Clinical and Translational Science Institute at Children’s National (CTSI-CN)

Mentored Career Development Award (KL2)
Information and Instructions for 2017-2018 Application

TABLE OF CONTENTS

I. Introduction.......................................................................................................................... 2
II. Important Dates.................................................................................................................... 2
III. Overview............................................................................................................................. 2
IV. Eligibility Requirements....................................................................................................... 4
V. Review Criteria..................................................................................................................... 4
VI. Content and Format of Application Submission................................................................. 5
VII. Reporting and Evaluation.................................................................................................. 10
VIII. Key KL2 Contacts............................................................................................................. 11
IX. CTSI-CN Related Resources............................................................................................ 11
X. Useful Links......................................................................................................................... 15
I. Introduction

National Center for Advancing Translational Sciences (NCATS) Mission

The mission of NCATS includes strengthening the entire spectrum of translational research. NCATS defines translational research broadly to include the early steps necessary to develop new therapeutics, devices, and diagnostics from basic discoveries, the steps necessary to establish real world efficacy, and the research needed to improve the practical implementation and dissemination of improved approaches to care. This breadth is described as T0 through T4.

- **T0 - Basic Science Discovery**: Working experimental models directed at mechanisms and treatments of human disease
- **T1 - Translation to Humans**: Testing basic science discoveries for clinical effect and/or applicability
- **T2 - Translation to Patients**: Testing new interventions in human subjects under controlled environments to form the basis for clinical applications and evidence-based guidelines
- **T3 - Translation to Practice**: Research on the application of new interventions or therapies in general practice; research that yields knowledge on best ways to implement new medical interventions in the clinic
- **T4 - Translation to Population**: Investigations of factors and/or interventions that influence the health of populations; ultimately results in improved health of the public

Clinical and Translational Science Institute at Children’s National version 2.0 (CTSI-CN v2.0) Vision and Mission

The Clinical and Translational Science Institute at Children’s National (CTSI-CN) was established in 2010 as a collaboration between Children’s National Health System (CNHS) and our academic partner, The George Washington University (GW). CTSI-CN v2.0 serves as a hub within the CTSA Network focused on promoting child health through clinical and translational research (CTR).

The vision of CTSI-CN v2.0 is that every child can reach his/her full potential and live a healthy and productive life assisted by advances in CTR.

To realize this vision, the CTSI-CN v2.0 serves as a catalyst for child-health CTR by focusing on five major themes: 1) improving the child health, particularly for underserved populations; 2) developing novel treatment strategies for rare genetic diseases; 3) designing new devices for pediatric care; 4) characterizing childhood precursors of disease along the lifespan; and 5) implementing systems for effective transition of children with chronic diseases to adult care systems.

II. Important Dates

- **RFA Release**: April 4, 2017
- **Letter of Intent**: April 17, 2017 by 5:00 pm
- **Notification to Apply**: April 19, 2017
- **Applications Due**: May 15, 2017 by 5:00 pm
- **Notification of Awards**: Late May 2017
- **Funds Available**: June 1, 2017 – May 31, 2018

III. Overview

A critical function of the CTSI-CN is to train highly motivated individuals from different disciplines with varied scholarly interests to conduct multidisciplinary clinical/patient-oriented research. This is one of several programs within the CTSI-CN and is called the Mentored Career Development Award (KL2).
In this round of the KL2 process, up to 2 awards will be made if sufficiently meritorious applications are received. Funding will be awarded for 2 years; a maximum of 3 years of funding will be considered if sufficient justification is provided for a 3-year research and training program.

The KL2 program recruits junior faculty early in their career who have demonstrated the aptitude and commitment to undertake multidisciplinary CTR. All applicants for KL2 grant consideration, including the Letter of Intent (LOI) stage, must be CTSI-CN members. Membership is free. Registration may be found at [www.ctsicn.org](http://www.ctsicn.org) (hit the BECOME A CTSI-CN MEMBER in the upper right corner) and enter your contact information.

