Request for Applications

Davis Bremer Pre-K Mentored Career Development Grant

Release Date: September 6, 2016
Letter of Intent Due: September 23, 2016
Application Deadline: November 1, 2016
Start Date: May 1, 2017

The OSU Center for Clinical and Translational Science (CCTS) and the College of Medicine Office of Research are seeking applicants to apply to an innovative career development program whose purpose is to train clinical investigators. The CCTS & COM Davis Bremer Pre-K Program supports the career development of investigators who have made a commitment to conduct either patient-oriented or translational research. The Davis Bremer Pre-K Award is available for a period of two years (contingent on satisfactory progress). The start date for the Davis Bremer Pre-K award is May 1, 2017.

Note: The CCTS fund two career development programs for junior faculty: the Davis Bremer Pre-K and the KL2 Awards. See Appendix 1 of this document for a comparison of the two programs.

On-line application: http://go.osu.edu/2016DavisBremer
Letter of Intent: http://go.osu.edu/LOIDavisBremer

Program Overview

Translational science enhances multidisciplinary collaboration and accelerates the application of that science from the laboratory to the patient to its adoption into practice to improve human health. Physician-scientists can be a critical catalyst of translational research. With one foot in the practice of medicine and the other in research and discovery or in exploring health services and public policy, they are uniquely positioned to bridge the gap between laboratory and bedside or the bedside to implementation of new health care approaches. Although, scientific advances have never been more accessible and directly applicable to human health, there remains a relative scarcity of physician-scientists. There is thus a critical need to support the career development of the next generation of clinician-scientists to engage in translational research teams of the future.

Recognizing the need to address this shortage of clinicians that are successfully engaged in clinical and translational research, the Center for Clinical and Translational Science (CCTS) at the Ohio State University has joined together with 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 to create a new pilot and career development program, the Davis-Bremer Scholars Award, to help to facilitate early career successes for outstanding physician-scientists at Ohio State committed to a career in academic medicine. This early career pilot award aims to place junior physician-scientists on the path to be competitive for NIH K Career Development Awards or, in exceptional circumstances, for R Awards.

Davis Bremer Pre-K Award Information Brown Bag
When: 09/16/16 Noon to 1 PM
Where: CCTS, Prior Hall, Ste. 260, room 236
Bring your lunch and learn about the KL2 programs
Topics include eligibility, benefits, and tips on writing a successful application.
To register: http://j.mp/1PCggzr
The awards support preliminary data collection for innovative projects that have high potential of receiving extramural funding. These grants are not intended to provide additional support for established areas of research or previously funded projects. Special consideration will be made for research focused toward clinical and translational studies. The CCTS specifically encourages transdisciplinary research, in which investigators from disparate scientific areas collaborate to bring unique approaches to address human health issues. We also encourage applications focused on the development of clinician investigators in health services (including process improvement research), outcomes and comparative effectiveness research.

This award is designed as a Pre-K program and provides mentorship and oversight in addition to pilot funds. A clear and robust mentorship plan towards successful extramural funding is a required component of the application. To facilitate a strong foundation in translational science, recipients will have the opportunity to participate in Tools of the Trade and Lunch and Learn Seminars through the CCTS relevant to an individual’s career development needs. To facilitate success in generating a competitive proposal for an extramural R or K application, awarded Davis-Bremer Scholars will be required to attend and utilize the resources offered through the OSU College of Medicine Office of Research supported grant writing workshops.

As required by the two endowments funding this program, all recipients of the Davis-Bremer Scholars Award must have an M.D. degree with a record of engagement in active clinical practice. Individuals with an M.D. Ph.D. and M.D. M.S. or other combinations of degrees (as long as one is an M.D.) are also eligible to apply. 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.

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 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. Examples of “transdisciplinary” research include clinical investigators teaming with basic scientists to launch a bench-to-bedside project, clinical investigators teaming with population researchers to understand how molecular or physiological events are manifested in larger cohorts, or clinician scientists collaborating with outcomes investigators to examine the process of translating research into practice. Program Preference will be given to junior faculty members with fewer than three years since their appointment, but junior faculty with three or more years since their appointment and research scientists with a research track record are eligible to apply.

