

## Overview Information

Funding Opportunity Title	<b>Path to K Mentored Career Development Grant Information Document</b>
Funding Opportunity Purpose	<p>The OSU Center for Clinical and Translational Science (CCTS), the Office of Health Sciences, and the College of Medicine are seeking applicants to apply to an innovative career development program whose purpose is to train clinical investigators and prepare them for a successful K grant application. The CCTS/OHS/COM Path to K Program supports the career development of investigators who have made a commitment to conduct either patient-oriented or translational research. The Path to K Grant is available for a period of up to two years (contingent on satisfactory progress).</p> <p>Early career junior faculty on the tenure or clinical track from the following health sciences colleges at the Ohio State University are eligible to apply: College of Dentistry, College of Medicine, College of Nursing, College of Optometry, College of Pharmacy, College of Public Health, and College of Veterinary Medicine.</p> <p>The CCTS seeks proposals that address scientific questions consistent with the CCTS mission to transform and advance the discipline of clinical and translational science at The Ohio State University. Proposals may come from any 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, as described in <a href="#">NIH NCATS' Translational Science Spectrum</a>.</p>

## Key Dates\*

Release Date	Around the start of the Fall Semester
Letter of Intent Due Date	Late September/early October
Full Application Due Date	Mid to late December
Study Section	Winter
Notice of Award Date	~ March 30
Funding Period	July 1 to June 30; renewable for one year thereafter based on satisfactory progress.

\*some dates may vary because of unanticipated circumstances

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## Section I. Funding Opportunity Description

### Purpose

The Path to K grant is designed to benefit a wide spectrum of clinical and/or translational researchers across OSU. The grant provides salary support to ensure protected time for mentored research and didactic training in clinical/ translational research across a wide variety of project topics and academic areas. The overall goal of the program is to equip early career investigators to advance on the path to be competitive for NIH K Career Development Grants (or equivalent).

The CCTS supports the full spectrum of clinical and translational research intended to have human applications. In this context, "translational" investigation is broadly defined. It includes, for example, laboratory research with potential human applications, "bench to bedside" research in which laboratory findings are studied in the human context, the interaction of small human studies with those in larger populations, and the translation of research into clinical practice and health policy.

Program Preference will be given to junior faculty members on the tenure or clinical track with fewer than three years since their appointment, but junior faculty with three or more years since their appointment are eligible to apply.

Typically, each year up to four grants will be made:

- Up to two grants will be awarded to applicants from the Colleges of Dentistry, Nursing, Optometry, Pharmacy, Public Health, and Veterinary Medicine. The funds for these awards are courtesy of the OSU Office of Health Sciences.
- Up to two grants will be awarded to physician-scientists from the College of Medicine. These grants are funded by the College of Medicine Office of Research (COM OR) and the Richard P. and Marie R. Bremer Medical Research Fund and the William H. Davis Endowment for Basic Medical Research.

Applicants will be selected based on a competitive application process in which the following will be key review considerations that determine funding:

- The transdisciplinary/translational science and quality of the research project
- The qualification of the applicant
- The experience of the mentorship team
- The quality of the training plan
- The probability of the proposed project developing into a competitive K grant application

A Study Section will make recommendations to the CCTS Executive Committee for the funding of up to two scholars. All applicants will receive reviewer comments on their applications.

Please note the following requirements:

- To be considered, all applicants must submit the required Letter of Intent form by 11:59 PM on the date noted above using the online form indicated above.
- Applicants must complete all sections of the entire application. Applications are due by 11:59 PM on the date noted above using the online form indicated above.
- No late LOI or applications will be accepted.

(Note: The CCTS fund two career development programs for junior faculty: the Path to K and the KL2 Awards. See Appendix 1 of this document for a comparison of the two programs.)

Please direct all questions to the Program Manager, Stuart Hobbs at 614-685-5972 or [stuart.hobbs@osumc.edu](mailto:stuart.hobbs@osumc.edu)

## Benefits of the Path to K Grant

- Funds up to \$50,000 to cover:
  - Salary support for up to a 10% FTE appointment to this grant (up to salary cap of \$15,000 maximum) for the applicant plus relevant fringe.
- A 10% match of salary and fringe from the applicants home department/division/college to create a total of 20% release time from clinical and other duties to devote to research and training
- Individualized career development and mentorship from the trainee's own appointed scientific committee.
- Support to develop an individual K grant to fund research at the conclusion of the Path to K funding.
- The CCTS will be providing other project resources. These include, but are not limited to:
  - Project management
  - Infrastructure services
  - Problem-solving
  - Financial tracking
  - Opportunities to disseminate research (posters and presentations)
  - Tools of the Trade seminars
  - Lunch and Learn seminars

## Expectations of Path to K Grantees

- Commit 20% of your effort to the Path to K Grant.
- Your participation in various CCTS / Path to K activities will be required:
  - A monthly Lunch and Learn program
  - Attendance at The Business of Science, a three-day workshop held during Fall Semester (next scheduled event fall 2022)
  - Attendance at the annual meeting of the Association for Clinical & Translational Science (ACTS, held in April)
  - Participation in the Annual CCTS Scientific Meeting
  - Mentor training, if your mentor has not already participated in the CCTS training
- Grantees will have the opportunity to attend CCTS Tools of the Trade workshops relevant to their career development needs and will be strongly encouraged to attend one of the College of Medicine-supported Office of Research grant writing workshops or K workshops.
- Interim progress reports and a final project closure report must be submitted to the CCTS. These will include:
  - Responses to reviewer criticisms stated in your award letter must be addressed in these reports.
  - Your progress in meeting the milestones described in your application must also be addressed in these reports.
- Short yearly progress reports will be required each year after the grant for tracking data for the CCTS success metrics for 3 years following the end of the grant. This is required for our NIH metrics of success and reports.

## Other Requirements

- No Path to K scholar or mentor will be permitted to work on any project involving live vertebrate animals or human subjects that has not been approved by the IACUC and/or IRB, as appropriate. If any scholar undertakes a project that includes human subject research studies, these must conform to the NIH policies on the inclusion of women, minorities, and children in study populations. Funds for non-compliant projects will be withheld.
- IRB or IACUC approval (if required) must be obtained prior to release of funds. If IRB/IACUC is not in place, regulatory approval must be obtained within 60 days of grant start date noted at the top of the RFA.