It is expected that the scholar will:

- **Devote 75% of his/her full-time professional effort to the KL2 program** for the training and clinical research activities. This is based on the entire amount of time worked in a typical week. The remaining 25% effort can be divided among other clinical, administrative, and teaching responsibilities that are consistent with the proposed goals of the KL2 program. Sources of support for the 75% effort include the CTSI-CN funds of up to $75,000 per year. The department of the scholar must cover the difference, if any, between the available $75,000 and 75% of the scholar's salary. The CTSI-CN will provide an additional $25,000 per year for KL2 program related educational and research expenses. *Please refer to Section IX of this RFA for additional information about NIH policy on receiving concurrent support.*

- **Obtain additional research training** through participation in coursework, workshops, and/or individualized programs of study. This requirement can, for example, be met by enrolling in the CTSI-CN Master's degree or Graduate Certificate in Clinical and Translational Research.

- **Engage in human-oriented research** relevant to the spectrum of translational research.

  **Definitions of translational research:**
  - Translation 1 ("T1"): from basic science to health application
  - Translation 2 ("T2"): from health application to evidence-based guideline
  - Translation 3 ("T3"): from evidence-based guideline to health practice
  - Translation 4 ("T4"): from health practice to health impact in the population

- **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. The lead mentor will also ensure that 75% of the Scholar's effort is protected from clinical and administrative duties and is fully dedicated to the KL2 program. A co-mentor or mentors should be selected with the background required to assure multi-disciplinary input to the KL2 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.

- **Participate in the activities of the CTSI-CN and the CTSA National Consortium** by presenting research results in various forums including the annual Association for Clinical and Translational Science (ACTS) meeting and assisting in the recruitment of additional trainees into the CTSI-CN supported educational and training programs.
IV. Eligibility Requirements

Candidates for the CTSI-CN KL2 award must:

• Be a US Citizen or Permanent Resident
• Possess a doctoral degree (MD, PhD, PharmD, DMD, DDS, OD, DNS/PhD in nursing, etc.) and be a junior faculty (assistant professor, instructor or equivalent), either currently appointed or newly recruited (within the past 5 years).
• Commit 75% of professional effort to the program
• Not be or have been a principal investigator on an NIH R01 or equivalent PHS or non-PHS peer-reviewed research grants that are over $100,000 in direct costs per year. Those who have been PI on an R02 or R21 are eligible. KL2 applicants may not have any other career development award (K08, K01, K23) pending at the time of review.
• Develop a multidisciplinary education, training and research plan.
• Commit to a career in CTR with past evidence of significant productivity and promise.
• Commit to CTR training through formalized coursework with emphasis in research methods for patient-oriented research (for example, the GW Master's degree or Graduate Certificate in Clinical and Translational Research).
• Have completed training in the Responsible Conduct of Research.
• Make time commitment to actively participate in quarterly KL2 Special Interest Group, grants training and presentation of scholarly work.
• Apply for independent research grant support DURING the period of KL2 support.

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

V. Review Criteria

• Overview of Review Process: The review of applications is performed in 3 phases: (1) LOI, (2) Scientific Review, and (3) Administrative Review. During the first phase, the 1-page LOI will be scored and ranked, and the top applicants will be invited to submit a formal 12-page full application. The number of applicants invited to apply will vary, judged by number and merit of applications received. No critiques will be provided to applicants during the LOI stage. During the second phase, the 12-page applications will be reviewed by 2-3 primary scientific reviewers, who will score the applications following KL2 program guidelines. All applications will also be reviewed by a larger scientific review committee during an in-person study section meeting. Following this meeting, applicant scores will be tabulated and ranked and KL2 program leaders will meet to discuss and determine awardees. Critiques from the second phase of the review will be provided to the applicants after awards are announced.

• Letter of Intent: The LOI consists of 1 page outlining the applicant’s research objectives (i.e. specific aims) and career development plan (including mentorship and training plan). The LOI should be accompanied by the candidate and lead mentor’s biosketches (NIH format).

LOI must be submitted electronically through the Services, Pricing, & Application for Research Center (SPARC) Request portal (see section IX for web address). If you do not have a SPARC account, please create a new account within the portal providing the following information Last Name, First Name, Institution, Email, Telephone Number, Username, and Password. For issues related to SPARC, please contact the SPARC helpdesk (sparcrequest@childrensnational.org).

