction with an existing grant if it shows the NSRP project could successfully leverage a new award or renewal.

C. Regulatory Requirements/Approvals and Training Certificates

- ***Human Subjects Research***

Awarded projects that propose research that involves human specimens and/or data must provide a Letter of Determination or Approval from the UMB Institutional Review Board (IRB). If the IRB determines that the project is Human Subjects Research (HSR), you will need to provide current CITI (Collaborative Institutional Training Initiative) human subjects research and HIPAA (Health Insurance Portability and Accountability) certifications for all team members. If the HSR project is also a clinical trial (ClinicalTrials.gov), all team members are required to have current Good Clinical Practice (GCP) training as well. More information about UMB HSR training can be found on the UMB IRB website. Please review for additional institutional requirements applicants, such as Data Use/Sharing Agreements, Biosafety registrations, Clinical Engineering clearance of devices, and Radiation Safety registration.

Although the IRB Letter of Determination/Approval and other documents are not required at the time of the grant application submission, **applicants are strongly encouraged to begin the IRB submission and gather all other necessary documents early.**

- ***Live Vertebrae Animal Research***

Awarded projects proposing research that involves live vertebrate animals must have the research approved by the Institutional Animal Care and Use Committee (IACUC).

All required documents and approvals must be received prior to the release of grant funds.

D. Conflicts of Interest (COI)

At the time of application, review process, before funds are awarded, and throughout the project period, it is the responsibility of the awardee and all members of the study team to report any financial or fiduciary interests that might appear to present a conflict of interest (COI). These interests must be reported to the ICTR and the Conflict-of-Interest Officer, UMB Research Integrity Office. The presence of a COI does not automatically disqualify investigators from receiving this award but will require the review and management of this conflict by the COI Officer. The failure of any member of the study team to disclose all outside interests could result in the termination of this award and the disallowance of all study costs.

UMB's COI Policy information, including examples of what constitutes an outside interest, may be found at https://www.umaryland.edu/oac/areas-of-responsibility/conflict-of-interest/

E. Potential Project Topics

Projects may cover a wide range of topics, including, but not limited to, the following topics:

- Identification and study of congenital origin, gene mutations and molecular events involved in renal morphogenesis and differentiation that may lead to progressive loss of renal function or cause severe metabolic imbalances.

- Discovery and validation of biomarkers that are associated with histopathological patterns or defined pathogenic mechanisms to aid in diagnosis, differentiation, and prognosis of NS;
- Identification of risk factors and predisposing factors contributing to the development of minimal change disease, membranous nephropathy, or focal segmental glomerulosclerosis in idiopathic NS or in patients with diabetes, lupus, amyloidosis, reflux nephropathy and other kidney diseases;
- Clinical, cellular, and molecular studies underlying the development and progression of glomerulonephritis, including the molecular changes affecting the glomeruli, alterations of the basement membrane, mechanisms leading to proteinuria, and the biochemistry of the nephron during pathological states;
- Investigation of clinical care disparities (e.g., race, ethnicity, socioeconomic status, rural versus urban) in the diagnosis and prognosis of NS;
- Study of lifestyle interventions (e.g., in dietary or exercise habits) for the prevention and/or treatment of NS;
- Development of animal models to advance understanding and treatment of NS;
- Study aided to prevent, contain, or treat disease-associated (e.g., infections, thromboembolism, anemia, and cardiovascular complications) or treatment-related (e.g., obesity, growth retardation in children, hypertension, alopecia) complication of the NS;
- Improve knowledge of the factors involved in de novo, recurrent or donor-derived glomerular disease in post-kidney transplantation;
- Implementation science or intervention trials to improve care of patients with NS.

F. Funding Restrictions

- Requests must be no more than $65,000 in direct costs per year. Budget requests must be realistic and well-justified in the budget justification.
- **Allowable expenses:** Research supplies (purchase or equipment rental; new equipment costs should be no more than 20% of the total budget); recruitment and compensation of study participant costs; research training for community partners. Salary support for all faculty-level team members listed on the grant cannot exceed $7,500 of the **total** budget for each year of the 2 year-budget. The $7,500 allowance is inclusive of fringe benefits. Faculty on more than one application cannot exceed the $7,500 salary limit across all projects.
- **Official quotes** from the provider of services, supplies, and/or equipment are required.
- **Unallowable Expenses:** Administrative support, tuition, alterations or renovations of laboratory space, purchase of laboratory or office furniture, purchase of periodicals or books, phone services and professional societies membership dues are not allowed.
- Travel: funds up to $1,000 may be used for travel with strong justification establishing the essential need for the conduct of research. Funds **cannot** be used for travel to present results at established meetings or conferences.
- **Funding will be for December 1, 2022 – November 30, 2024. No-cost-extensions will only be considered in extreme circumstances.**

- The ICTR will consider payments to an outside partnering organization, where appropriate, as a "service provider" (not as a sub-award). This expense should be justified and itemized under "Other Expenses" in the budget template form.
- Indirect costs should not be included in the budget.
- Required regulatory approvals (see previous section C) **must be obtained** prior to disbursement of funds.
- Funds will be disbursed in two installments, with the second installment contingent upon submission of a satisfactory progress report at 12 months.

