

Creighton University
Translational Hearing Center
Pilot Project Proposal Guidelines
Application Deadline: Monday September 27th, 2021 4:30 p.m.,

Pilot Project proposals

Eligible applicants will be junior investigators without a history of R01-level funding **as PI** ($\geq \$210,000$ in a single year from a funding agency) or prior IDeA research project funding from INBRE, CoBRE or CTR sources, 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, clinical-, research- or 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 independent, federal funding, preferably R01-level funding. 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 CoBRE. 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 as a single PDF file by email to Stacy Barney at stacybarney@creighton.edu before 4:30 pm, Monday September 27th, 2021, **with "THC Pilot Project proposal" in the subject line.** Notification of funding decisions will be made by Friday November 5th, 2021. 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.

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>). This needs to be signed by your institutional official and all fields on the NIH Face Page must be complete and correct. Please leave dates of proposed period of support and signing by an institutional official blank.

- **Biographical Sketch** for the PI and any other Key Personnel, **Project Summary** (limited to 30 lines or less of text)
- **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** (e.g. 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)

RESEARCH PLAN: (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. **Specific Aims (1-page max):** 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: January 1st, 2022 if IRB and/or IACUC approvals obtained by November 22nd 2021. Receipt of IRB or IACUC approvals after November 22nd, 2021 will delay submission to NIGMS for approval with subsequent delay in the Pilot Project start date 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 before 4:30 pm, Wednesday, September 22nd, 2021.

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 Research Project grant 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 before November 22nd, 2021).**

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 reports 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.