KL2 Scientific Review will be consistent with NIH review system as follows:

• Candidate
• Career Development Plan/Career Goals & Objectives
• Research Plan
• Mentor, Co-Mentor(s), Consultant(s), Collaborator(s)
• Department/Division Chief’s Commitment to the Candidate

Additional Review Criteria 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)

Additional Review Considerations include the following:
• CTR representing the continuum from infancy to childhood
• Pediatric Health relevance, defined as either the investigation of a child health condition or the adult expression of childhood circumstances/risk
• Joint Children’s National-GW mentoring

The reviewers will use the NIH 9-point rating system for the impact priority score of 1 (exceptional) to 9 (poor).

1. Assigned reviewers will provide ratings for each review criteria described above using the 9-point scale.
   • 1 to 3 = high impact
   • 4 to 6 = moderate impact
   • 7 to 9 = low impact

2. An overall score will be assigned to each application in the range of 1-9.

Individual reviewer scores will be averaged and the result multiplied by 10 to determine the final impact score (range of 10-90).

VI. Content and Format of Application Submission

The KL2 application includes the following required elements: Use the standard SF424 (R&R) forms for budget, biosketch and other support; 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.

Additional resources can be found at NIH K Kiosk:

https://researchtraining.nih.gov/programs/career-development

Detailed Career Development Award Application Instructions can be found at:


<table>
<thead>
<tr>
<th>Required Elements</th>
<th>Instruction/Format</th>
</tr>
</thead>
<tbody>
<tr>
<td>Face Sheet</td>
<td>See Attached</td>
</tr>
<tr>
<td>KL2 Career Development Plan (4 pages)</td>
<td>Candidate’s Background: Describe your past scientific history, indicating how the award fits into past and future research career development. If there are consistent themes or issues that have guided previous work, these should be made clear; if your work has changed direction, the reasons for the change should be indicated. Any additional information not described in the Biographical Sketch Format Page, such as research and/or clinical training experience, may be included in this section.</td>
</tr>
<tr>
<td>Required Elements</td>
<td>Instruction/Format</td>
</tr>
<tr>
<td>-------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td>Suggested points to include:</td>
<td></td>
</tr>
<tr>
<td>• Describe the candidate's commitment to an academic career in Clinical / Translational Research. Include a description of all of the candidate's professional responsibilities in the grantee institution and elsewhere and show their relation to the proposed activities on the career award.</td>
<td></td>
</tr>
<tr>
<td>• Present evidence of the candidate's ability to interact and collaborate with other scientists.</td>
<td></td>
</tr>
<tr>
<td>• Describe prior training and how it relates to the objectives and long-term career plans of the candidate.</td>
<td></td>
</tr>
<tr>
<td>• Describe the candidate's research efforts to this point in his/her research career, including any publications, prior research interests and experience.</td>
<td></td>
</tr>
<tr>
<td>• Provide evidence of the candidate's potential to develop into an independent investigator.</td>
<td></td>
</tr>
<tr>
<td>• Include a statement that the candidate will commit at least 9 person-months (75% of full-time professional effort) to the KL2 program and related career development activities. The mentor or department chair must agree and provide a statement in the application documenting that this percent of the candidate’s time will be protected.</td>
<td></td>
</tr>
<tr>
<td>Career Goals and Objectives:</td>
<td></td>
</tr>
<tr>
<td>Describe your short-term and long-term career goals and objectives are, and how the career development award is envisioned to enable you to develop and/or expand your research career. It is important to justify the need for the award. You are encouraged to include a timeline, including plans to apply for subsequent grant support (i.e. to become an independent investigator).</td>
<td></td>
</tr>
<tr>
<td>Candidate’s Plan for Career Development/ Training Activities During Award Period:</td>
<td></td>
</tr>
<tr>
<td>• Describe the new or enhanced research skills and knowledge you will acquire as a result of the proposed award. If you have considerable research experience in the same areas as the proposed research, reviewers may determine that the application lacks potential to enhance your research career.</td>
<td></td>
</tr>
<tr>
<td>• Describe any structured activities that are part of the developmental plan, such as coursework, or workshops that will help you learn new techniques or develop needed professional skills. The didactic (if any) and the research aspects of the plan must be designed to develop the necessary knowledge and research skills in scientific areas relevant to the candidate's career goals. The candidate must demonstrate they have received training or will participate in courses such as: data management, epidemiology, study design (including statistics), hypothesis development, drug development, etc., as well as the legal and ethical issues associated with research on human subjects. If coursework is included, provide course numbers and descriptive titles. Briefly discuss each of the activities, other than research, in which you expect to participate.</td>
<td></td>
</tr>
<tr>
<td>• Describe the professional responsibilities/activities including other research projects) beyond the minimum required 75% effort commitment to the KL2 award. Explain how these</td>
<td></td>
</tr>
<tr>
<td>Required Elements</td>
<td>Instruction/Format</td>
</tr>
<tr>
<td>-------------------</td>
<td>--------------------</td>
</tr>
<tr>
<td></td>
<td>responsibilities/activities will help ensure career progression to achieve independence as an investigator conducting patient-oriented research.</td>
</tr>
<tr>
<td></td>
<td>• The sponsor/mentor may form an advisory committee to assist with the development of the program of study or to monitor the candidate's progress through the career development program.</td>
</tr>
</tbody>
</table>