- OSU CITI training in Human Subjects Protection and Responsible Conduct of Research as well as Good Clinical Practice certification must be completed by all research personnel who have access to personally identifiable data collected as part of this study. This requirement includes the Path to K Scholar, as well as research staff funded by the award, if any. These modules are available at <http://orrrp.osu.edu/irb/training-requirements/>
- Grant recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded by the grant will be free from bias resulting from an Investigator's Financial Conflict of Interest.
- All scholars appointed to this grant who are involved with human subjects must have completed education on the protection of human subjects and Good Clinical Practice (GCP) in accordance with NIH policy.
- Any individual involved in the design and conduct of a study not included in any certification must satisfy this requirement prior to participating in the project.
- Signed letter of offer and cost overrun form must be received prior to the release of funds. This form includes a requirement for department chartfield information to accommodate possible overrun of the Path to K account

## Section II. Eligibility Information

### Eligible Applicants

- Applicants must be considered a principal investigator. Eligibility information can be found at the OSU Office of Research website. < <https://research.osu.edu/building-your-research-program/becoming-principal-investigator> > Residents and clinical and postdoctoral fellows are not eligible.
- Applicants must be from one of the following colleges: College of Dentistry, College of Medicine, College of Nursing, College of Optometry, College of Pharmacy, College of Public Health, and College of Veterinary Medicine
- College of Medicine applicants, as required by the two endowments funding the College of Medicine arm of this program, must have an MD degree with a record of engagement in active clinical practice and be physicians credentialed by the OSU Wexner Medical Center. Individuals with dual degrees are eligible as long as one is an MD (acceptable examples: MD, PhD; and MD, MPH; MD, MS; etc.). Candidates must have faculty appointments and PI status at The Ohio State University. Residents, clinical fellows and post-doctoral fellows are not eligible to apply.
- Applicants may not have previously been a PI on a NIH individual or institutional K Grant or an R01 or an equivalent non-PHS grant with more than \$100,000 in direct costs
- Applicants must commit to spending 20% effort engaged in conducting the research supported through this grant. The Path to K Grant will compensate 10% of the committed time (up to salary cap of \$150,000), with the remained cost-shared by the college/department/division (as appropriate to the pattern of administration of the grantee's home unit). The dean or department/division chair must sign the signature page agreeing to the release time and cost sharing should the applicant be funded.
- Applicants and mentors must become CCTS members. Go to [ccts.osu.edu](http://ccts.osu.edu) and click on <Become a Member>.

## Section III. Application and Submission Information

This grant program involves a two-phased application process: a Letter of Intent to Apply (LOI) and a Full Application.

### Phase One: Letter of Intent

**To be eligible, it is required that you indicate your intention to apply via the Letter of Intent through an online REDCap form, which will be in the RFA.**

The purpose of the Letter of Intent is twofold:

1. To let program staff know of your intent to apply for the Path to K Grant in order that they may organize the Study Section.
2. So applicants can fill-out the eligibility checklist to know that they are eligible.

All Letters of Intent must be submitted through the online process by 11:59 PM EST on the date at the top of the RFA. **No late Letters of Intent will be accepted.**

The process of completing the eligibility checklist will clearly tell you if you are eligible to go on to apply for the Path to K. You should review carefully the eligibility criteria found at the top of this page before applying.

Staff will use the information you submit about your project to organize the Path to K Study section. The information about your project that you submit in the Letter of Intent will not undergo scientific review. **Do not expect further contact from project staff after submitting the Letter of Intent.** If you answered the eligibility questions accurately, and did not receive an ineligible notice, you should be eligible to apply. If there are any issues in your LOI, CCTS staff will contact you within in 7 days.

If you have questions or concerns, **please contact the Program Manager, Stuart Hobbs at 614-685-5972 or [stuart.hobbs@osumc.edu](mailto:stuart.hobbs@osumc.edu)**

## Phase Two: Full Application

Applications and supporting materials are to be submitted **by 11:59 p.m. EST on the date noted at the top of the RFA. No late applications will be accepted.**

Please read these instructions carefully before going online to apply. The application must be completed and submitted online at the web address noted on page 1 of this document. The application process is designed so that you can save your information and return to it. You will be given a code, so be prepared to save that information.

### Format Specifications

All applications must adhere to the following guidelines:

- Font
  - Use Arial 11 points or larger
  - Type density, including characters and spaces, must be no more than 15 characters per inch.
  - Type may be no more than six lines per inch.
- Page Margins
  - Use at least one-half inch margins (top, bottom, left, and right) for all pages
- Application Paging
  - The application must be single-spaced.
- Figures, Graphs, Diagrams, Charts, Tables, Figure Legends, and Footnotes
  - You may use a smaller type size but it must be in black ink, readily legible, and follow the font typeface requirement.
  - Do not include figures or other materials that are not inserted directly into the body of the application.
- Documents and file name. All documents asked for in the application must be submitted online in A single combined PDF document. Name your document using the following guideline:  
< lastname\_firstname\_path\_to\_k\_Application\_2021 >

Upon receipt of your application, the CCTS will send you an email confirmation. Please inquire within 24 hours if you do not receive this email. The program will not be responsible for late submissions if not notified.

Investigators are strongly encouraged to visit the [CCTS website](#) to search for and make use of other CCTS resources relevant to your project.

## Grant Application Checklist

The Application consists of several parts. You can use the following as a checklist to help you gather, enter,

and complete the application.

- ☐ Personal Information  
(Includes Employee ID Number, OSU name.#)
- ☐ Campus Address
- ☐ Current University Employment Information (including job title, Department name, tenure track status)
- ☐ Administrative departmental contact (name, email)
- ☐ Previous CCTS funding
- ☐ NIH new investigator or early stage investigator status  
[http://grants.nih.gov/grants/new\\_investigators/investigator\\_policies\\_faqs.htm#2650](http://grants.nih.gov/grants/new_investigators/investigator_policies_faqs.htm#2650)
- ☐ Mentor(s) and collaborators (name/title/role on project/department)
- ☐ Race, ethnicity, and additional such reporting information asked for by the NIH
- ☐ Project Title and Abstract (up to 250 words)
- ☐ Project Description – 9 page maximum (to be uploaded to the Application; see these instructions for complete details)
  - ☐ Personal Statement (1 page maximum)
    - ☐ Who are you? Why have you chosen a research career?
    - ☐ Your previous research experience?
    - ☐ What are your clinical privileges and expectations?
    - ☐ How you believe this training program will change the trajectory of your career or enhance your movement towards your goals?
  - ☐ Mentorship & Career Development Plan (up to 2 pages)
    - ☐ The role of your mentor(s) in developing your skills
    - ☐ Your strategy for a K-proposal submission within 12 to 18 months.
    - ☐ How will you meet the NIH requirements for training in responsible conduct of research
  - ☐ Research Plan (6 pages maximum). The following topics should be addressed:
    - ☐ Specific Aims & hypothesis
    - ☐ Significance
    - ☐ Innovation
    - ☐ Preliminary Data
    - ☐ Approach
    - ☐ Milestones
  - ☐ References to Scientific Literature (not included in page count.)
- ☐ Itemized Project Budget (see below for form) and Budget Justification.
- ☐ NIH Formatted Biosketches (to be uploaded to the Application)
  - ☐ Applicant
  - ☐ Lead Mentor
  - ☐ All other mentors
- ☐ Letters of support from your:
  - ☐ Mentor
  - ☐ Other members of your mentoring team.
- ☐ Regulatory (IACUC or IRB) approval (if applicable)
- ☐ Signature of dean or department or division chair agreeing to the release time and cost-sharing should the application be funded

## Application Components: Personal Statement

A one-page personal statement addressing the following points:

- Who are you? Why have you chosen a research career?
- Your previous research experience
- What are your clinical privileges?
- How you believe this training program will change the trajectory of your career or enhance your movement towards your goals

## Application Components: Mentorship & Career Development Plan

This section can be up to 2 pages and should address:

- The role of your mentor(s) in developing your skills
- Your plan for receiving training to develop the additional skills you need to be a physician scientist.
- How you will meet the NIH requirements for instruction in the responsible conduct of research (see <http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html> for more information). Note the CITI GCP and RCR training is required also, but does not fulfill this requirement.
- Your strategy for a K-proposal submission within 12 to 18 months.