The award is designed to benefit a wide spectrum of clinical or translational researchers across OSU. The award provides salary support to ensure protected time for mentored research and didactic training in clinical research across a wide variety of project topics and academic areas.

### Review Criteria

A Study Section will make recommendations to the CCTS Executive Committee for funding up to three Davis Bremer Pre-K scholars. The awarded scholars will be notified in approximately January, 2017. The position will commence May 1, 2017. All applicants will receive reviewer comments on their applications.

Davis Bremer Pre-K Scholars will be selected based on a competitive application process in which the following will be key review considerations that determine funding:

- Is the project substantially innovative (as opposed to descriptive)?
- Is the project extramurally fundable at NIH level?
- Addresses an important problem in human clinical and/or translational research or in an area that impacts human health.
- Includes transdisciplinary and/or cross-institutional collaborative research
• Award is used as seed money rather than continuing support for ongoing projects
• Does the investigator have an academic and/or research profile compatible with extramural funding?
• Is there a strong mentor and mentoring plan?
• Does the department Chair clearly commit to 20% release time for research?
• Can the project be completed within the proposed budget and one year timeline?

Up to 3 awards are expected to be funded in 2017 in the amount of (up to) $50,000 in total direct costs over one year. Competitive renewal of awards for a second year of support may be considered after completion of this award based upon project and investigators need and progress towards scientific and career development milestones.

Please note the following requirements:
• To be considered, all applicants must submit the required Letter of Intent form by 11:59 PM, September 23, 2016 (found online at: http://go.osu.edu/LOIDavisBremer
• Applicants must complete all sections of the entire application. Incomplete applications will not be accepted. The online application can be found here: http://go.osu.edu/2016DavisBremer
• No late applications or letters will be accepted. Applications are due at 11:59 PM on November 1, 2016.

Please direct all questions to the Program Manager, Stuart Hobbs at 614-685-5972 or stuart.hobbs@osumc.edu

Benefits of the Davis Bremer Pre-K Award

• Funds up to $50,000 to cover:
  o Salary and fringe support for up to a 10% FTE appointment to this award (capped at $15,000 maximum) for the applicant is anticipated.
  o Research supplies, travel, research staff, etc. (see Budget section, below, for more detail)
• Access to the CCTS professional services and staff including assistance in the areas of biostatistics, subject recruitment, and human subject’s research.
• Access to a training curriculum in clinical and translational research methodology and specialized training seminars.
• Individualized career development and mentorship from the trainee’s own appointed scientific committee.
• Support to develop a K grant to fund research at the conclusion of the Davis Bremer Pre-K funding.
• The CCTS will be providing other project resources. These include, but are not limited to:
  o Project management
  o Infrastructure services
  o Problem-solving
  o Financial tracking
  o Opportunities to disseminate research (posters and presentations)
  o Tools of the Trade seminars
  o Lunch and Learn seminars

Expectations of Davis Bremer Pre-K Awardees

• Commit 20% of your effort to this Davis Bremer Pre-K Scholar Award.
• Your participation in various CCTS / Davis/Bremer activities will be required:
  o A monthly Lunch and Learn program
  o A meeting with the Translational Therapeutics Think Tank (T4) to discuss your project, particularly any challenges you encounter (https://ccts.osu.edu/node/4424)
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

- Awardees 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 (4 and 8 months) 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 award for tracking data for the CCTS success metrics for 3 years following the end of the award. This is required for our NIH metrics of success and reports.
- 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 award start date May 1, 2017.
- Applicants and mentors must become CCTS members by completing a CCTS membership form.
  https://ccts.osu.edu/member/join
- Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator’s Financial Conflict of Interest.
- Any clinical trial supported by this grant will have an NCATS approved DSM plan or DSM Board, as appropriate, and the researcher will comply with that plan. (Note: Clinical trials beyond the end of Phase IIA cannot be supported by this grant).
- No Davis Bremer Pre-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 which 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.
- All scholars appointed to this award 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.
- Award acceptance 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 Davis Bremer account