**Mentor Statement**

This letter will be co-signed by Mentor and Co-Mentor(s)

The Lead Mentor and Co-Mentor(s) 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. It should discuss expectations for publications over the entire period of the proposed project and define what aspects of the proposed research project the candidate will be allowed to take with him/her to start their own research program.

- The source of anticipated support for the candidate’s research project for each year of the award period.

- 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.

- The candidate’s anticipated teaching load for the period of the award (number and types of courses or seminars), clinical responsibilities, committee and administrative assignments, and the portion of time available for research.

- A plan for transitioning the candidate from the mentored stage of his/her career to the independent investigator stage by the end of the project period of the award. 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.

**Training in the Responsible Conduct of Research**

- Applications must include a plan to obtain instruction in the responsible conduct of research.

- This section should document prior instruction in responsible conduct of research during the applicant’s current career stage (including the date of last occurrence) and propose plans to receive instruction in responsible conduct of research.

- The plan may include career stage-appropriate, individualized instruction or independent scholarly activities that will enhance the applicant’s understanding of ethical issues related to their specific research activities and the societal impact of that research.

- The role of the sponsor/mentor in responsible conduct of research instruction must be described.

**KL2 Department / Division Chair Statement (1 page)**

Instruction for the Chair: *Please indicate the resources that you will provide to support the candidate's research. Be specific as to amount of space, number and kind of staff, clinical and lab resources, and dollars you will make available to the scholar (this has an important impact on our funding decision).*

**Two (2) Letters of Reference**

These letters should come from other individuals who can comment on the applicant’s qualifications for future career as an independent clinical and
<table>
<thead>
<tr>
<th>Required Elements</th>
<th>Instruction/Format</th>
</tr>
</thead>
<tbody>
<tr>
<td>CTSI-CN Mentored Career Development Award (KL2) RFA</td>
<td></td>
</tr>
<tr>
<td>Required Elements</td>
<td></td>
</tr>
<tr>
<td>Project Summary/Abstract (no longer than 30 lines)</td>
<td>The Project Summary must contain a summary of the proposed activity suitable for dissemination to the public. It should be a self-contained description of the project and should include a statement of objectives and methods to be employed. It should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically literate lay reader. This Summary must not include any proprietary/confidential information. The Project Summary is meant to serve as a succinct and accurate description of the proposed work when separated from the application. State the application's broad, long-term objectives and specific aims, making reference to the health relatedness and translational nature of the project. Describe concisely the research design and methods for achieving the stated goals. This section should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically literate reader. Avoid describing past accomplishments and the use of the first person. This section must be no longer than 30 lines of text, and follow the required font and margin specifications.</td>
</tr>
<tr>
<td>Biographical Sketches (maximum 5 pages per biographical sketch)</td>
<td>Provide a biographical sketch for the candidate, Mentor, co-Mentor(s), and any other senior/key personnel, as applicable. Use PHS 398 format, provided here: <a href="http://grants.nih.gov/grants/forms/biosketch.htm">http://grants.nih.gov/grants/forms/biosketch.htm</a></td>
</tr>
<tr>
<td>Specific Aims (1 page)</td>
<td>State precisely the goals of the proposed research and summarize the expected outcome(s) including the impact that the results of the proposed research will exert on the research field(s) involved. List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.</td>
</tr>
<tr>
<td>Research Strategy (8 pages)</td>
<td>Organize the Research Strategy in the specified order and using the instructions provided below. Start each section with the appropriate section heading – Significance, Innovation, Approach. Cite published experimental details in the Research Strategy section and provide the full reference in the Bibliography and References Cited section. (a) Significance • Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses. • Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields. • Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved. (b) Innovation • Explain how the application challenges current research or clinical practice paradigms. • Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.</td>
</tr>
</tbody>
</table>
(c) Approach

