Draft Email Text
Subject Line: CoBRE Pilot Project Funds for auditory/vestibular research

The Translational Hearing Center is an NIH/NIGMS-funded Center of Biomedical Research Excellence (CoBRE) *committed to developing a cadre of translational auditory/vestibular research scientists developing biomedical and ototherapeutic solutions that preserve or restore hearing and vestibular function.*

The Center has 2 specialized Research Cores, the *Auditory & Vestibular Technology Core* and the *Drug Discovery & Delivery Core*, to assist PIs in meeting their research goals. **Up to four 1-year Pilot Project research** awards are available with the earliest possible start date of September 1st, 2024.

Pilot Project awards ($50k) support junior faculty investigators to acquire compelling pilot data that allow them to successfully compete for an upcoming CoBRE-funded Replacement Research Project Leader slot or external federal funding (e.g., R-series or K-series from NIH). Meritorious proposals will fit the Center's theme, i.e., mechanistically elucidate an etiology underlying hearing loss, or identify/validate candidate compounds that preserve or restore hearing.

Eligibility: tenure-track or non-tenure track faculty without a history of R01-level funding (i.e., >$210,000 direct cost per year from a single entity), **prior CoBRE funding*, or INBRE funding that will be concurrent with any CoBRE funding.*** Applicants will be located at Creighton University, Boys Town National Research Hospital or University of Nebraska Medical Center and eligible to compete for RPL slots or independent R or K awards from NIH. Submission deadline is 4.30 pm Monday April 15th, 2024. See attached document for examples of research areas and complete submission instructions.

Project inquires can be addressed to Peter Steyger, PhD, Director of the Translational Hearing Center at petersteyger@creighton.edu, and proposal submission enquires to Stacy Barney at stacybarney@creighton.edu or Jacob Walker at Jacobwalker@creighton.edu

All Pilot Project proposals will be submitted as a single PDF file, with all the required elements (see attachment)

Submit Here- https://blueq.co1.qualtrics.com/jfe/form/SV_51hOuq5wvciy77U

Notification of review outcomes will be made by September 1st, 2024. IRB and IACUC approvals are required by July 1st, 2024.

Creighton University
Translational Hearing Center
CoBRE-Pilot Project Proposal Guidelines
Application Deadline: Monday April 15th, 2024, 4:30 p.m.,

Pilot Project Proposals

Eligible applicants will be junior investigators without a history of R01-level funding **as PI** (≥*$210,000 in a single year from a funding agency), prior IDeA research project funding from CoBRE, or INBRE (or CTR) funding that will be concurrent with any CoBRE.* Eligible applicants will be located at Creighton University, Boys Town National Research Hospital or the University of Nebraska Medical Center. Proposals will be budgeted for 1 year for a maximum award of $50,000. Each proposal will name a volunteer Internal Mentor. Applicants with diverse backgrounds such as gender, race, ethnicity, and disability are encouraged to apply. Meritorious proposals will fit the Center's theme, i.e., **mechanistically elucidate an etiology underlying hearing loss, or identify/validate candidate compounds that preserves or restores hearing.** Funding for a second year will be competitively reviewed, requiring demonstrated progress and need. Only proposals from eligible faculty (including non-tenure track) investigators with an identified Internal Mentor will be reviewed.

Relevant Areas of Research: Innovative translational auditory and/or vestibular neuroscience that leads the recipient to successfully compete for a CoBRE-funded RPL slot or independent, federal funding (e.g., R or K series from NIH). Examples of research projects supported by the Translational Hearing Center include, but are not limited, to the following:

- Identification and validation of novel therapeutics that preserve or restore hearing and balance function
- Characterization of signaling pathways that lead to hearing loss or vestibular disorders
- Characterization of signaling pathways involved in hair cell regeneration
- Mechanisms underlying poorly characterized etiologies of hearing loss and vestibular disorders
- Translation of nonclinical studies into human studies to better understand how to preserve or restore hearing and/or balance functions
- Impact of aging, infection, ototoxicity, (noise) trauma and genetic polymorphisms on auditory and vestibular structure and function across the lifespan.

