Children's National Stimulating Access to Research in Residency (CNStARR) Program

Information and Instructions for 2020-2021 Application

I. Introduction

Children's National Stimulating Access to Research in Residency (CNStARR) Program Mission

The goal of CNStARR is to provide research and training opportunities to a diverse group of promising and committed pediatricians-in-training who aim to pursue careers in academic medicine and acquire skills to perform high quality, impactful, and hypothesis driven research. The program will stress disciplinary and demographic diversity of Scholars including special recruitment and retention efforts for those who are from backgrounds under-represented in medicine (including racial, ethnic, LGBTQ, disabled, and disadvantaged populations) and who are women.

II. Important Dates

- **RFA Release:** October 1, 2020
- **Applications Due:** Rolling (needs to be submitted at least 6 months prior to award start date)
- **Notification of Awards:** Within 1 month of application submission
- **Funds Available:** as soon as 6 months after application

III. Overview

The CNStARR program recruits pediatric residents who have demonstrated the aptitude and commitment to undertake multidisciplinary clinical and translational research (CTR). Each year, up to 6 awards will be made if sufficiently meritorious applications are received. Funding will be awarded for 1 year; a maximum of 2 years of funding will be considered if sufficient justification is provided for a 2-year research and training program.
It is expected that the scholar will:

- **Devote 80% of his/her full-time professional effort to the CNSTARR program** for the training and clinical research activities. The CNStARR program will provide an additional $5,000 per year for related educational and research expenses, with opportunity to apply for up to $20,000 per year for additional research expenses. *Please refer to Section IX of this RFA for additional information about NIH policy on receiving concurrent support.*
- **Engage in human-oriented research** relevant to the spectrum of translational research.
- **Develop a mentorship team**. The scholar must select a lead mentor who will have the overall responsibility for helping the scholar develop an independent career in clinical and translational research. The lead mentor will provide guidance to assure that the scholar's projects are moving satisfactorily on the path to publications, presentations, and grant applications. A co-mentor or mentors should be selected with the background required to assure multi-disciplinary input to the CNSTARR scholar. The mentors must have a demonstrated track record of successfully developing the career of junior colleagues. At least one of the mentors should have active peer reviewed funding which can help support the proposed research for the duration of the scholar's funding if required.

IV. Eligibility Requirements

Candidates for the CTSI-CN CNSTARR award must:

- Be a US Citizen or Permanent Resident;
- Be a current or incoming Children's National pediatric resident;
- Commit 80% of professional effort to the program for 12-24 months;
- Have high potential for completing clinical training and being Board-eligible in pediatrics;

- Have demonstrated commitment to research meeting our identified content areas of interest (immunology, HIV/AIDS, airway disease, cardiology, sickle cell disease, hematology, allergic diseases including asthma or food allergy, infectious diseases);
- Develop a mentor team and a multidisciplinary education, training and research plan.
- Have potential for a productive and independent research career;
- Demonstrate quality, creativity, and innovation in the specific proposed research investigation.
- Engage in training in the Responsible Conduct of Research (RCR) including instruction on conflict of interest, authorship, data management, human subjects, animal use, laboratory safety, research misconduct, research ethics. This will include 8 substantive live contact hours of RCR annually and can be drawn from the following opportunities:
    - Completion of the Collaborative Institutional Training Initiative (CITI) web-based training program.
    - Completion of Introduction to the Principles and Practice of Clinical Research, a course that is now web-based and uses archived presentation, readings and other materials.
    - The GWU Graduate Program offers 3-credit, elective courses: Current Issues in Bioethics (HSCI 2105) or Bioethical Implications of Health Research (THS 8203). These courses are open to the CNStARR Scholars as well as other seminars and lectures that are relevant to their program and their training.
    - Scholars who participate in human subjects investigation or animal research should attend at least one IRB and/or IACUC meeting as guests to understand better the process and the issues addressed by these oversight committees.

Individuals from underrepresented minority groups, women and candidates with disabilities are encouraged to apply.

V. Review Criteria

Application must be submitted directly to Dr. Andrea Hahn (ahahn@childrensnational.org).