### Davis Bremer Pre-K Eligibility

- Applicants must be physicians credentialed by the OSU Wexner Medical Center and have not previously received Davis/Bremer funds or other CCTS Pilot award (CCTS technology dissemination awards are acceptable).
- Applicants must be considered a principal investigator. Eligibility information can be found at the [Ohio State Office of Research website](http://www.osu.edu) and the [NIH website](http://www.nih.gov). Residents and clinical and postdoctoral fellows are not eligible.
- Applicants may not have previously been a PI on a NIH individual or institutional K Award or an R01 or an equivalent non-PHS grant
- Applicants must commit to spending 20% effort engaged in conducting the research supported through this award. Up to half of the committed time may be compensated by the Davis-Bremer Scholars Award with the remained cost-shared by the department. The department chair must submit a Letter of Support agreeing to the release time and cost-sharing as part of the submitted application.
- Applicants and mentors must become CCTS members by completing a [CCTS membership form](http://www.ccts.org).


To be eligible, it is required that you indicate your intention to apply via the Davis Bremer Pre-K Letter of Intent form found here: https://redcap.bmi.osumc.edu/redcap/surveys/?s=phFFMBF2h9

The purpose of the Letter of Intent is twofold:

1. To let program staff know of your intent to apply for the Davis Bremer Pre-K Award 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 September 23, 2016. 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 Davis Bremer Pre-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 Davis Bremer Pre-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 project staff have questions or concerns they will contact you.

If you have questions or concerns, please contact the Program Manager, Stuart Hobbs at 614-685-5972 or stuart.hobbs@osumc.edu

Applications and supporting materials are to be completed by November 1, 2016 by 11:59 p.m. EST.

The application is an online process. Please click here or copy and paste the link into a web browser: https://redcap.bmi.osumc.edu/redcap/surveys/?s=AAn4Cr3THU

Please read these instructions carefully before going online to apply.

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).

All documents asked for in the application must be submitted online in PDF format.

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. A single combined pdf file should be used and should be named using the

following guideline [ last_first_DavisBremer_11-1-2016]

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.

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.#, and ERA Commons username)

☐ 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

☐ 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 – 10 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?

☐ How you believe this training program will change the trajectory of your career or enhance your

movement towards your goals?

☐ Mentorship & Career Development Plan (1 page)

☐ The role of your mentor 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)

☐ Specific Aims & hypothesis

☐ Significance

☐ Innovation

☐ Preliminary Data

☐ Approach

☐ Milestones

☐ References to Scientific Literature (not included in page count. 1 page maximum)

☐ Itemized Project Budget (see below for form) and Budget Justification (3 pages maximum)

☐ NIH Formatted Biosketches (to be uploaded to the Application)

☐ Applicant
☐ Lead Mentor
☐ Any collaborators or additional mentors

☐ Two letters of support from your:
  ☐ Mentor
  ☐ Department Chair guaranteeing 20% protected research time for the duration of the award

☐ Regulatory (IACUC or IRB) approval (if applicable)

## Project Description

This section cannot exceed 8 type-written, single-spaced pages. Please use Arial size 11 font. Margins should be no smaller than 0.5” on all sides.

### Personal Statement (1 page)

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

### Mentorship & Career Development Plan (1 page)

A one-page statement addressing:

- The role of your mentor in developing your skills
- Your strategy for a K-proposal submission within 12 to 18 months.
- 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](http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html) for more information).

### Research Plan (6 pages)

The research plan 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. No more than 5 figures accommodated; figures can be multi-panel if addressing a common theme; fully self-explanatory legends.

- **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. (Funding will be released upon meeting milestones).

### References to Scientific Literature (1 page maximum)

This section is not included in the 8-page limit but should not exceed 1 page.
Itemized Project Budget and Justification

Use provided budget worksheet or PHS 398 form (3 pages maximum: budget and justification)

Allowable costs:

- Salary and fringe support for up to a 10% FTE appointment to this award (capped at $15,000 maximum) for the applicant is anticipated.
- Salary and fringe support for undergraduate or graduate students, clinical trainees, post-doctoral and clinical fellows is permitted. Salary and fringe support for faculty and administrative personnel are not permitted.
- Supplies, travel, and other expenses, such as research beds, nursing or bionutrition staff, routine laboratory measures, and generation of preliminary data.
- Travel funds needed for study conduct (e.g. participant travel or reimbursement for mileage for the conduct of community-engaged research) are allowable expenses. Travel to present at scientific meetings is not allowable under this award.
- Equipment that is essential for the study, and is not otherwise available, may be requested, but large equipment expenditures are discouraged.

