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

Mentored Career Development Award (KL2)

Information and Instructions for 2019-2020 Application

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I. Introduction

National Center for Advancing Translational Sciences (NCATS) Mission

The mission of NCATS includes strengthening the entire spectrum of translational research. The translational science spectrum represents each stage of research along the path from the biological basis of health and disease to interventions that improve the health of individuals and the public. The spectrum is not linear or unidirectional; each stage builds upon and informs the others. At all stages of the spectrum, NCATS develops new approaches, demonstrates their usefulness and disseminates the findings. Patient involvement is a critical feature of all stages in translation.

- **Basic Research:** Basic research involves scientific exploration that can reveal fundamental mechanisms of biology, disease or behavior. Every stage of the translational research spectrum builds upon and informs basic research. NCATS scientists typically do not conduct basic research; however, insights gained from the Center's studies along the translational spectrum can inform basic research.
- **Pre-Clinical Research:** Pre-clinical research connects the basic science of disease with human medicine. During this stage, scientists develop model interventions to further understand the basis of a disease or disorder and find ways to treat it. Testing is carried out using cell or animal models of disease; samples of human or animal tissues; or computer-assisted simulations of drug, device or diagnostic interactions within living systems.
- **Clinical Research:** Clinical research includes studies to better understand a disease in humans and relate this knowledge to findings in cell or animal models; testing and refinement of new technologies in people; testing of interventions for safety and effectiveness in those with or without disease; behavioral and observational studies; and outcomes and health services research. The goal of many clinical trials is to obtain data to support regulatory approval for an intervention.
- **Clinical Implementation:** The clinical implementation stage of translation involves the adoption of interventions that have been demonstrated to be useful in a research environment into routine clinical care for the general population. This stage also includes implementation research to evaluate the results of clinical trials and to identify new clinical questions and gaps in care.
- **Public Health:** In this stage of translation, researchers study health outcomes at the population level to determine the effects of diseases and efforts to prevent, diagnose and treat them. Findings help guide scientists working to assess the effects of current interventions and to develop new ones.

Clinical and Translational Science Institute at Children's National version 2.0

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 Clinical and Translational Science Award (CTSA) Network focused on promoting 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 CTR by focusing on five major themes: 1) improving the health, particularly for underserved populations; 2) developing novel treatment strategies for rare genetic diseases; 3) designing new devices for pediatric care; 4) characterizing disease and disorders along the lifespan and 5) implementing systems for effective transition of children with chronic diseases to adult care systems.

II. Important Dates

- **RFA Release:** January 8, 2019
- **Letter of Intent:** January 18, 2019 by 5:00pm
- **Notification to Apply:** January 22, 2019
- **Applications Due:** March 5, 2019 by 5:00 pm
- **Notification of Awards:** April 1, 2019
- **Funds Available:** June 1, 2019 (pending human subjects approval) – May 31, 2020

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 (click ***Join the CTSI-CN!*** 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 $100,000 per year. The department of the scholar must cover the difference, if any, between the available $100,000 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 X 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.
- **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 CTR. 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 that 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 terminal 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 grant that has 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 MSHS in Clinical and Translational Research, Graduate Certificate in Clinical and Translational Research, or Graduate Certificate in Clinical Research Practice).
- 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 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 X 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 must be submitted in single-spaced text, 0.5-inch margins, no smaller than 11 point with applicant's name in the upper right corner of each page. Required elements are listed in the table below. ***The complete application must be uploaded as a single PDF file and submitted electronically through the Services, Pricing, & Application for Research Center (SPARC) Request portal*** (see section X for web address). For issues related to SPARC, please contact the SPARC helpdesk (sparcrequest@childrensnational.org).

Additional resources can be found at the NIH K Kiosk:

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

Detailed Career Development Award Application Instructions can be found at:

https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/career-forms-e.pdf

Face Sheet	**See attached**
R&R Senior/ Key Person Profile	Biosketches for all key personnel–including, scholar, lead and co-mentors–using the current NIH template (5-page limit each). https://grants.nih.gov/grants/forms/biosketch.htm
Budget Justification and Budget	Use the Budget Justification to provide a detailed description and justification for specific items within the Research Development Support costs (e.g., all equipment, supplies, and other personnel that will be used to help achieve the

	career development and research objectives of this award). PHS389 budget form must be included (see Section X below).
Candidate Section **(12-page limit combined with Research Strategy)**	Organize your attachment into three sections, following the headings and specified order below, and discuss each of the points listed below. Start each section with the appropriate section heading – Candidate's Background, Career Goals and Objectives, and Candidate's Plan for Career Development/Training Activities During Award Period. Also include any additional information requested in the FOA. ***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. Alternatively, if your work has changed direction, indicate the reasons for the change. ***Career Goals and Objectives:*** • Describe your short-term and long-term career goals. • Justify the need for the award by describing how the career development award will enable you to develop and/or expand your research career. • You are encouraged to include a timeline, including plans to apply for subsequent grant support. ***Candidate's Plan for Career Development/Training Activities During Award Period:*** • Describe the new or enhanced research skills and knowledge you will acquire as a result of the proposed award. • 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. • If coursework is included, provide course numbers (if available) and descriptive titles. • Briefly discuss each of the activities, other than research, in which you expect to participate. • For each activity, other than research, explain how it relates to the proposed research and to the career development plan. Indicate the percentage of time to be dedicated to each activity by year, expressed in person-months.
Research Plan Section **(Specific Aims: 1-page limit; Research Strategy: 12-page limit combined with Candidate section)**	The Research Plan is a major part of the overall career development goal. It is important to relate the proposed 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. Also describe how the research and other developmental activities will enable the candidate to launch and conduct an independent research career or enhance an established research career. A Career Development Award (CDA) Research Plan is expected to be tailored to the experience level of the candidate and to allow him/her to develop the necessary skills needed for further career advancement. Reviewers will evaluate the plan accordingly. The plan should be achievable within the requested time period. Pilot or preliminary studies and routine data gathering are generally not appropriate as the sole part(s) of a CDA Research Plan.

Specific Aims (1-page limit):

- State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will have 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).

Research Strategy (12-page limit combined with Candidate Section):

Organize the Research Strategy in the specified order and use the instructions provided below. Start each section with the appropriate heading – Significance, Innovation, Approach:

Significance

- Explain the importance of the problem or critical barrier to progress that the proposed project addresses.
- Describe the scientific premise for the proposed project, including consideration of the strengths and weaknesses of published research or preliminary data crucial to the support of your application.
- 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.

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.

Approach

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Describe the experimental design and methods proposed and how they will achieve robust and unbiased results. Include how the data will be collected, analyzed, and interpreted, as well as any resource sharing plans as appropriate.
- For trials that randomize groups or deliver interventions to groups, describe how your methods for analysis and sample size are appropriate for your plans for participant assignment and intervention delivery. These methods can include a group- or cluster-randomized trial or an individually randomized group-treatment trial.
- 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.
- Explain how relevant biological variables, such as sex, are factored into research designs and analyses for studies in vertebrate animals and humans. If you are proposing to gain clinical trial research experience (i.e., you will not be leading an independent clinical trial), briefly describe your role on the clinical trial.

Training in the Responsible Conduct of Research **(1-page limit)**	Mentored CDA applications should describe a plan to acquire instruction in the responsible conduct of research (RCR). Attach a description of plans for obtaining or providing instruction in RCR. This section should document prior instruction or participation in RCR training during the applicant's current career stage (including the date instruction was last completed). This section should also propose plans to receive instruction to meet the frequency requirement of RCR training. The plan must address the five required instructional components outlined in the NIH Policy on Instruction in the Responsible Conduct of Research (RCR), as more fully described in the NIH Grants Policy Statement, Section 12.4.1.4: Training in the Responsible Conduct of Research. 1. *Format:* Describe the required format of instruction, i.e., face-to-face lectures, coursework, and/or real-time discussion groups (a plan with only on-line instruction is not acceptable). 2. *Subject Matter:* Describe the breadth of subject matter (e.g., conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, research ethics). 3. *Faculty Participation:* Describe the role of the mentor(s) and other faculty involvement in the instruction. 4. *Duration of Instruction:* Describe the number of contact hours of instruction, taking into consideration the duration of the program. 5. *Frequency of Instruction:* Instruction must occur during each career stage and at least once every four years. Document any prior instruction during the applicant's current career stage, including the inclusive dates instruction was last completed. The plan may include career stage-appropriate individualized instruction or independent scholarly activities. Instruction and activities should 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 mentor in RCR instruction must be described.
Mentor, Co-Mentor, Consultant, Collaborators Section **(6-page limit total)**	Plans and Statements of Mentor and Co-Mentor(s)**:** The mentor and co-mentor(s) (if applicable) must each document their role and willingness to participate in the project, and explain how they will contribute to the development of the candidate's research career. Each statement should include all of the following: 1. The plan for the candidate's training and research career development. Include information not only about research, but also about other developmental activities, such as seminars, scientific meetings, training in RCR, and presentations. Discuss expectations for publications over the entire period of the proposed project. Define what aspects of the proposed research project the candidate will be allowed to continue to pursue as part of his/her independent research program. 2. The source of anticipated support for the candidate's research project for each year of the award period. 3. 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. 4. The candidate's anticipated teaching load for the award period (number and types of courses or seminars), clinical responsibilities, committee and administrative assignments, and the portion of time available for research.