Overview of Application Process: Applications will consist of: (1) Personal Statement (1 page), (2) Curriculum Vitae, (3) Research and Training Proposal (up to 3 pages) and (4) Mentor Letter of Support. All applications will also be reviewed by a Scientific Review Committee.

CNSTARR Scientific Review will be based on the strength of the following considerations:

- Candidate
- Career Development Plan/Career Goals & Objectives
- Research Plan
- Mentor, Co-Mentor(s), Consultant(s), Collaborator(s)

Additional Review Considerations include the following:

- Protection of Human Subjects from Research Risk (if applicable)
- Care and Use of Vertebrate Animals in Research (if applicable)
- Biohazards (if applicable)
- CTR representing the continuum from infancy to childhood in one of the defined areas of special focus (immunology, HIV/AIDS, airway disease, cardiology, sickle cell disease)

VI. Content and Format of Application Submission

Applications must be submitted in single spaced text, 0.5-inch margins, no smaller than 11 point with applicant's name in the upper right-hand corner of each page. The CNSTARR application includes the following required elements:

Personal Statement (1 page): This section should describe the candidate's background and research experience and summarize his/her career goals and objectives. It should *not* be a recitation of the candidate's CV and training-to-date. Instead, it should outline the candidate's projected career trajectory with an emphasis on the integration of the candidate's clinical and research interests.

Curriculum Vitae

Research Proposal (up to 2 pages – not including references): For most types of research, the plan should include: a specific hypothesis; a list of the specific aims and objectives that will be used to examine the hypothesis; a description of the methods/approaches/techniques to be used in each aim. The Research Plan is expected to be appropriate for, and tailored to the experience level of the candidate, and allow him/her to develop the necessary skills needed for further career advancement and should be achievable within the requested time period.

Training Proposal (up to 1 page): The Training Proposal should stress the new enhanced research skills and knowledge the candidate will acquire as a result of the proposed award. It should describe structured activities, such as course work or technique workshops, which are part of the career developmental plan. Briefly discuss each of the training activities. It is important to relate the research to the candidate's scientific career goals. Describe how the research, coupled with other developmental activities, will provide the experience, knowledge, and skills necessary to achieve the objectives of the career development plan. In particular, it should be integrated in into an approach to launch an independent research career.

Mentor Letter of Support: This statement should include all of the following:

- The plan for the candidate's training and research career development. This description must include not only research, but also other developmental activities, such as seminars, scientific meetings, training in the responsible conduct of research, and presentations.
- The nature and extent of supervision and mentoring of the candidate, and commitment to the candidate's development that will occur during the award period.
- A plan for transitioning the candidate from the CNStARR program to the next phase of his/her career.
- The mentor should describe previous experience as a mentor, including type of mentoring (e.g., graduate students, career development awardees, postdoctoral students), number of persons mentored, and career outcomes.
- Identify all co-mentors, consultants and collaborators involved with the proposed research and career development program (if applicable).

VII. Reporting and Evaluation

Scholars and their mentors will meet on a regular basis, agree on productivity goals, discuss the scholar's progress and document these at least quarterly using the Individual Academic Career Development Plan or an equivalent, validated tool. In addition, scholars will participate in a bidirectional evaluation process semi-annually. This will be a proactive process designed to identify and overcome any barriers to success and to promote accelerated career development through networking.

All publications derived from work performed during this CNSTARR award must include the following text in the acknowledgements: ***"This publication [or project] was supported by Award Numbers R38 AI140298-01"***

VIII. Key CNSTARR Contacts

- Stephen Teach, MD, MPH (STeach@childrensnational.org) – Program Director
- Robert Freishtat, MD, MPH (RFreishtat@childrensnational.org) – Associate Director
- Andrea Hahn, MD, MS (ALHahn@childrensnational.org) – Director of Resident Research

IX. CTSI-CN Related Resources

The Clinical and Translational Science Institute at Children's National (CTST-CN) supports the CNStARR Program. CTSI-CN fosters broad collaborative investigation that accelerates discovery and drives dialogue across the bench, bedside, and community continuum. Investigators are encouraged to consult with CTSI-CN resources to further develop their proposals.