Preference will be given to those proposals likely to lead to submission of Research Project Leader proposals to the Translational Hearing Center (via a subsequent RFA). Applications not relevant to the Center's mission will be returned without review. For questions pertaining to whether your research would qualify for Center support, please contact Peter Steyger by email only at petersteyger@creighton.edu.

DEADLINE AND APPLICATION FORMAT: Proposals for each application must be submitted using the link below as a single PDF using the submission link before 4:30 pm, Monday April 15th, 2024. You will receive a confirmation of your submission. Funding decisions will be made by Wednesday September 1st, 2024. Funding for a second year will be competitively reviewed. Renewal decisions will be based on project progress, scientific integrity and rigor, potential for Center synergy, and potential for submission of Research Project Leader proposals, or successful external funding.

Submit Here- https://blueq.co1.qualtrics.com/jfe/form/SV_51hOuq5wvciy77U

PREPARATION OF APPLICATIONS: Using standard NIH PHS398 forms and instructions (https://grants.nih.gov/grants/funding/phs398/phs398.html), the following sections need to be submitted (with ½ inch margins, Arial font size 11 margins [top, bottom, left, and right]; see also this page: https://grants.nih.gov/grants/guide/notice-files/NOT-GM-14-111.html):

NIH Face Page (https://grants.nih.gov/grants/funding/phs398/phs398.html). The NIH Face Page will need to be signed by your institutional official. This does not need to be signed at the of time application submission. If the application is recommended for funding, we will ask that the application then be signed by an institutional office.

- **Biographical Sketch** for the PI and any other Key Personnel,
  Project Summary (limited to 30 lines or less of text)
- **Creighton Excel Budget Form. <u>You must include a minimum of 3% effort of your base salary to the budget.</u>**
- **Research plan** (limited to seven pages in total; more guidance further below)
  - **a. Specific Aim(s)** (one page maximum, and can be shorter)
  - **b. Research Strategy** (six pages maximum):
    - **i. Significance:** a) the rigor of prior research -- the strengths and weaknesses of the research that is used to form the basis for the proposed research question.
    - **ii. Innovation**
    - **iii. Approach:** Can include preliminary data, although not required. Experimental design, including steps taken to ensure scientific rigor (robust and unbiased experimental design, sample, measures, procedures, analysis, interpretation and reporting of results, explained as appropriate for a pilot project) and consideration of key biological variables if applicable (please see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-011.html).
    - **iv. Plans for extramural funding applications** to NIH or other agencies (please specify) upon successful completion of this project.
- **Literature cited** (excluded from the above page limits)
- **If the proposed study involves human subjects:**
  - Current PHS Human Subjects and Clinical Trials Information Form https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.500-phs-human-subjects-and-clinical-trials-information.htm
  - Institutional Review Board (IRB) approval
  - Human Subjects Education Certification (required even when research is exempt)

  Note: Within 30 days after receiving NIGMS approval for clinical research projects, the grantee must enter study data in the Human Subjects System (HSS).

- **If the proposed project involves Vertebrate Animals:**
  - IACUC approval
  - Vertebrate Animal Section (see https://grants.nih.gov/grants/olaw/vertebrate_animal_section.htm)

<u>RESEARCH PLAN:</u> *(No more than 7 total pages for the following sections of the Research Plan)*
Please follow the outline below for the proposal narrative. This section should include sufficient information needed for evaluation of the project, independent of any other document. Be specific and informative and avoid redundancies. Discussion of the inclusion of human subjects or animals must be included within the 6 pages of the Research Plan. There are no specific form pages for the research plan, but use the following format:

1. **<u>Specific Aims (1-page max)</u>:** Concisely state the goals of the proposed research and summarize the expected outcomes(s), including the impact that the results of the proposed research will have on the research field(s) involved. List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.