	5. 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. Describe the mentor's (and co-mentor's) previous experience as a mentor, including type of mentoring (e.g., graduate students, career development awardees, postdoctoral fellows), number of persons mentored, and career outcomes. **Note for co-mentor statements:** Co-mentors must also address the nature of their role in the career development plan and how the responsibility for the candidate's development is shared with the mentor. Describe respective areas of expertise and how they will be combined to enhance the candidate's development. Also describe the nature of any resources that will be committed to this CDA. **Note for mentors of CDA applicants who are proposing to gain clinical trial research experience under a mentor's supervision (i.e., but will not be leading an independent clinical trial):** In addition to the information above, your statement must include the following: Source of funding; ClinicalTrials.gov Identifier (e.g., NCT87654321), if applicable; and a description of how your expertise is appropriate to guide the applicant in any proposed clinical trials research experience.
Letters of Support from Collaborators, and Consultants **(6-page limit total)**	Letters of support from collaborators, contributors, and consultants will be required for any such person who will contribute to the scientific development or execution of CDA application's proposed project. Letters are not required for personnel (such as research assistants) not contributing in a substantive, measurable way to the scientific development or execution of the project.
Environment and Institutional Commitment to Candidate Section **(2-page limit)**	Description of Environment and Institutional Commitment to Candidate's Research Career Development: The Department Chair or Center Director should provide a document on institutional letterhead that describes its commitment to the candidate and the candidate's career development, independent of the receipt of the CDA. It is also essential to document the institution's commitment to the retention, development, and advancement of the candidate during the period of the award. The "Institutional Commitment to Candidate's Research Career Development" attachment should generally document the institution's agreement to provide adequate time (explicitly state 75% effort), support, equipment, facilities, and resources to the candidate for research and career development activities. See the list below for specific items to include in the document. In the document describing its institutional commitment, the applicant organization must: 1. Agree to release the candidate from other duties and activities so that the candidate can devote the required percentage of time for development of a research career. 2. Describe actions that will be taken to ensure that the candidate can devote the required time to research career development (e.g., reduction of the candidate's teaching load, committee and administrative assignments, and clinical or other professional activities for the current academic year). If the candidate's clinical or teaching responsibilities will be reduced, describe how this will be accommodated (e.g., hiring additional staff, reassigning staff). 3. Describe the candidate's academic appointment, bearing in mind that the appointment must be full-time, and that the appointment (including all rights and privileges pertaining to full faculty status if in an academic setting) and the continuation of salary should not be contingent upon the receipt of this award.