## Application Components: Research Plan

This section can be up to 6 pages and should include:

- Specific Aims and hypothesis of the project. Preferably no more than 2 aims
- Significance of the problem and how the proposed project will improve scientific knowledge and/or change the field of study.
- Innovation – explain how the proposed project challenges current practice or creates a novel approach to the problem.
- Preliminary Data. Any research findings that help demonstrate the feasibility of your project; figures can be multi-panel if addressing a common theme; fully self-explanatory legends. Preliminary data can be integrated within various sections and does not have to constitute an independent section.
- Approach – Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project, noting in particular how it is clinical and/or translational. Schematic illustrations desired. Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims. For materials and methods, highlight powerful non-routine approaches, summarize routine approaches, and address statistical approach.
- Milestones. A list of milestones to be met and set dates for meeting.

References to Scientific Literature. This section is not included in the 6-page limit

## Application Components: Itemized Project Budget and Justification

Use budget worksheet provided at: < >

The Path to K grant has a budget of up to \$50,000. Allowable costs:

- Salary support for the Path to K PI up to a 10% FTE appointment to this grant (capped at \$15,000 maximum) for the applicant, plus appropriate fringe.
- Salary and fringe support for research staff, including undergraduate or graduate students, clinical trainees, post-doctoral and clinical fellows, is permitted.
- Research supplies and other expenses needed for carrying out the project, such as research beds, nursing or bionutrition staff, and routine laboratory measures.
- Travel funds needed for study conduct (e.g. participant travel or reimbursement for mileage for the conduct of community-engaged research) are allowable expenses. Funds to travel to the Association for



Clinical & Translational Science (ACTS) meeting in Washington, DC, in April should be included in your budget ~\$2,000).

- Equipment that is essential for the study, and is not otherwise available, may be requested, but large equipment expenditures (over \$5,000) are not allowed.

The budget justification should briefly provide explanation for line items within each category, such as roles and responsibilities for personnel, how supplies relate to your aims. If requesting equipment, the justification must explain why the current equipment is insufficient to accomplish the proposed research and how the new equipment's use will be allocated specifically to the proposed research. Finally, describe any overlap with submitted or funded applications, and existing funding including start-up

### **Application Components: Scientific Mentorship Team**

Your Scientific Mentorship Team must consist of at least three members. Your team must include among its membership a Lead Mentor, a statistical mentor, and one other mentor (additional mentors are optional).

**Lead Mentor.** The applicant will identify a faculty member mentor in his or her area of clinical or translational research. Your mentor (or each co-mentor) is responsible for:

- Providing career development and counseling;
- Guiding and encouraging the design and execution of an original, high quality, research project;
- Collaborating with the mentorship team to support the Path to K Scholar.
- Attending CCTS sponsored events including a mentor training program and an on-boarding session, as well as other meetings with program leaders and administrators as needed.

The letter of support from your lead mentor should acknowledge his or her understanding of these requirements, and describe their mentoring plan for your development. The letter should also describe the Mentors experience with mentoring, including number of mentees.

**Biostatistician.** Your mentorship team must include one statistician who will help you to develop a research plan that meets the highest standards of rigor and reproducibility. The biostatistician will also biostatistical analysis of data and mentor you in biostatistical analysis. If your department or division does not provide access to biostatistical support, you can arrange for a consultation with the Center for Biostatistics. Go to the Center's project request form at:

<https://medicine.osu.edu/departments/biostatistics/service-request-form>

**At least One Additional member of the mentorship team.** The Mentorship Team provides additional expertise in the scientific area of research chosen for the project, complementary to the interests of the lead mentor. It is highly desirable that the other member of your Mentorship Team be drawn from another discipline so that he or she can provide transdisciplinary input into your project. Your mentorship team members may also include a University faculty member who is not a regular member of the graduate faculty (e.g., an adjunct professor), a University staff member, or a qualified individual outside the University who can provide expertise in your discipline.

### **Mentor Letters of Support**

Letters of support are required: (1) from Lead mentor; and (2) from the other members of your mentoring team. Include these letters in your application PDF.

The Mentors should acknowledge awareness and support of the project and address the role and qualifications of the mentor for the project.

Address the letters to:

Cynthia Carnes, PharmD, PhD  
The Ohio State University  
338 West Tenth Avenue  
Columbus, OH 43210



## Application Components: NIH Biosketches

You must upload (as PDFs) NIH formatted biosketches of yourself, your lead mentor, and any other mentors or collaborators. The NIH has revised the biosketch form and requires the use of that form after January 2022. It is recommended you and your team use the new form for this application.

Biosketch Instructions, samples, and format pages can be found here:

<https://grants.nih.gov/grants/forms/biosketch.htm>

## Application Components: Signature Page

Your dean or department/division chair must sign the signature page agreeing to the release time and cost sharing should you be funded. The pattern of administration in your unit will determine who the signing individual is. It should be the person who has ultimate authority for your time.

## Section IV. Application Review Information

Three reviewers will read each application. Applications will receive an Impact Score (NIH 1-9 scale). Individual components will also be scored 1-9.

The overall impact will reflect an evaluation of the trainee, the mentoring team, the training plan, and the proposed research. All are equally weighted and the study section will assess the overall fit of the components together.

Each application will also receive biostatistical review that will not be formally scored but will be reported to the study section. Rigorous biostatistics are an important part of scientific research.

## Section V. Integrating Special Populations

Applicants are encouraged to integrate special populations into their projects. The term “Special Populations” encompasses a multitude of groups and communities that are commonly underrepresented in clinical and translational research, and the CCTS is actively working to correct this problem. These groups include, but are not limited to, the following:

- Fetuses, neonates, and children
- Pregnant or nursing women
- Older adults
- Individuals with physical disabilities
- Individuals with communication or sensory impairments (hearing, vision)
- Racial, ethnic, or cultural minorities
- Non-English speaking individuals
- Underinsured or socioeconomically disadvantaged patients
- Gender or sexual minorities (LGBTQ+)
- Individuals with intellectual disabilities
- Isolated urban or rural communities

Socioeconomic or demographic factors may contribute to the systematic underrepresentation of special populations, regardless of whether these groups are explicitly targeted for research participation. Historical cases of research misconduct have also ingrained a deep-rooted mistrust of the medical establishment in certain communities. Investigators often encounter additional challenges when recruiting or retaining special populations for research, such as how to effectively obtain informed consent for individuals with intellectual disabilities or how to ensure success for a study requiring multiple clinic visits for individuals with limited physical mobility. All of these factors contribute to the underrepresentation in research of specific populations.

