

Creighton University
Translational Hearing Center
Research Project Leader (RPL) Proposal Guidelines
Application Deadline: 4:30 p.m., Friday, April 1st, 2022

Open Research Project Leader slot

Eligible applicants will be junior investigators with tenure-track status at Creighton University without a history of R01-level funding **as PI** ($\geq \$210,000$ in a single year from a funding agency) or prior RPL funding. Proposals will be budgeted for 3 years, with an annual budget of \$200,000 and to include a minimum of 75% effort (protected research time) for the applicant. Second- and third-year funding is dependent on satisfactory progress and review by the External Advisory Committee (EAC). Each proposal will name an Internal Mentor, and an External Mentor who is a clinician-scientist to guide translation of the project towards clinical studies. 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.**

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.

Priority will be given to proposals likely to lead to extramural funding. Applications not relevant to the Center's mission will be returned without review. For questions regarding research directions eligible for Center support, please contact Peter Steyger by email only at petersteyger@creighton.edu.

DEADLINE AND APPLICATION FORMAT: Applications must be submitted as a single PDF file using the link below before 4:30 pm, Friday, April 1st, 2022. The proposal will be reviewed internally, and comments returned to the applicant by Monday April 11th, 2022. A response to reviewers' comments (a 1-page Introduction) and a revised proposal must be received by 4.30 pm Thursday, April 28th, 2022. Notification of funding outcomes will be made by May 16th, 2022.

Submit Application- https://blueq.co1.qualtrics.com/jfe/form/SV_cxdQ4sk2mBNoTgW

APPROVALS: Internal grant applicants must follow established University approval procedures.

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]):

- **NIH Face Page** (<https://grants.nih.gov/grants/funding/phs398/phs398.html>). 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.
- **Project Summary** (limited to 30 lines or less of text)
- **Budget** for 3 years
- **Budget Justification**

- **Biographical Sketch** for the PI and any other Key Personnel,
- **Updated Other Support**
- **Research plan** (limited to seven pages in total; more guidance further below)
 - **a. Specific Aim(s)** (one page max)
 - **b. Research Strategy** (six pages max):
 - **i. Significance:** a) the rigor of prior research - the strengths and weaknesses of prior research that formed 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)
- The Research Project selected for funding will be notified by Monday May 16th, 2022 and will be required to have obtained all regulatory approvals before May 19th, 2022, to be considered for funding by NIGMS for a start date of July 1st, 2022.

BUDGET: Use PHS398 Budget forms, following PHS398 instructions, for all budget information. All full-time Creighton personnel added to the budget will receive a salary release email. Their name will be listed on the budget; indicate person-months and salary in the budget for any participating faculty.

BUDGET JUSTIFICATION: Describe the specific functions of all personnel. Provide a complete justification for all non-personnel items requested. No specific form page is required for the budget justification.

PHS 398 BIOGRAPHICAL SKETCH: Provide a biographical sketch for the applicant and key personnel involved in the proposed project. Use the current PHS 398 Biographical Sketch form. The Biographical Sketch form and a sample can be found at: <https://grants.nih.gov/grants/forms/biosketch.htm>.

RESEARCH PLAN: *(No more than 7 pages for the following sections of the Research Plan)*
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 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 (up to 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:

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, expected outcomes 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 limit)*

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: July 1, 2022, if IRB and/or IACUC approvals obtained by 4.30 pm Thursday May 19th, 2022, and submitted to Peter Steyer at Petersteyger@creighton.edu

CERTIFICATIONS: University procedures for projects involving human subjects (IRB), vertebrate animals (IACUC), or biohazardous materials (IRB) 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, Monday, March 28th, 2022

RPL review criteria. Complete proposals will be reviewed, and feedback offered by Monday April 11th, 2022, to respond to reviewers' comments (Introduction) and submission of a revised application with the Introduction by 4.30 pm Thursday April 28th, 2022, for review by the External Advisory Committee (EAC). 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](#)). Second- and third-year funding is dependent on satisfactory progress and review by the EAC. Receipt of R01-level funding by an RPL is a major milestone and a criterion for graduation from mentored COBRE support.

Special Considerations, Institutional Approvals, and Reporting

Budget Restrictions: A minimum of 75% FTE is required for the RPL. 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

Institutional Regulatory Approvals: If your project includes vertebrate animals (IACUC), human subjects (IRB) or select agents/toxins (IBC), approval from your home institution is required before the project can be sent for NIGMS approval and before funds can be released. Approval of **IACUC, IRB or IBC protocols must be sent to Dr. Steyger before 4.30 pm Thursday May 19th, 2022.**

Additional Requirements: RPLs must select an Internal Mentor and an External Mentor who can advise on translating the project to clinical studies, as well as their specific career guidance and research needs. The Translational Hearing Center will compensate the Internal Mentor at 0.6 calendar months from separate funds, as is the fee for the External Mentor. RPLs must participate in weekly journal clubs, a monthly Research Data Club, and attend weekly Research Seminars. There will be monthly meetings with the Executive Team and mentors to discuss progress. RPL must also submit a quarterly tracking report that list the status of manuscripts and grants and indicate their current uncommitted project budget. A presentation of research progress will also be required at the yearly EAC meeting. Second- and third-year funding is dependent on satisfactory progress and review by the EAC. The RPL must submit an annual Research Performance Progress Report and Scientific Information Reporting System using the software Piestar. The RPL is expected to submit an investigator-initiated R01-level federal proposal before the end of two years of COBRE support. *Receipt of R01-level funding by an RPL is a major milestone* and a criterion for graduation from mentored COBRE support at the start of the R01-level funding period.