G. Reporting Requirements

- All funded projects are required to have a **milestone telephone update** three, six, twelve, and eighteen months from the Jan 1st start date. A **written report** on the progress of the milestones and budget expenditures will be required at the twelve-month time-period and a final, written progress report will be due within 90 days of the end of the award (24-month time-period). Failure to attend milestone telephone updates and submit progress reports in a timely manner can have significant implications for the project and may result in termination of funding.
- Additionally, semi-annual reports will be requested for up to 10 years to track grant applications/awards, publications, and technological/intellectual property development/licensing resulting from the project.

ROLE OF THE ICTR NAVIGATOR

ICTR Navigators will provide guidance and answer questions related to the application and review process, the scope of work that is suitable for funding, and post-award activities. They will assist research teams in identifying resources needed for successful completion of research projects, including the referral of researchers to appropriate services, university cores and additional sources of support for translational research. They will review applications to ensure compliance with submission guidelines and may contact investigators to provide additional information. Throughout the award, research navigators serve as project managers, monitoring the progress of the projects, and may provide guidance, resources, and feedback to ensure the proposed translational milestones are met.

NSRP APPLICATION PROCESS

Please access the NSRP Application directly through the UMB ICTR website, FOA page. You will be prompted to enter your UMID username and password.

Prepare each of the following sections and submit electronically via the NSRP Application link. Information about **formatting is found in following Section L, page 10**. The application is maintained in the UMB **RE**search **D**ata **Cap**ture (REDCap) system. See the **required budget and milestones templates** available on the **UMB ICTR website**.

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A. Cover Letter (Limited to <u>one page</u>)

- Title of NSRP Grant application. The title of project must match the title on the IRB letter.
- State whether application is for the NSRP Basic, Clinical or Epidemiology/Data Analysis Research
- Names, academic ranks, and appointments of the designated primary (Lead) PI and one Co-PI if applicable.
- Salary support amounts requested for each faculty listed on the grant.
- Signature of PI(s).
- Signature of School Dean (or designee [e.g., department chair]) for Lead PI and Co-PI (if applicable) indicating support for submission.

B. Abstract (Limited to <u>one page</u>. See section L for formatting)
The abstract is **<u>not included</u>** in the 5-page Research Plan. The abstract **<u>should not</u>** contain proprietary confidential information. The abstract should include:

- A brief background of the project;
- The significance of the proposed research;
- The unique features, new collaborations, and innovation of the project;
- The methodology (action steps) to be used;
- Expected results;
- Relevance to the translational nature of the ICTR NSRP Grant; and
- Potential for improving the health of patients with NS within the next 3-5 years

C. Specific aims, objectives, or hypotheses (Limit to one page. See Section L formatting)

D. Research plan (Limited to five pages. See section L for formatting). The abstract, specific aims, and references are separate from the research plan.

The research plan should include the following sections:

- **Brief Introduction:** This section is intended to help orient the reviewers to better understand the scientific basis for the project, why the work is being proposed as well as the suitability of the research for ICTR NSRP Grant funding. Any new collaborations or highly innovative aspects should be succinctly noted.
- **Project Milestones and Timeline**: Submissions must include a timeline of one or more milestones for each Specific Aim with clear outcome endpoints. The timeline must be realistic for completion within the funding period and approved final budget. This summary may be presented as a chart, a paragraph, or incorporated throughout the experimental design. Milestones should highlight specific goals to be attained relative to the specific aims and, when appropriate, hypotheses to be tested. Milestones must include both the scientific objectives of the application and the procedural issues involved in executing them in a realistic and achievable way. ***<u>NOTE</u>:*** *In addition to the milestone/timeline summary presented in the research plan, you must include a* ***Project Milestone Timeline document*** *(see section G).*

- **Background (including Preliminary Results, if available), and Significance**: In addition to scientific background and significance, this section may indicate how success of the grant will affect subsequent research. It should also clarify how the research will advance the field and **should also discuss the project's potential for improving the health of patients within the next 3-5 years.**

- **Research Design**: Method description should be sufficiently detailed to convince reviewers of feasibility and validity. Details should focus on the novel aspects of the project rather than published or standard techniques. If obtaining data from human subjects, provide inclusion/exclusion criteria for study group(s), and briefly outline recruitment, recruitment site(s), consenting, where research activities will take place, risks to participants (if applicable) and participant compensation plan (if applicable). Statistical approaches to data analysis should be outlined where applicable. Quantifiable goals for the completion of each milestone should be delineated. A brief section outlining any collaborative links to any other clinical or laboratory cores is necessary.

- **Statement of Collaborative Effort**: If applicable, include a specific statement as to how the collaboration between investigators from each school will further the goals of the proposal. Include processes for maintaining communication and interactions between the schools and monitoring equitable distribution of intellectual involvement.

- **Anticipated Problems and Possible Solutions**: Any anticipated experimental or interpretive problems should be addressed, with alternative approaches described when possible. The feasibility of using alternative approaches to complete the project within the constraints of the presented ICTR NSRP budget as well as the 2-year time limit of this grant must be assured in the application. All risks and drawbacks from using any proposed alternative approach must be addressed, especially if human subjects are involved.