Therefore, though this is not a scored category, applicants are encouraged to design research projects that address the needs of special populations; devise recruitment and retention plans that will optimize the participation of one or more special population; or pursue other strategies that integrate underrepresented groups into clinical and translational research.

## Section VI. Grant Administration Information

### Grant Notices

Meritorious applications will receive formal notice in the form of a Letter of Offer provided to the applicant. A completed and signed CCTS Grant Acceptance Letter is required before the start date.

### Reporting

You will provide brief interim progress reports three times per year and an annual progress report at the end of the year in which you will report on the progress of meeting the project milestones you listed in your application. The annual report will also include a brief presentation about your experience as a KL2 scholar to the CCTS Executive Committee.

Trainees, Lead Mentors, and the Program Directors will meet every six months to review progress on the scholars Training Plan.

### Citation Requirements:

All investigators must acknowledge the CCTS, the Office of Health Science, and/or the College of Medicine in all publications, posters and presentations resulting from the supported studies. Where applicable, please include one of the following texts:

The project described was supported by a Path to K award from the Ohio State University Office of Health Sciences and the Center for Clinical & Translational Science. The content is solely the responsibility of the authors and does not necessarily represent the official views of the university, or the Center for Clinical & Translational Science.

For College of Medicine awardees:

The project described was supported by a Path to K award from the Ohio State University College of Medicine Office of Research and the Center for Clinical & Translational Science through the Richard P. & Marie R. Bremer Medical Research Fund and William H. Davis Endowment for Basic Medical Research. The remarks and opinions are the sole responsibility of the authors and do not necessarily reflect the views of the Davis / Bremer Research Fund, the CCTS, or The Ohio State University Medical Center.

## Section VII. Agency Contacts

### Grant Management Contact

If you have any questions regarding the Path to K Grant, please contact:

#### **Stuart D. Hobbs, PhD, MBA**

Associate Director, Research Education, Training, & Career Development  
Center for Clinical & Translational Science  
Ste. 260 Prior Hall, 376 W. 10th Avenue, Columbus, OH 43210  
614-685-5972 Office  
[stuart.hobbs@osumc.edu](mailto:stuart.hobbs@osumc.edu) [ccts.osu.edu](http://ccts.osu.edu)

### Program Co-Directors

Cynthia Carnes, PharmD, PhD  
Path to K Program Director  
Associate Dean for Graduate Studies & Research  
College of Pharmacy  
[Carnes.4@osu.edu](mailto:Carnes.4@osu.edu)

Loren Wold, PhD, FAHA  
Path to K co-Director  
Professor of Nursing and Medicine (Physiology and Cell Biology)  
Assistant Dean for Biological Health Research  
College of Nursing  
[wold.5@osu.edu](mailto:wold.5@osu.edu)

This is the signature page that will need to be completed for your application:

### Signature: Protected Time and Salary Coverage

I acknowledge that this individual is qualified for this program and will receive support for all requirements for protected time and financial needs according to the RFA, and specifically:

1. I agree that if this applicant is awarded a Path to K grant, this individual will receive the required 20% protected time beginning July 1, 2021, and continuing until May 31, 2023, assuming satisfactory progress as determined by the CCTS Executive Committee.
2. I agree that the department and/or college will provide the amount of salary and benefits not covered by this grant beginning with the award date, and continuing for up to two years. The grant covers 10% of salary up to a salary cap of \$150,000 (i.e. 10% of \$150,000 = \$15,000), plus relevant fringe benefits.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

Printed Name & Title: \_\_\_\_\_

Note: The above should be signed by your College Dean or your Department or Division chair: whoever is the appropriate person to make these commitments.

### Signature Applicant

I certify that the statements herein are true and complete to the best of my knowledge, and that I will comply with all applicable CCTS terms and conditions governing my potential appointment. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

\_\_\_\_\_  
Applicant's signature

\_\_\_\_\_  
Date

## Appendix 1: CCTS Career Development Awards Compared

The Path to K grant is designed to benefit a wide spectrum of clinical and/or translational researchers across OSU. The grant provides salary support to ensure protected time for mentored research and didactic training in clinical/ translational research across a wide variety of project topics and academic areas. The overall goal of the program is to equip early career investigators to advance on the path to be competitive for NIH K Career Development Grants (or equivalent).

Early career junior faculty on the tenure or clinical track from one of the following health sciences at the Ohio State University are eligible to apply: College of Dentistry, College of Nursing, College of Optometry, College of Pharmacy, College of Public Health, and College of Veterinary Medicine are eligible to apply.

Faculty from the College of Medicine are eligible for the Davis Bremer component of the Path to K. The Davis Bremer Path to K awards grants to facilitate early career successes for outstanding physician-scientists at Ohio State committed to a career in academic medicine. Applicants for the Davis must be physicians with OSU Wexner Medical Center credentials. This requirement reflects funding restrictions on the Richard P. and Marie R. Bremer Medical Research Fund and the William H. Davis Endowment for Basic Medical Research, which fund the Davis-Bremer/College of Medicine Path to K component.

All applicants for Path to K grants must have not previously been a PI on an NIH individual or institutional K, or R01 Award or other major grant with more than \$100,000 in direct costs. All applicants must have a research or health-professional doctoral degree.

The CCTS also manages an NIH institutional K award, the KL2. The qualifications for the KL2 are similar to those for the Path to K. However, the KL2 is designed for more advanced researchers who are preparing to apply for an NIH R01 grant or equivalent.

The Path to K grant is for researchers who are preparing to apply for an NIH K award or equivalent.

## Appendix 2: Options for Fulfilling Requirements in Responsible Conduct of Research

### Courses:

#### **Pharmacy 8520 - Research Ethics**

Basic concepts of integrity in the process of research. The course covers all areas of responsible conduct of research including mentor/trainee roles, data management, animal use, human subjects. Often offered May term. The course fulfills NIH requirement for research ethics. Dr. Cynthia Carnes, instructor. 1 credit

#### **Vision Science 7960 - Ethics in Biomedical Research**

Provides a general understanding of the issues surrounding the ethical conduct of science including issues related to research involving human subjects, scientific misconduct, and authorship of scientific papers. Real-life case studies will be used. Often offered Fall Term. Dr. Karla Zadnik, instructor. 2 credits.

#### **Nursing 7781 - Responsible Conduct of Research**

Concepts and policies for the responsible conduct of research (RCOR), Institutional Review Boards, and dissemination of findings. Offered Online, Spring. Dr. Amy Mackos and Dr. Karen Williams, instructors. 3 credits

#### **HTHRHSC 7883 - Responsible Conduct of Research**

Seminar encompassing a variety of professional skills in Health and Rehabilitation Sciences Research including the process of writing, publishing, and reviewing journal manuscripts; human & animal subjects in research & responsible conduct. 1 credit.