	4. Describe the proportion of time currently available for the candidate's research and what the candidate's institutional responsibilities will be if an award is made. 5. Describe how the institution will provide the candidate with appropriate office and laboratory space, equipment, and other resources (including access to clinical and/or other research populations) to carry out the proposed Research Plan. 6. Describe how the institution will be supportive of any proposed mentor(s) and/or other staff consistent with the career development plan.
Other Project Information Sections	***Bibliography & References Cited*** ***Facilities & Other Resources:*** Describe how the scientific environment in which the research will be done contributes to the probability of success (e.g., institutional support, physical resources, and intellectual rapport). In describing the scientific environment in which the work will be done, discuss ways in which the proposed studies will benefit from unique features of the scientific environment or from unique subject populations or how studies will employ useful collaborative arrangements. If there are multiple performance sites, describe the resources available at each site. Describe any special facilities used for working with biohazards and any other potentially dangerous substances. **Note: Information about select agents must be described in the Research Plan, Select Agent Research.**
Human Subjects and Clinical Trails Information	NIH requires a Protection of Human Subjects attachment that is commensurate with the risks of the study, its size, and its complexity. Organize your attachment into four sections, following the headings and specified order below, and discuss each of the points listed below. Start each section with the appropriate section heading – Risks to Human Subjects, Adequacy of Protection Against Risks, Potential Benefits of the Proposed Research to Research Participants and Others, and Importance of the Knowledge to be Gained. Also include any additional information requested in the FOA. **1. Risks to Human Subjects** **a. Human Subjects Involvement, Characteristics, and Design** • Briefly describe the overall study design. • Describe the subject population(s) to be included in the study; the procedures for assignment to a study group, if relevant; and the anticipated numbers of subjects for each study group. • List any collaborating sites where human subjects research will be performed, and describe the role of those sites and collaborating investigators in performing the proposed research. **b. Study Procedures, Materials, and Potential Risks** • Describe all planned research procedures (interventions and interactions) involving study subjects; how research material, including biospecimens, data, and/or records, will be obtained; and whether any private identifiable information will be collected in the proposed research project. • For studies that will include the use of previously collected biospecimens, data or records, describe the source of these materials, whether these can be linked with living individuals, and who will be able to link the materials. • Describe all the potential risks to subjects associated with each study intervention, procedure or interaction, including physical, psychological, social, cultural, financial, and legal risks; risks to privacy and/or confidentiality; or other risks. Discuss the risk level and the likely impact to

subjects.
- Where appropriate, describe alternative treatments and procedures, including their risks and potential benefits. When alternative treatments or procedures are possible, make the rationale for the proposed approach clear.

2. Adequacy of Protection Against Risks

a. Informed Consent and Assent

Describe the process for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. When appropriate, describe how potential adult subjects' capacity to consent will be determined and the plans for obtaining consent from a legally authorized representative for adult subjects not able to consent.

For research involving children: If the proposed studies will include children, describe the process for meeting HHS regulatory requirements for parental permission and child assent (45 CFR 46.408). See the HHS page on Research with Children FAQs and the NIH page on Requirements for Child Assent and Parent/Guardian Permission.

If a waiver of some or all of the elements of informed consent will be sought, provide justification for the waiver. Do not submit informed consent document(s) with your application unless you are requested to do so.

b. Protections Against Risk

- Describe planned strategies for protecting against or minimizing all potential risks identified, including strategies to manage and protect the privacy of participants and confidentiality of research data.
- Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects on participants.
- Describe plans for handling incidental findings, such as those from research imaging, screening tests, or paternity tests.

c. Vulnerable Subjects, if relevant to your study

- Explain the rationale for the involvement of special vulnerable populations such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals, or others who may be considered vulnerable populations. 'Prisoners' includes all subjects involuntarily incarcerated (e.g., in detention centers).
- Pregnant Women, Fetuses, and Neonates or Children: If the study involves vulnerable subjects subject to additional protections under Subparts B and D (i.e., pregnant women, fetuses, and neonates or children), provide a clear description of the risk level and additional protections necessary to meet the HHS regulatory requirements. Refer to HHS regulations and OHRP guidance: HHS Subpart B - Additional Protections for Pregnant Women, Fetuses, and Neonates; HHS Subpart D - Additional Protections for Children; OHRP Guidance on Subpart D Special Protections for Children as Research Subjects; and the HHS 407 Review Process.
- Prisoners: If the study involves vulnerable subjects subject to additional protections under Subpart C (i.e., prisoners), describe how proposed research meets the additional regulatory requirements, protections, and plans to obtain OHRP certification for the involvement of prisoners in research.

	Refer to HHS regulations and OHRP guidance: HHS Subpart C - Additional Protections Pertaining to Prisoners as Subjects; and OHRP Subpart C Guidance on Involvement of Prisoners in Research. **3. Potential Benefits of the Proposed Research to Research Participants and Others** • Discuss the potential benefits of the research to participants and others. • Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to research participants and others. • **Note: Financial compensation of subjects should not be presented as a benefit of participation in research.** **4. Importance of the Knowledge to be Gained** • Discuss the importance of the knowledge to be gained as a result of the proposed research. • Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.
Diversity Questionnaire Checklist	See Attached

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 Module Leads 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 two years of guaranteed support followed by the option of a third year after competitive review contingent on meeting the programmatic, professional, and productivity expectations identified above.