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately in Item 21 (Resource Sharing Plan), include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.
- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
- If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high-risk aspects of the proposed work.
- Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised.

Institutional Environment (1 page)

Specify specific resources that support the proposed research.

Bibliography and References Cited (no specific page limitation applies)

Provide a bibliography of any references cited in the Project Narrative. Each reference must include the names of all authors (in the same sequence in which they appear in the publication), the article and journal title, book title, volume number, page numbers, and year of publication. Include only bibliographic citations. Applicants should be especially careful to follow scholarly practices in providing citations for source materials relied upon when preparing any section of the application.

Protection of Human Subjects (no specific page limitation applies, but please be succinct)

This section is required for applicants whose project involves human subjects. Do not use the protection of human subjects section to circumvent the page limits of the Research Strategy.

Vertebrate Animals (no specific page limitation applies, but please be succinct)

This section is required for applicants whose project involves vertebrate animals. If so you must address the following five key points. In addition, when research involving vertebrate animals will take place at collaborating site(s) or other performance site(s) provide this information before discussing the five points. Although no specific page limitation applies to this section of the application, be succinct.

1. Provide a detailed description of the proposed use of the animals in the work outlined in the Research Strategy section. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.
2. Justify the use of animals, the choice of species, and the numbers to be used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers.
3. Provide information on the veterinary care of the animals involved.
4. Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury.
5. Describe any method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines on Euthanasia. If not, include a scientific justification for not following the recommendations.

If the involvement of animals is indefinite, provide an explanation and indicate when it is anticipated that animals will be used. If an award is made, prior to the...
<table>
<thead>
<tr>
<th>Required Elements</th>
<th>Instruction/Format</th>
</tr>
</thead>
</table>
| **Select Agent Research**         | **This section is required for applicants whose project involves select agents.**                                                                                       

Select Agents are hazardous biological agents and toxins that have been identified by DHHS or USDA as having the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products. CDC maintains a list of these agents. See http://www.cdc.gov/od/sap/docs/salist.pdf. 

If any of the activities proposed in your application involve the use of Select Agents at any time during the proposed project period, either at the applicant organization or at any other performance site, address the following three points for each site at which Select Agent research will take place. Although no specific page limitation applies to this section, be succinct. 

1. Identify the Select Agent(s) to be used in the proposed research. 
2. Provide the registration status of all entities* where Select Agent(s) will be used. 
   - If the performance site(s) is a foreign institution, provide the name(s) of the country or countries where Select Agent research will be performed. 
   *An “entity” is defined in 42 CFR 73.1 as “any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.” 
3. Provide a description of all facilities where the Select Agent(s) will be used. 
   - Describe the procedures that will be used to monitor possession, use and transfer of the Select Agent(s). 
   - Describe plans for appropriate biosafety, bio-containment, and security of the Select Agent(s). 
   - Describe the bio-containment resources available at all performance sites. |
| **Budget and Justification**      | **Within the guidelines of this RFA Provide a budget for Initial Budget Period using PHS 398 format provided in the link below** http://grants.nih.gov/grants/funding/phs398/phs398.html (Form Page 4)                                                                                                                                                                                                                     |
| **Diversity Questionnaire**       | **Self-explanatory**                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| **Checklist (required by NIH)**   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |

**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 be required to submit period REDCap progress reports. This will be a proactive process designed to identify and overcome any barriers to success, facilitate access to CTSI-CN resources, and promote accelerated career development through networking. Scholars will also present their work in progress at a combined
annual retreat for CTSI-CN training programs, and will work with CTSI-CN Core Directors to help advance the CTSI-CN mission by serving on committees and assisting in the recruitment and training of scholars to other CTSI-CN educational programs. In addition, scholars will be asked to provide advice and feedback regarding the success of this program and methods for improving it. Documentation from both scholars and their mentors will be submitted at regular intervals.