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.

Mentor

You are required to have a Mentor. (Additional mentors are optional).

It is expected that the applicant will identify a faculty member mentor in his or her area of clinical or translational research. Under guidance from your mentor, you will prepare a proposal that describes the clinical research project to be undertaken.

Your mentor (or each co-mentor) is responsible for:

- Guiding and encouraging the design and execution of an original, high quality, clinical research project;
- Supervising the preparation of a final report; and
- Providing career development and counseling

The lead mentor will be expected to attend CCTS sponsored events including a mentor training program, if he or she has not already done so.

You may have other mentors or collaborators. These might be individuals drawn from another discipline so that they can provide transdisciplinary input into your project. Your team 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.
NIH Biosketches

You must upload (as PDFs) NIH formatted biosketches of yourself, your lead mentor, and any other mentors or collaborators.

Biosketch Instructions can be found here: http://www.grants.nih.gov/grants/funding/2590/biosketchsample.pdf

A blank Biosketch form can be found here: http://grants.nih.gov/grants/funding/phs398/biosketch.pdf

Letters of Support

Two letters of support are required: (1) from Lead mentor; and (2) from your department chair, affirming protected research time.

The letters should be addressed to:

Cynthia Carnes, PharmD, PhD
Mark Wewers, MD
The Ohio State University
338 West Tenth Avenue
Columbus, OH 43210-1280

Include these letters in your application packet that you will upload by 11:59 p.m. on November 1, 2016.
Appendix 1: CCTS Career Development Awards Compared

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<th>Pre-K Davis Bremer</th>
<th>vs</th>
<th>KL2</th>
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<td>• For early career physician-scientists/ investigators committed to a career in academic medicine; who have not previously been a PI on an NIH individual or institutional K, or R01 Award or received a pilot award from the CCTS.</td>
<td></td>
<td>• For junior faculty who have not yet been a PI on a major federal or private sector research grant or who have not previously received a K award.</td>
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<td>• Applicants must be physicians with OSU Wexner Medical Center credentials.</td>
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<td>• For clinical and translational researchers with a research or health-professional doctoral degree.</td>
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<td>• Provides salary and fringe support for up to a 10% FTE (capped at $15,000) and approximately $35,000 in research expense support for one year.</td>
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<td>• Provides 75% salary support and research funding for three years (two years CCTS support; one year home college support).</td>
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<tr>
<td>• Aims to place junior physician-scientists on the path to be competitive for NIH K Career Development Awards.</td>
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<td>• Support to develop an R grant to fund research at the conclusion of the KL2 funding.</td>
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<tr>
<td>• WHO SHOULD APPLY? If you picture yourself using the data from your project to apply for a K award in one to two years, apply for the Pre-K Davis Bremer.</td>
<td></td>
<td>• WHO SHOULD APPLY? If you picture yourself using the data from the proposed project to apply for an R grant in two to three years, apply for the KL2.</td>
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Important note: You can apply for one or the other, but not both of these awards at the same time.

Complete RFAs and instructions can be found at the CCTS website:

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<th>Pre-K Davis Bremer</th>
<th>KL2</th>
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<td><a href="https://ccts.osu.edu/node/4683">https://ccts.osu.edu/node/4683</a></td>
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The Davis Bremer award is only available to MDs because of stipulations placed on the funds by donors. If you are not an MD, talk to your College Dean about partnering with the CCTS to establish a Pre-K program related to your discipline.

Further Information

Please direct questions to the education programs manager, Stuart.Hobbs@osumc.edu (614-685-5972).

The Director for the CCTS Research Education, Training, and Career Development programs is Dr. Joanna Groden.