Human Subjects Approval

The Clinical and Translational Science Institute and Children's National (CTSI-CN) is required to comply with the National Center for Advancing Translational Sciences (NCATS) policy regarding research involving human subjects. According to the policy, all CTSI-CN-funded Pilot and K projects that involve human subjects are required to secure prior approval from NCATS before funds can be released and project work can begin. This process enables NCATS to ensure that human subjects are protected and appropriate data safety monitoring is used.

Detailed information about the necessary documentation will be sent to the awardees. Please note

that this process is estimated to take a minimum of 30 days. The official award notification cannot be released until approval is secured. We recognize that this is going to lengthen the time between submission and award and will do everything we can to expedite the process. If your proposal is selected for funding, CTSI-CN staff at your home institution (Children's National Health System or the George Washington University) will work with you to compile the documents and submit to NCATS. Prior approval requests for projects funded through the George Washington University must be submitted to Children's National through GWU's Authorized Organizational Representative.

Animal Studies

NCATS requires prior notification for animal studies. Any new study involving animal subjects that was not reviewed in the competing application must be submitted for prior approval. This includes the Vertebrate Animals Section four points and IACUC approval and verification of an approved Animal Welfare Assurance. If your proposal is selected for funding, CTSI-CN staff at your home institution (Children's National Health System or the George Washington University) will work with you to compile the documents and submit to NCATS.

VIII. Key KL2 Contacts

- Naomi L.C. Luban, MD (NLUBAN@childrensnational.org) – Project Lead
- An Massaro, MD (ANguyenM@childrensnational.org) – Co-Lead

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) – Co-Lead
    - Hiroki Morizono, PhD (HMorizono@childrensnational.org) – Co-Lead
    - Don DuRousseau, PhD (ddurousseau@email.gwu.edu) – 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) – 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.
    - Kevin Cleary, PhD (kcleary@childrensnational.org) – Co-Lead

- Sean Cleary, PhD, MPH (sdcleary@email.gwu.edu) – Co-Lead
- Susan Knoblach, PhD (SKnoblach@cnmcresearch.org) – Co-Lead
- Gataeno Lotrecchiano, PhD (glotrecc@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) – Co-Lead
  - Reamer Bushardt, PharmD, PA-C (rbushardt@email.gwu.edu) – Co-Lead
  - Allison Hall, PhD (akhall@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.
  - Maureen Monaghan, PhD, CDE (MMonagha@childrensnational.org) – Co-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), 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. KL2 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 (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.
    - Sheila Garrity, JD, MPH, MBA (srgarrity@email.gwu.edu) – Co-Lead
    - Julia Slutsman, PhD (jslutsman@childrensnational.org) – Co-Lead
    - Tomas Silber, MD, MASS (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) – Co-Lead
    - Ginger Winston, MD (gwinston@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.
    - Kirsten Williams, MD (KMWillia@childrensnational.org) – Co-Lead
    - Melissa Napolitano, PhD (mnapolitano@email.gwu.edu) – Co-Lead
    - Gary Simon, MD (gsimon@mfa.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) – 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) – Co-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.
  - Kolaleh Eskandanian, PhD, MBA, PMP – Co-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

- NIH policy concerning concurrent support from Mentored Career Development (K) Award and a Research Grant: http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-08-065.html
- Children's National Institutional Review Board Electronic Application Review (IRBear) system:

http://irbear.org/

- NIH Policy regarding human subjects research prior approval: https://ncats.nih.gov/funding/grantees/approval-faq
- Clinical and Translational Science Institute at Children's National (CTSI-CN): http://ctsicn.org/
- Design, Epidemiology, and Biostatistics Component: https://www.ctsicn.org/BiostatisticsServices
- CTSI-CN Membership: http://visitor.r20.constantcontact.com/manage/optin/ea?v=001L7pmMP5BCBxm_bXFa-W_bg%3D%3D
- Grants Enhancement Program: https://www.ctsicn.org/GEP
- National Center for Advancing Translational Sciences (NCATS): http://www.ncats.nih.gov/
- NIH Biosketch Template: http://grants.nih.gov/grants/funding/phs398/phs398.html
- NIH Scoring System and Procedure: http://grants.nih.gov/grants/peer/guidelines_general/scoring_system_and_procedure.pdf
- PHS 398 Form Page 4 (Budget Template): http://grants.nih.gov/grants/funding/phs398/phs398.html
- SPARC Request Portal: https://sparc.ctsicn.org/service_requests/1929128/catalog