All publications derived from work performed during this KL2 award must include the following text in the acknowledgements: “This publication [or project] was supported by Award Numbers UL1TR001876 and KL2TR001877 from the NIH National Center for Advancing Translational Sciences. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the National Center for Advancing Translational Sciences or the National Institutes of Health.”

The KL2 award allows for 2-years of guaranteed support followed by the option of a 3rd year after competitive review contingent on meeting the programmatic, professional, and productivity expectations identified above.

VIII. Key KL2 Contacts

- Naomi L.C. Luban, MD (NLUBAN@childrensnational.org) – Project Lead
- Reamer Bushardt, ParmD, PA-C (rbushardt@email.gwu.edu) – Project Co-Lead
- An Massaro, MD (ANGuyenM@childrensnational.org) – Associate Director
- Patricio Ray, MD (PRAY@childrensnational.org) – Diversity Enhancement Officer

IX. CTSI-CN Related Resources

The 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) – Lead
  - Hiroki Morizono, PhD (HMorizono@childrensnational.org) – Co-Lead
  - Qing Zeng, PhD (zengq@email.gwu.edu) – Co-Lead
  - Brian Jacobs, MD (bjacobs@childrensnational.org) – 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) – 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.

- Kevin Cleary, PhD (kcleary@childrensnational.org) – Co-Lead
- Sean Cleary, PhD, MPH (sdcleary@email.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.

- Mary Ottolini, MD (MOTTOLIN@childrensnational.org) – Lead
- Reamer Bushardt, PharmD, PA-C (rbushardt@email.gwu.edu) – 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.

- Robert Freishtat, MD, MPH (rfreishtat@childrensnational.org) – Lead
- Timothy McCaffrey, PhD (mcc@email.gwu.edu) – 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), Mary Rose, Stephan Ladisch, 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. KL2 scholars will be required to enroll in the GEP for preparation of their extramural proposal during the award period.

- Peter Scheidt, MD (PScheidt@childrensnational.org) – Director
• **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 ([ibost@childrensnational.org](mailto:ibost@childrensnational.org)) – Lead
  - Samuel Simmons, PhD ([simmens@email.gwu.edu](mailto: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.

  - Lawrence Deyton, MSPH, MD ([ldeyton@email.gwu.edu](mailto:ldeyton@email.gwu.edu)) – Lead
  - Tomas Silber, MD, MASS ([TSILBER@childrensnational.org](mailto:TSILBER@childrensnational.org)) – Co-Lead

• **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.

  - Catherine Limperopoulos, PhD ([CLimpero@childrensnational.org](mailto:CLimpero@childrensnational.org)) – 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.

  - Sheela Magge, MD, MSCE ([ShMagge@childrensnational.org](mailto:ShMagge@childrensnational.org)) – Lead
  - Gary Simon, MD ([gsimon@mfa.gwu.edu](mailto:gsimon@mfa.gwu.edu)) – Co-Lead
  - Melissa Napolitano, PhD ([mnapolitano@email.gwu.edu](mailto:mnapolitano@email.gwu.edu)) – Co-Lead
  - Kirsten Williams, MD ([KMWillia@childrensnational.org](mailto:KMWillia@childrensnational.org)) – Scientific Director

  - **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) biospecimen 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) – 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

- **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.
  - Peter Kim, MD (PKim@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
X. Useful Links


- Design, Epidemiology, and Biostatistics Component: [http://ctsicn.org/node/110](http://ctsicn.org/node/110)

- CTSI-CN Membership: [http://visitor.r20.constantcontact.com/manage/optin/ea?v=001L7pmMP5BCBxm_bXFa-W_bg%3D%3D](http://visitor.r20.constantcontact.com/manage/optin/ea?v=001L7pmMP5BCBxm_bXFa-W_bg%3D%3D)

- Grants Enhancement Program: [http://ctsicn.org/node/49](http://ctsicn.org/node/49)


- SPARC Request Portal: [http://ctsicn.org/node/159](http://ctsicn.org/node/159)