- **Informatics Core:** The Informatics Core provides a comprehensive, integrated informatics ecosystem to investigators and their study teams by unifying bioinformatics and medical informatics and provides investigators and their teams with easy access to data and analytic tools required for current and future CTR needs. The Informatics Core also provides investigators and their teams with training in informatics methods and tools in order to promote self-sufficiency among researchers in the use of informatics across the enterprise.
    - Keith Crandall, PhD (kcrandall@email.gwu.edu) – Co-Lead
    - Hiroki Morizono, PhD (HMorizono@childrensnational.org) – Co-Lead
    - Qing Zeng, PhD (zengq@email.gwu.edu) – Co-Lead
- **Community Engagement:** The Community Engagement module focuses on two communities and their interconnection in support of CTR: the lay public in the Washington, DC region and the multidisciplinary academic community of the CTSI-CN. In a broad sense, community engagement starts at the early stages of a research project's development and continues through its completion and dissemination.
    - Kathleen Roche, PhD, MSW (kroche@email.gwu.edu) – Co-Lead
    - Chaya Merrill, DrPH (CMerrill@childrensnational.org) – Co-Lead
- **Collaboration and Multidisciplinary Team Science (CMTS):** The goal of the CMTS module is to foster collaborative research teams among the varied scientific and clinical disciplines and the broad community (e.g. lay public, patient advocacy groups, foundations, industry). The strategy involves identifying, training, utilizing, and disseminating best practice in team science as applied to child health CTR. It also includes crediting each member of the team appropriately in recognition of his/her contribution.
    - Susan Knoblach, PhD (sknoblach@childrensnational.org) – Co-Lead
    - Kevin Cleary, PhD (kcleary@childrensnational.org) – Co-Lead
    - Sean Cleary, PhD, MPH (sdcleary@email.gwu.edu) – Co-Lead
    - Sharon Hill, PhD (nshill@email.gwu.edu) - Co-Lead
    - Lynn Offermann, PhD (lro@gwu.edu) - Co-Lead
- **Translational Workforce Development (TWD):** The overall objective of the TWD module is to provide workforce members with a flexible and continuous learning environment that will lead to high quality, efficient, and effective CTR. The major TWD initiatives focus on: 1) an expanded portfolio of on-demand training opportunities targeted at faculty and trainees, as well as staff and community members; 2) integrating a team science curriculum into our training and educational initiatives; and 3) focusing on team and leadership development within translational research teams.