#### **BioPhrm 7510 – Professional & Ethical Issues in Biomedical Sciences**

A discussion course based on case scenarios dealing with ethical issues facing biomedical researchers, such as publishing practices, confidentiality, mentoring. Typically offered in Spring Semester. Dr. Frederick Villamena, instructor. 2 credits.

#### **Biomedical Engineering 6983 - Research Ethics**

Introduction to professional and ethical issues confronting biomedical research and researchers and approaches to dealing with such issues. Prereq: Grad standing, or permission of instructor. Offered Autumn term. Dr. Alan Litsky, instructor. 2 credits.

#### **Surgery 8814 - Responsible Conduct of Research: Human Participants and the Use of Animals in Biomedical Research**

Responsible conduct of research with human participants and the use of animals in biomedical research is crucial to maintaining the public trust in both the results and the methods of biomedical research. Offered Spring semester. Dr. Tatiana Oberyszyn, instructor. 2 credits.

### Other Training Programs

#### **Webcast from the NIH: Ethical and Regulatory Aspects of Clinical Research:**

This is a live webcast that the CCTS hosts most autumns. The sessions are typically Wednesday mornings from mid-September to November. Participants watch the webcasts and take part in discussions. By attending 6 of 7 sessions and completing evaluations and pre and post tests, participants receive certification. More information:

<https://www.bioethics.nih.gov/courses/ethical-regulatory-aspects.shtml>

Contact Karen Carter of the CCTS at [KarenK.Carter@osumc.edu](mailto:KarenK.Carter@osumc.edu) for local hosting information.

#### **Conversations about Research Ethics (CARE) Training Program**

The Center for Ethics and Human Values (CEHV) offers a semester-long, multidisciplinary, and discussion-based RCR program called the CARE Training Program. It involves 8 hour-long sessions led by CEHV ethicists. Each session uses a “flipped classroom” model, providing participants with resources prior to each discussion.

Details here: <https://cehv.osu.edu/care-training-program>

#### **Responsible Conduct of Research Training at Nationwide Children’s Hospital**

Nationwide Children’s Hospital offers a Responsible Conduct of Research Training Series during the summer. The course fulfills NIH requirements. For details, contact [Katie.Campbell@nationwidechildrens.org](mailto:Katie.Campbell@nationwidechildrens.org).

### **Appendix 3: Sample Personal Statements & Mentoring/Career Development Plans**

These are sample pages from successful applications to the Path to K predecessor program, the Davis Bremer Path to K grant. Included are Personal Statements & Mentoring/Career Development Plans.

Also included is a sample budget.

Sample One Path to K Grant Text: Personal Statment & Mentoring and Career Development Plan

**Personal Statement**

I am currently an Assistant Professor of Neurology in the Division of Cerebrovascular Diseases and Neurocritical Care at The Ohio State University (OSU) and the medical director of the Neurosciences Critical Care Unit (NCCU). I provide my expertise in the NCCU, acute stroke unit and telestroke services where I manage a wide range of patients with acute brain injury including ischemic and hemorrhagic strokes. Since my arrival at OSU, I have developed a research interest in understanding the pathophysiological mechanisms associated with cerebral small vessel disease (CSVD) and specifically the role of microRNAs (miRNAs) in the development and progression of CSVD. The Path to K grant will provide the required protected time, mentorship support and training to achieve my short-term goal of obtaining an NIH K-08 award and eventual long-term goal of becoming an independently funded and leading translational physician scientist in CSVD by discovering novel miRNA targets for this disease.

My motivation to uncover the mysteries of the human brain led me to a career in medicine and subsequently neurology. I joined medical school as an honor student after I ranked among the top three on the national medical school entry examination in Syria. As an ambitious young physician aiming to pursue fine training in neurology, I joined neurology residency program at a College of Medicine. The next step in my career, a research and clinical fellow in neurocritical care at The Impressive University, solidified my career goal as a physician scientist. I gained expertise and specific training in MRI acquisition and analytical methods. Under the mentorship of Dr. Percy Alleline I completed projects utilizing advanced diffusion tensor imaging (DTI) to investigate CSVD in normally appearing individuals. These projects have shifted my attention to the lab to discover the role and underlying mechanisms of miRNAs in this disease. As a junior faculty at OSU, I was awarded an NIH StrokeNet research fellowship which enabled me to acquire the lab skills by working with the lead mentor on this project: Dr. Connie Sachs, PhD over the past two years. Dr. Sachs laboratory has extended expertise in using laser capture microscopy (LCM) technology. The technology employed in this study was adopted from his laboratory. During this fellowship, I developed skills to use LCM, quick frozen immunohistochemistry staining and various other lab activities. Furthermore, my research received multiple other competitive awards at OSU. First, I received an award from the Center for Faculty Advancement, Mentoring and Engagement (FAME) as a finalist in a research competition across the College of Medicine faculty for my work on creating automated processing pipelines of CSVD MRI lesions. Second, I successfully competed for a pilot award from the Chronic Brain Injury (CBI) initiative at OSU looking at outcomes of acute stroke patients using our developed automated pipeline for CSVD quantification. Finally, the acquired lab skills enabled me to secure another competitive funding award from the neurological research institute at OSU which is the basis of the preliminary data for this proposal. On the other hand, my clinical and leadership skills were recognized by being selected as the associate medical director of the NCCU and I have recently transitioned to the medical director role. In addition to my background in research and clinical skills, I have assembled an expert mentorship team of NIH funded investigators including Dr. Connie Sachs, PhD (Associate Professor at OSU) as the lead mentor, Dr. Toby Esterhazy, PhD (Professor of Scientific Discipline at OSU) as a co-mentor, and Dr. Percy Alleline, MD (Professor of Neurology at Impressive University) as a co-mentor. This mentorship team will work collaboratively to enable me to complete the proposed project, fill in my training gaps and progress towards my career goals.

My short term goals during the Path to K Grant are: to complete the proposed project and identify miRNA targets for CSVD, collect the preliminary data to apply for NIH K08 award, enhance my basic/translational science skills and acquire the required lab training. By the end of 2 years, I aim to have published 2-3 first author high impact papers and gain national reputation by presenting my findings at nationally recognized meetings to eventually progress to a K-08 Career Development Award. My future studies will focus on characterizing the pathophysiological roles of the identified miRNA targets in both animal models and humans. In summary, This CCTS Path to K grant will transform my career by providing the protected time, training and education to complete the proposed project and achieve my career goal as a translational physician scientist working to develop novel therapies for CSVD.