- **External Funding Plan:** Identify future funding sources that will be applied for. Specifically identify National Institutes of Health (NIH), National Science Foundation (NSF), Department of Defense (DOD), or other external funding opportunities that the team will be prepared to apply for within 24 months of the start of the award.

E. Comprehensive budget/Detailed budget justification

- Applicants must use the budget template available on ICTR website.
- All project team members must be noted on the budget template, even if no salary support is requested. Include school location of all team members and to-be-determined team members.
- Each item of the budget should be itemized to less than $1000.
- List each component of equipment with the amount requested separately and justify each purchase.
- **Itemize supplies in separate categories**, such as glassware, drugs, chemicals, radioisotopes.
- If animals are to be purchased, state the species, number to be used, and cost per animal.
- The budget **MUST** include an explanation of other funding sources that will be used to cover costs not covered by ICTR NSRP grant funds.
- A **detailed** budget justification is required for salary, supplies, equipment, travel for

the conduct of the research, and any other expenses required to complete the study. For individuals receiving salary support, provide a brief paragraph in the budget justification about the role of each support staff and their qualifications.

- **Recent, official quotes** for budgeted services, supplies, and equipment

F. Biographical sketch information

- A biographical sketch in NIH-format for the PI(s) and other faculty-level study team members and resumes for non-faculty (5-page limit each).
- Full "Other support" pages from PI(s)

G. Project Milestone Timeline

- Applicants MUST use template provided on ICTR website.
- The project timeline must include one or more milestones for each Specific Aim described in the research plan and the time required for each activity.
- The timeline ***must*** be realistic for completion within the funding period and final approved budget.
- Please note that IRB/IACUC submissions/approvals or subsequent grant applications/planned publications **should not** be included in this milestones' timeline.

H. Reference list of up to 30 references

I. NSRP Key Personnel Information

You are required to complete a brief Key Personnel Information form in the electronic application for the PI(s) and for each person on your proposal's team. For your convenience, we have provided a template as a guide only to what information is needed to be entered into the fields in the electronic application. For the Lead PI and Co-PI (if applicable), you will also need to provide additional, NIH-required information on gender, race, etc. as well as the NIH eRA Commons Username and an Open Researcher and Contributor ID (**ORCiD**). Information about the 16-digit ORCiD author ID can be found here https://guides.hshsl.umaryland.edu/impact/authorid. If you believe you have an ORCiD, but cannot recall, type your name in the search field on the ORCiD home page https://orcid.org/ or submit an inquiry via https://support.orcid.org/hc/en-us/requests/new.

J. Regulatory Approvals

If already available. Do not upload regulatory documents that are not specific to this application.

K. Multiple PI Leadership Plan

Only for multi-PI applications (limit to 1 Lead PI (the applicant) and 1 Co-PI). A Multiple PI Leadership Plan describing the respective roles must be included with the application. In multi-PI applications, the Lead PI will serve as the point of contact for communications.

L. Formatting Guidelines

- **Font size**: Must be 11 points or larger. Smaller text in figures, graphs, diagrams, and charts is acceptable, if it is legible when the page is viewed at 100%. If you are converting to PDF, some PDF conversion software reduces font size. It is important to confirm that the final PDF document complies with the font requirements.
- **Font types:** Arial, Georgia, or Helvetica
- **Type density:** Must be no more than 15 characters per linear inch (including characters and spaces).
- **Line spacing:** Must be no more than six lines per vertical inch.
- **Text color: black**
- **Name of the applicant** (Last name, First name) should appear in the top right-hand corner of each page.
- **Page numbers** should appear on the bottom right-hand corner of each page.
- **Paper Size and Margins**
  - *Standard letter paper size (8 ½" x 11")*.
  - Provide at least one-half inch margins (*½")* - top, bottom, left, and right - for all pages.

ICTR NSRP GRANT REVIEW CRITERIA AND PROCESS

Applications will be evaluated and scored using the following six criteria:

1. **Relevance to translation**: Are there plans to move the project through to the next step along the research pathway?

2. **Scientific impact, novelty, and merit, including experimental design**

3. **Feasibility of project completion within defined budget period**

4. The **creation or potential for creation of collaborations** between investigators and/or academic-community partnerships

5. Whether the project will promote the development of new translational researchers by **moving junior or senior investigators into a new research area**

6. **Plans for submitting a grant application for external funding.**

ACKNOWLEDGING UMB ICTR NSRP

All publications, abstracts, poster presentations, grant/funding applications, intellectual/technological developments and licensing resulting from research supported by the UMB ICTR NSRP Grant Program should cite the University of Maryland, Baltimore, Institute for Clinical & Translational Research, the Nephrotic Syndrome Research Program (NSRP) as a contributing source of support. Please include the following citation:

"We acknowledge the support of the University of Maryland, Baltimore, Institute for Clinical & Translational Research (ICTR) and the Nephrotic Syndrome Research Program (NSRP)."