    - Reamer Bushardt, PharmD, PA-C (rbushardt@email.gwu.edu) – Co-Lead
    - Debra Regier, MD (DRegier@childrensnational.org) – Co-Lead
- **Pilot Translational and Clinical Studies Program (PTCS):** The PTCS program is an essential underpinning of a strong CTR program. Without the support to develop methods, test concepts, or establish feasibility, the successful conduct of definitive evaluative research is virtually impossible.
    - Timothy McCaffrey, PhD (mcc@email.gwu.edu) – Co-Lead
    - Maureen Monaghan, PhD, CDE (MMonagha@childrensnationa.org) – Co-Lead
- **Grants Enhancement Program (GEP):** The GEP provides critical support for junior faculty in writing and implementing career development awards; a mechanism for monitoring the progress of early-stage investigators; a venue for review/critique of grant applications from senior investigators, and guidance/assistance with questions and problems with assembly and packaging of applications. Building on a program of research support for junior faculty led by Dr. Peter Scheidt, the GEP was established in 2012 under the CTSI-CN. The goal of this program is to improve grant applications submitted by CNHS junior faculty and new investigators in order to maximize the chance of success. GEP is comprised of Drs. Peter Scheidt (Director), Stephan Ladisch, Mendel Tuchman, and Cynthia Rand. The GEP conducts a variety of activities to support and encourage junior and mid-level faculty in development of competitive proposals and obtaining funding. Providing internal review, feedback, and consultation of proposals by GEP faculty (in addition to those of mentors and supervisors) is the core and most important function of the GEP. Reviews and consultations are available and conducted at any time in the course of developing a proposal from the initial draft of specific aims to a final proposal. In addition, when appropriate subject-matter expertise is not available at CNHS, the GEP facilitates and obtains in-depth external review of well-developed proposals by carefully selected experienced external reviewers. GEP also organizes and leads monthly group meetings with peer investigators who are “in the same boat” for those seeking Mentored Career Development Awards (the K group) and for those seeking R01 type funding (the Emerging Independent Investigator–E2I–Group). Through these group activities, participants share current updated information on the whole process of grant preparation, access examples of successful applications, and other supporting materials, and obtain peer review and feedback on their evolving proposals. Finally, the GEP organizes both study section-like reviews of proposals in a conference setting with multiple reviewers for feedback and for educational benefit and seminar-like sessions for investigators who are seeking broad input, creative ideas, and collaboration opportunities early in project development. CNSTARR scholars will be required to enroll in the GEP for preparation of their extramural proposal during the award period.
    - Stephan Ladisch, MD (sladisch@childrensnational.org) – Director
    - Peter Scheidt, MD, MPH (pscheidt@childrensnational.org)
- **Biostatistics, Epidemiology and Research Design (BERD):** BERD provides high quality biostatistical and epidemiological expertise for the development and design of pediatric and lifespan CTR. It provides brief consulting for data analysis and assists investigators in identifying qualified statisticians, epidemiologists, and data managers for additional support of their studies beyond what CTSI-CN can provide. Where appropriate, GW Biostatistics Practicum graduate students provide additional data analysis needs to CTSI-CN investigators, and K awardees receive more support, should they require it. Consultations are coordinated through the CTSI-CN supported SPARC portal (Services, Pricing, & Application for Research Centers).
    - James Bost, PhD (jbost@childrensnational.org) – Co-Lead
    - Samuel Simmens, PhD (simmens@email.gwu.edu) – Co-Lead
- **Regulatory Knowledge and Support (RKS):** The primary goal of the RKS module is to assist CTR investigators and their teams by providing proactive, innovative regulatory and research

ethics education and support services to assure that child health CTR research meets the highest standards of ethical conduct and regulatory compliance.
    - Naynesh Kamani, MD (NKAMANI@childrensnational.org)
- **Integrating Special Populations (ISP):** We define special populations as: 1) children from underserved populations, i.e. those experiencing health disparities; 2) fetuses and their mothers; and 3) children with rare genetic disorders. ISP provides support, resources, and innovative tools to assist investigators in including these special populations in CTR projects.
    - Debra Regier, MD, PhD (DRegier@childrensnational.org) – Co-Lead
    - Catherine Limperopoulos, PhD (CLimpero@childrensnational.org) – Co-Lead
    - Ginger Winston, MD (GWinston@mfa.gwu.edu) – Co-Lead
    - Nancy Gaba, MD ((Ngaba@mfa.gwu.edu) – Co-Lead
- **Participant and Clinical Interactions (PCI):** The mission of PCI is to provide a high-quality, safe, and welcoming environment for pediatric study participants and investigators. PCI encompasses a variety of resources and services divided in sub-components. Each sub-component provides specialized services for investigators/research staff and their clinical research protocols. Services can be performed in the PCI or in other hospital areas, both inpatient and outpatient. All PCI personnel are trained in GCP as well as comprehensive training to perform each service/task with the highest level of efficiency, quality, and ethical standards. In addition, the PCI leadership and management team has many years of combined experience in clinical research in pediatrics and other vulnerable populations.
    - Suvankar Majumdar, MD (smajumdar@childrensnational.org) – Lead
    - Elizabeth Wells, MD – (ewells@childrensnational.org) - Co-Lead
    - Mardi Gomberg-Maitland, MD (mgomberg@mfa.gwu.edu) - Co-Lead
    - Melissa Napolitano, PhD (mnapolitano@email.gwu.edu) – Co-Lead
    - Richard Lush, PhD (RMLush3@email.gwu.edu) – Co-Lead
    - **ClinicalTrials.gov Support:** In partnership with the IRB, PCI sends reminders to electronic submitters to register and provide study results on ClinicalTrials.gov and in collaboration with the Informatics Core, ensures that the ClinicalTrials.gov NCT# is entered in our EHR for patients enrolled in research studies.
    - **Scientific Review Committee (SRC):** The new SRC pre-screens the following human research IRB submissions: 1) pilot projects, 2) clinical trials by K or T awardees, or other trainees, or 3) foundation, small pharmaceutical or biotech grants. The SRC exempts proposals with prior rigorous peer-review (e.g. NIH R, other federal awards) unless the associated human research protocol has not been reviewed.
    - **Bionutrition Services:** This service provides: 1) caloric intake assessment; 2) special meal design; 3) nutrient analysis; 4) anthropometric measurements using stadiometers, length board, knee height and Lange calipers, infant and standing weight scales; 5) body composition assessments using air displacement plethysmography and/or bioelectrical impedance analysis; and 6) energy expenditure and fitness studies utilizing a metabolic cart. Up to 4-hours of free services are provided for preliminary data gathering with structured cost recovery built into subsequent grant budgets.
    - **Neurobehavioral and Psychosocial Evaluation Core (NPEC):** This Core function provides assessments of infants, children, adolescents, and adults, including cognition, behavior, social/environmental and family dynamics assessments, as well as consultation on behavioral phenotyping, selection of optimal assessment tools, and functional MRI applications for research on neurodevelopmental disorders.
    - **Biorepository:** The CTSI-CN Biorepository provides expert assistance with: 1) bio-specimen collection, processing (e.g. DNA and or protein extraction), and storage for IRB-approved protocols; and 2) data and sample management including the FreezerPro laboratory management system of over 10,000 samples. In addition to maintaining this resource, the CTSI-CN Biorepository leverages existing expertise and resources to include a state-of-the-art HIV-related biorepository.