## Mentorship and Career Development Plan

I am submitting this Path to K Grant application to support my academic career development into an independent translational physician scientist focused on identification of novel targets for cerebral small vessel disease (CSVD). The main short term goal of this award is to acquire the skills and preliminary data to successfully compete for an NH K-08 award within the next 18 months. As an NIH StrokeNet fellow, I noted specific areas for development while working in the lab over the previous year. Specifically, through the protected time and mentorship provided by this award, I aim to enhance my knowledge and skills in translational laboratory techniques and methods (objective 1), biomedical informatics analysis (objective 2) and grant writing (objective 3). In order to achieve these goals, I have assembled a training plan with my mentors that include both formal and informal training. The identified courses along with the mentor specific training environment will address my career development objectives (table 1 list the timeline and plan for meeting my training objectives).

### 1) Mentors' specific training environment and mentorship plan:

#### a) Lead Mentor: Dr. Connie Sachs, PhD:

Dr. Sachs is the Named University Professor lorem ipsum dolor sit amet, consectetur adipiscing elit. She is an expert in venenatis pretium purus nec auctor. Dr. Sachs is funded by several NIH grant, including: Cras viverra purus lorem, id elementum eros euismod sed. . In eget purus eros. Sed id augue et mauris blandit molestie. Feugiat risus viverra, varius nulla. Cras lobortis neque eu metus luctus aliquam. Quisque ultricies ac leo vel posuere. Dr. Sachs has served as my co-mentor during the NIH Named fellowship and I have been closely working with her over the prior two years. We have been conducting lab meetings every Wednesday afternoon (30 minutes) over the previous year and this will continue throughout the award period. Working with Dr. Sachs will address all my three learning objectives. In addition, Dr. Sachs will play an integral role in the proposed research as the novel methods that I have developed for Laser Capture Microdissection (LCM) has been initially developed in her lab, and I further optimized for my specific experiment. Furthermore, I have access to her lab space and LCM lab that she leads to perform my research.

#### b) Co-Mentor: Dr. Toby Esterhazy, PhD:

Dr. Esterhazy is Research Professor and Vice Chair of Important Department at OSU. Dr. Esterhazy is an expert in donec ornare dictum risus eget semper. His research is funded by multiple grants from the NIH including Nullam sed diam pulvinar, posuere dolor at, gravida dui. Meetings with Dr. Fernandez will be held on monthly basis (60 minutes). Dr. Esterhazy will provide critical input for analysis of miRNA targets and mapping the involved cellular pathways. Furthermore, he will provide career advises and training in biomedical informatics methods and grant writing (objectives 2 and 3).

#### c) Co-mentor: Dr. Percy Alleline, MD:

Dr. Nyquist is the Professor of Neurology at The Impressive University. He is a physician scientist investigating Vestibulum in libero ultricies through a previous NIH R01 Award. Under his mentorship during my fellowship, I have completed multiple projects utilizing Diffusion Tensor Imaging (DTI) in CSVD. Dr. Alleline will provide career and scientific advises given his knowledge of the field and train me on grant writing and future grant submission (objective 3). I will be meeting with him monthly through Skype (60 minutes) in addition to an in-person meeting at the International Scientific Research Conference (ISRC).

### 2) Plan for formal coursework:

As a faculty at OSU, I have access to a wide range of formal courses across the campus. Together with my mentors, we have identified the following formal courses that will provide educational and formal training in the different elements of the proposed project to meet my objectives during the award period:

#### a) Objective 1: Enhance my knowledge in translational laboratory methods and techniques: To achieve this goal, I aim to attend the following two courses:

- BSGP 8800: Research Tools – Laser Capture Microdissection (LCM): This course is taught by my lead mentor: Dr. Cameron Rink, PhD at OSU College of Medicine – Biomedical Sciences Graduate

Program. This course will provide essential knowledge in LCM methods which are essential for the success of my project. I will take this course in the first year of the award.

- BIOPHRM 6785: DNA Microarray Technology: This course is offered at OSU College of Medicine – Department of Biological Chemistry and Pharmacology. I will take this course in the second year which will provide me with training in microarray technology which is integral for miRNA isolation and analysis.

b) Objective 2: Biomedical informatics analysis: I will attend the following relevant courses:

- Biomedical Informatics Course: BMI 5710 (Intro to Biomedical Informatics): This course is offered at OSU College of Medicine – Department of Biomedical Informatics. This is carefully selected from OSU Master of Public Health with specialization in Biomedical Informatics Curriculum. This course will provide essential knowledge in biomedical informatics methods. I will take it in the first year.
- RNA-seq Data Analysis Workshop: This workshop is offered by the Department of Biomedical Informatics at OSU every fall. It is a two-day course and it will provide training in RNA-seq and pathway analysis relevant to my study. I will take this course in the second year of the award.

c) Objective 3: Grant writing training and training in the Responsible Conduct of Research (RCR):

- The Neurological Research Institute (NRI) at OSU offers a one-day NIH Professional Grant Development Workshop in the fall by the Grant Training Center that I will attend in the first year.
- PHM 8520: Research Ethics: I will meet the requirements for RCR by attending this course that covers all the areas of RCR and it is offered typically in May by the College of Pharmacy. I will take it in the first year. Furthermore, I have completed all the required research training including CITI CGP and RCR.

**3) Research support and training through the Neurological Research Institute (NRI) and the Center for Clinical and Translational Sciences (CCTS) at OSU:**

As part of the NRI, I have access to research and statistical support for data collection and analysis. In addition, there are multiple experienced core laboratory services at OSU which will provide support and consultation for the study procedures and testing such as the Small Animal Imaging Core (SAIC) for the rat brain MRI, The Genomics Shared Resource (GSR) at OSU Cancer Center that provide important insights for appropriate miRNA collection and their service will be utilized for miRNA identification. Furthermore, I will utilize the resources available through the CCTS to achieve my learning objectives including the Tools of the Trade, Lunch and Learn seminars and Business of Science Workshop.

**4) K08 Proposal Submission Strategy:**

My main goal of submitting this Path to K Grant application is to support my career development by successfully competing for an NIH K08 Award within 18 months. Specifically, the mentorship and protected time through this award will be essential in completing the proposed research and achieving my career development objectives. During this award period, I aim to 1) publish 2 original research papers with my mentors detailing our novel methods for epithelial cells and pericyte isolation in this proposal and the natural history of CSVD in our translational model 2) present the preliminary data of the identified miRNA targets from this project and the involved cellular pathways at the International Scientific Research Conference (ISRC) to gain the required national reputation and 3) work with my mentors and complete the proposed courses to fill in my training gaps. Achieving these aims will be essential to successfully competing for my K-08. The subject of the subsequent K-08 award application will be to verify the biological relevance of the identified miRNA targets and cellular pathways in cell culture and mice

models. This will lead to verified targets of the disease	translational laboratory techniques (Objective 1)	Biomedical Informatics Analysis (objective 2)	Grant Writing and Research Ethics (Objective 3)
Mentor specific training	Rink (30 minutes/week)	Rink (30 minutes/week) Fernandez (1 hour/month)	Sachs (30 minutes/week) Esterhazy and Alleline (1 hour/month)
Formal Courses	BSGP 8800 (2 credits, Spring 2020) BIOPHRM 6785 (1.5 hour credit, 2 <sup>nd</sup> year)	BMI 5710 (3 credit hours, fall/2019) RNA-seq data analysis two days (10/2020)	Grant training workshop (one day, 09/2019) PHM 8520 (1 semester hour, 05/2020)
CCTS and NRI Research Support		NRI statistical support	CCTS courses (1 hour/month)

Table 1: The timeline of the proposed career development plan during the Path to K Grant.