2. **Research Strategy (6 pages max):** Organize the Research Strategy in the specified order and using the instructions provided below. Start each section with the appropriate section heading—Significance, Innovation, Approach.

a. Significance:

- Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
- Describe how the concepts, methods, technologies, treatments, services, or preventive interventions that drive this field will be changed if the proposed aims are achieved.

b. Innovation:

- Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
- Describe any novel theoretical concepts, approaches, or methodologies; instrumentation or intervention(s) to be developed or used; and any advantage over existing methodologies, instrumentation, or intervention(s).
- Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.

c. Approach:

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted, as well as any resource sharing plans, as appropriate.
- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
- If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high-risk aspects of the proposed work.
- Discuss your plans for potential sources of future support for continuing the research program initiated by this application. Specify intramural and extramural funding agencies to be approached. In addition, if this research is included in any currently pending external proposal, identify that proposal.

LITERATURE CITED: *(Not included in 6-page limitation)*
List all references. Each reference must include the title, names of all authors, book or journal, volume number, page numbers, year of publication, and PMID. Be concise and select only those literature references pertinent to the proposed research.

EARLIEST START DATE: September 1st, 2024, if IRB and/or IACUC approvals obtained by Monday July 1st, 2024. Receipt of IRB or IACUC approvals after July 1st, 2024, will delay submission to NIGMS for approval with subsequent delay in the Pilot Project start date, typically by ~6 weeks after receipt.

CERTIFICATIONS: Institutional procedures for projects involving human subjects, vertebrate animals, or biohazardous materials must be observed. Approval must be received prior to submission to NIGMS for final approval and release of funds.

QUESTIONS: If you have any application or submission questions, please contact Stacy Barney at stacybarney@creighton.edu or Jacob Walker Jacobwalker@creighton.edu

Review criteria. Complete proposals will be reviewed. Review criteria include the quality and feasibility of the proposal, relevance to Center mission, and the benefit of participating in the Center to the applicant. The EAC will provide constructive feedback and score proposals using R01 Summary Statement templates. Meritorious proposals will demonstrate assurance of full compliance with all applicable federal policies, rules, and guidelines for research involving human subjects, vertebrate animals, and/or biohazards (see "Post-Award Program Requirements" under Section VI of PAR-19-313).

Special Considerations, Institutional Approvals, and Reporting

Budget Restrictions: Student/post-doctoral salary/wages are permissible. Wages for technical personnel are permissible. Any equipment (>$5,000 per item) and/or computer purchases must be well-justified. Renovations and/or Honoraria are not allowed. Travel to locations outside of the US & Canada is not allowed.

Indirect Costs (F&A): Indirect costs associated with Pilot Project Awards will be awarded to the investigator's institution. *Please work with your Departmental Administrator or Sponsored Programs office to ensure that your proposal budget includes your institution's correct F&A rate.*

Clinical Trials: Not allowed

Regulatory Approvals: If your project includes vertebrate animals, final IACUC approval from your home institution is required before the project can be sent for NIGMS approval and before funds can be released. If your project includes human subjects, final IRB protocol approval from your home institution is required before the project can be sent for NIGMS approval and before funds can be released. Protocols must be submitted and pending approval prior to submission of the Pilot Project proposal, and **final** approval must be sent to Stacy Barney by Monday July 1st, 2024).

Additional Requirements: Pilot Project applicants must select a volunteer Internal Mentor who can advise on the project management, research needs and progress towards a Research Project Leader proposal, or other NIH funding opportunity. Pilot Project Leaders (PPLs) are expected to participate in Center activities such as weekly journal clubs, a monthly Research Data Club, and attend weekly Research Seminars. PPLs must also submit a quarterly tracking report that list the status of manuscripts, proposals and indicate their current uncommitted project budget. A presentation of progress will also be required at the annual External Advisory Committee meeting.