- **Liaison to Trial Innovation Centers (LTIC):** The goal of the LTICs module is to provide an efficient and effective environment and trial readiness to participate in multicenter studies through the CTSA TICs streamlined procedures for the implementation of multicenter research projects. The primary objective of LTICs is to facilitate the initiation and implementation of clinical studies in CTSI-CN, functioning as a liaison between CTR investigators and the planned CTSA TICs.
    - Adelaide Robb, MD (AROBB@childrensnational.org) – Co-Lead
    - Michael Bell, MD (MBell@childrensnational.org) – Co-Lead
    - Richard Lush, PhD (RMLush3@email.gwu.edu) – Co-Lead
    - Mardi Gomberg-Maitland, MD (mgomberg@mfa.gwu.edu) - Co-Lead
- **Liaison to Recruitment Innovation Centers (LRIC):** LRIC assists with maximizing the recruitment to pediatric and rare genetic diseases studies in the CTSI-CN by using a variety of existing and developing informatics tools, educating users on their use, and reaching out to the community to maximize the buy-in of community stakeholders and their encouragement of their constituents about participation in CTR.
    - Olga Acosta Price, PhD (oaprice@gwu.edu) – Lead
    - Madison Berl, PhD (MBerl@childrensnational.org) – Co-Lead
    - Daisy Le, PhD, MPH/MA (daisyle@gwu.edu) – Co-Lead
- **Orphan Product Accelerator – Innovations Incubator (OPA-II):** OPA-II provides the infrastructure, assistance, and training for CTR investigators in the development of orphan products, specifically those aimed at the diagnosis and treatment of rare diseases, many of which are particularly relevant to children. The overarching goal of the OPA-II is to develop innovative methods for reducing both the cost and time required to bring orphan products to market.
    - Kolaleh Eskandanian, PhD, MBA, PMP (keskanda@childrensnational.org) – Lead
    - Igor Efimov, PhD (efimov@email.gwu.edu) – Co-Lead
- **Child Health Research Acceleration Through Multisite Planning (CHAMP):** CHAMP seeks to provide the infrastructure, assistance, and training for CTR investigators in the performance of multi-site clinical studies. For rare genetic diseases and other disorders of childhood, natural history studies, in combination with clinical trials, are essential for advancing child health. The CHAMP program seeks to develop the infrastructure and training program for multi-center trials initially involving CTSA hubs that have a strong pediatric focus.
    - Lisa Guay-Woodford, MD (LGuaywoo@childrensnational.org) - Lead