As a pediatric urologist, I care for a myriad of diseases of the kidney and bladder, often with the primary goal of preserving kidney function. Early in fellowship, I recognized deficiencies in the understanding of kidney injury as a result of urologic disease, specifically how the lower urinary tract, including the bladder, affects chronic kidney disease (CKD) progression. Realizing the importance of research in this area and lacking a skillset necessary to optimally investigate this complex process, I pursued a Master in Public Health degree from The Ohio State University with a focus on clinical and translational science. Following completion of fellowship, I accepted a surgeon-scientist position at Nationwide Children's Hospital (NCH) with 50% protected research time in the Center for Surgical Outcomes Research (CSOR). Over this time, I have developed unique relationships with highly successful clinical and basic science investigators both within my own Center (Drs. Peter Minneci MD MHSc and Jennifer Cooper PhD) and the Center for Clinical Translational Research (Drs. Brian Becknell MD PhD and Christina Ching MD). Through these collaborations, my research has generated 13 senior author, 5 first author and 24 co-author peer reviewed manuscripts, the most recent of which have focused on prediction of kidney failure in children with congenital urinary tract obstruction (CUTO).

My clinical and research success, specifically in children with CKD due to CUTO has also provided a leadership opportunity where I was recently appointed Co-Director of the Urology Nephrology Clinic at NCH. In this role I am privileged to work in tandem with Dr. Becknell, managing patients with complex obstructive uropathies at a single patient encounter. This relationship has allowed further opportunities for collaboration and honed my clinical and research interests to the care and study of CKD in children with CUTO. It was through these multispecialty clinical encounters that I realized the importance of looking at obstructive uropathy from both a urologist's and nephrologist's perspective and that anything less is incomplete. Also, by forging these unique relationships with my nephrology colleagues, I was able to seek out and participate in what had historically been a unique opportunity for nephrologists. In 2017, I attended the Chronic Kidney Disease in Children (CKiD) workshop in Baltimore where enthusiastic kidney researchers are introduced to the intricacies of this NIDDK funded database and biorepository. It was at this workshop that I first met Dr. Susan Furth MD PhD (PI of CKiD). At this time and over subsequent conversations, Dr. Furth expressed strong support for my interest in leveraging CKiD for the study of urologic pathologies, specifically through the lens of a urologist, which had not previously been proposed. Once granted access to CKiD data and associated biosamples, I was able to leverage the expertise of local mentors and Center statistical resources to complete high level analysis, which to date has led to 3 CKiD publications on kidney injury risk in CUTO.

Research efforts to investigate markers of renal progression in CUTO are ongoing and multifaceted in my lab. As a founding member of the Pediatric Urology Midwest Alliance (PUMA), I spearheaded an investigation to identify optimal cutoff values for lowest serum creatinine in the first year of life for children with posterior urethral valves (the most common cause of obstructive uropathy in children). Through this investigation we were able to predict with high certainty which children would require dialysis or renal transplantation, the results of which were published in *Pediatrics*. In another effort to improve risk stratification of children with obstructive urologic diseases, I have also recently developed a multi-center prospective database and biobank of local urine samples from children with CUTO, with the expectation to expand biobanking to other PUMA sites in the near future.

My 5-year goal is to achieve financial independence which would allow my continued research in the field of CKD progression in CUTO. Obtaining the Davis Bremer Path to K Mentored Career Development Grant would be a vital step for these career goals, which will ideally lead to a K23 and an eventual R01. Additionally, the Davis Bremer award would provide an opportunity for continued professional development through services offered by the CCTS to best prepare me as I continue down the path towards funding independence.

## **Mentorship and Career Development Plan: Mentorship**

As a young surgeon-scientist, I am extremely privileged to start out my career at Nationwide Children's Hospital (NCH) where I have been afforded 50% research time protection. As a Principal Investigator in the Center for Surgical Outcomes Research (CSOR), I have forged relationships with highly talented investigators across multiple areas of expertise. Early research endeavors with these collaborators have led to numerous publications and the establishment of vital mentoring relationships. As a part of obtaining the Davis Bremer Path to K Mentored Career Development Grant, I plan to expand on current mentoring relationships with the creation of a formal mentoring committee. The committee includes:

Lead Mentor: Dr. Peter Minneci MD, MHSc, is a pediatric surgeon at NCH and Co-Director of CSOR. With a research focus on clinical outcomes in pediatric surgical patients, Dr. Minneci has received numerous funding awards which includes R01-equivalent federal funding through the Patient Centered Outcomes Research Institute (PCORI). Dr. Minneci is also currently a faculty mentor on a K12 Training Program Award and a co-mentor on three career development awards. Sharing an interest in improving clinical outcomes in pediatric surgical patients, Dr. Minneci and I have collaborated on numerous projects and publications. Through these experiences we have developed a close mentorship relationship. Dr. Minneci also has experience with design and implementation of multi-centered prospective studies. Through his continued mentorship, acquiring these skills will allow me to expand my current research beyond NCH to optimize the study of rare urologic disease in children. To accomplish these goals, we plan to meet biweekly throughout the funding period.

Co-Mentor: Dr. Brian Becknell, MD, PhD, is a pediatric nephrologist at NCH who has a track record for successful transition from K08 to R01 funding. Dr. Becknell and I have a strong record of collaboration, leading to multiple publications where he has contributed expertise regarding clinical risk factors, biomarkers and pathophysiology of chronic kidney disease progression in obstructive uropathy. Dr. Becknell's lab has proficiency in processing, measuring and interpreting biomarkers related to urinary obstruction which is integral to the proposed project. He also acts as a Co-Director in the Urology Nephrology Clinic where we jointly see patients in a clinical setting monthly. It is this close clinical relationship that has led to the success of our research collaborations. Dr. Becknell and I currently meet biweekly to discuss research progress and this will continue throughout the proposed project.

Collaborator: Dr. Jennifer Cooper PhD, is a clinical epidemiologist and biostatistician and is Co-Director of CSOR. She has over 8 years of experience leading and collaborating on clinical and health services research studies in pediatric surgery. Dr. Cooper serves as Principal Investigator on an NIH-funded R01 evaluating the impact of the Affordable Care Act Medicaid expansion on racial/ethnic and socioeconomic disparities in trauma care and outcomes in young adults. She also serves as a statistical collaborator on multiple NIH, PCORI, and foundation-funded grants and contracts. Dr. Cooper and I have collaborated on numerous research projects, and she has mentored me in the areas of research study design and data analysis and interpretation. Dr. Cooper's input has been integral to the study design and analytic plan described in the current proposal, and she will continue to provide mentorship in clinical prediction model development and validation as I continue to enhance my knowledge in this area. Dr. Cooper and I will meet biweekly.

Collaborator: Dr. Susan Furth MD, PhD, is a pediatric nephrologist and chief of the Division of Nephrology at Children's Hospital of Philadelphia. Dr. Furth is a Principal Investigator at The Chronic Kidney Disease in Children (CKiD) Study and has acted as liaison and collaborator for my recently published biomarker studies. Dr. Furth has been and continues to be an integral mentor and collaborator, providing both clinical and research expertise and access to highly coveted biosamples through CKiD. We continue to work closely on the current proposal and she will remotely attend my quarterly research advisory committee meetings.

Collaborator: Dr. Christina Ching MD, is a colleague in the Department of Urology and local collaborator who will provide expertise on urothelial biomarkers of obstructive uropathy, as she has piloted the use of these markers in the setting of congenital ureteropelvic junction obstruction. As an early career investigator, former Davis Bremer Path to K Mentored Career Development Grant recipient, and current NIDDK K08 awardee, Dr. Ching will serve as a contemporary peer mentor for career development.

**DETAILED BUDGET FOR INITIAL BUDGET PERIOD  
DIRECT COSTS ONLY**FROM  
06/1/202-THROUGH  
05/31/202-List PERSONNEL (*Applicant organization only*)

Use Cal, Acad, or Summer to Enter Months Devoted to Project

Enter Dollar Amounts Requested (*omit cents*) for Salary Requested and Fringe Benefits

NAME	ROLE ON PROJECT	Cal. Mnths	Acad. Mnths	Summer Mnths	INST.BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS	TOTAL
Peter Guillam	PD/PI	0.58			241,686	15,000	3,170	18,170
Jerry Westerby	Research Associate	2.4			44,553	9,089	4,802	13,891
<b>SUBTOTALS</b> →						<b>24,019</b>	<b>7,972</b>	<b>32,061</b>

CONSULTANT COSTS

EQUIPMENT (*Itemize*)SUPPLIES (*Itemize by category*)

Rat cost: 5,000.

Antibodies for LCM:

2,600. MRI cost: 5,000

Supplies: 3,330.

15,930

TRAVEL

Travel to the Association for Clinical &amp; Translational Science (ACTS) in Washington, DC.

2,000

INPATIENT CARE COSTS

OUTPATIENT CARE COSTS

ALTERATIONS AND RENOVATIONS (*Itemize by category*)OTHER EXPENSES (*Itemize by category*)

CONSORTIUM/CONTRACTUAL COSTS

DIRECT COSTS

**SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD** (*Item 7a, Face Page*)**\$ 49,991**

CONSORTIUM/CONTRACTUAL COSTS

FACILITIES AND ADMINISTRATIVE COSTS

**TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD****\$ 49,991**

**Budget justification:****Initial First year budget (06/01/2019 – 05/31/2020):**

- 1) Personnel:** Dr. Guillam is the principle investigator and 20% of his effort will be devoted to the project (\$15,000) funded by the award and the rest will be funded by the Department of Neurology. Jerry Westerby is a research associate in the department of neurology. He will be devoted 20% of his effort for this project to perform: animal monitoring, blood pressure and behavioral testing.
- 2) Travel:** to attend the Association for Clinical & Translational Science (ACTS) in Washington, DC as required by the award term.
- 3) Supplies:** The following supplies which are required for the project will be requested:
  - Animal costs: \$5,000 to purchase the rats for experiment.
  - Antibodies for endothelial and pericyte labeling: \$2,600.
  - Cost to perform the brain MRI: \$5,000.
  - Lab supplies (alcohol, formalin, cassettes, PBS, OCT, etc.): \$3,330.

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## Mentorship and Career Development Plan: Career Development

**Skill 1: Measurement of candidate urinary biomarkers.** I will perform enzyme-linked immunosorbent assays (ELISA) in the Becknell Laboratory to quantify candidate urinary biomarkers. Under the supervision of Dr. Becknell and his highly experienced laboratory staff, I will develop skills in sample preparation, ELISA optimization, and data analysis. Once I have mastered these skills, I will utilize a similar approach to perform multiplexed assays of kidney injury biomarkers using the Meso Sector S 600 instrument.

**Skill 2: Longitudinal data analysis.** To improve my skillset on longitudinal data analysis I will enroll in OSU PUBHBIO 7230 which covers statistical models and methods for the analysis of data arising from longitudinal studies with repeated measurements on subjects over time. Knowledge acquired through this course work in combination with direct mentorship from Dr. Cooper will provide vital skills necessary for success in current and future longitudinal research projects.

**Skill 3: Validation and interpretation of clinical prediction models.** In order to improve my knowledge of complex risk modeling I will enroll in multivariate regression methods (PUBHBIO 6250), focusing on model interpretation, hypothesis testing, confidence intervals, confounding, interaction, and model selection. The addition of these skills in combination with direct tutelage from Dr. Cooper will not only allow successful completion of the current project aims but also provide a vital skill set for future risk modeling study design, analysis and interpretation.

**Strategy for a future K-proposal submission:** Utilizing preliminary data acquired through the current proposal, I will submit a K23 application to the NIDDK in the first 18 months of the funding period. The K23 proposal will focus on expansion of current study aims to include multi-institutional level clinical data and biosamples, collected through a regional consortium of pediatric urologists (Pediatric Urology Mid west Alliance, PUMA), for which I am a founding member. This data will set the stage for an R01 submission and provide continued progress to becoming an independent investigator and a leading researcher in the field of chronic kidney disease in congenital urinary tract obstruction.

Activity	Year 1				Year 2			
	July-Sept	Oct-Dec	Jan-March	April-June	July-Sept	Oct-Dec	Jan- March	April- June
Structured Mentorship								
Primary Mentor	Biweekly one-on-one mentorship meetings							
Peter Minneci	Quarterly research advisory committee meetings							
Co-Mentor	Biweekly one-on-one mentorship meetings							
Brian Becknell	Quarterly research advisory committee meetings							
Collaborator	Biweekly statistical mentorship meetings							
Jennifer Cooper	Quarterly research advisory committee meetings							
Collaborator: Susan Furth	Quarterly research advisory committee meetings							
Collaborator: Christina Ching	Quarterly research advisory committee meetings							
Coursework, Professional meetings, Publications								
Biostatistics (PUBHBIO 7230)			X	X				
Biostatistics (PUBHBIO 6250)					X	X		
American Urological Association Annual Meeting				X				X
American Society of Nephrology Annual Meeting		X				X		
ACTS annual meeting				X				X
Manuscript submission					X		X	
Responsible Conduct in Research								
Ongoing Institutional Training	X	X	X	X	X	X	X	X
Manuscript submission								
Publications						X		X
Grant Submission								
NIDDK K23 drafting			X	X	X			
NIDDK K23 submission						X		