

March 20, 2024

TO: NIH Intramural and Extramural Investigators

FROM: Program Director, Office of Clinical Research Education and Collaboration Outreach,

Office of Intramural Research

SUBJECT: 2024 Bench-to-Bedside Call for Proposals

Timeline:

Call for Proposals: March 20, 2024

Letter of Intent (LOI) due date: May 12, 2024

Notification of invitation to submit full proposal: June 9, 2024

Application due date: July 14, 2024 **Applications reviewed:** September 2024

Investigators notified of decisions: December 2024

Earliest start date: January/February 2025

We are pleased to announce a call for proposals for the NIH Bench-to-Bedside and Back Program (BtB). This is the 25th cycle of BtB funding for two-year awards designed to provide seed funding for new translational research projects. The program promotes meaningful collaborations between basic and clinical investigators, which can involve either intramural investigators from different laboratories, or intramural and extramural investigators.

Project Requirements:

This program supports innovative small/pilot research projects designed to translate basic scientific findings into therapeutic interventions for patients, and to increase understanding of important clinical observations of disease processes. Every project must include an intramural investigator who is responsible for submitting the application, and s/he must have at least one intramural and/or extramural co-investigator. Projects may have single or multiple Principal Investigator(s) but must have collaborators. A single applicant will not be accepted. Although projects can be exclusively among intramural investigators **preferably from more than one IC and cannot be exclusively** from the same branch. Collaborations between intramural and extramural investigators are equally encouraged, there is **NO** preference to either collaboration.

Extramural investigators may initiate or lead projects, though the extramural investigator must still have an intramural co-investigator who submits the application. Extramural investigators who need assistance identifying intramural partners may consult:

• NIH's database of all current intramural research at http://intramural.nih.gov/search/index.tml;

- Intramural Principal Investigator Directory at http://irp.nih.gov/our-research/principal-investigators;
- "Search the Studies" website to identify investigators on relevant protocols at http://clinicalstudies.info.nih.gov/index.html; or
- BtB Program Office (<u>BenchtoBedside@mail.nih.gov</u>) for assistance in identifying intramural partners.

Eligibility:

All NIH principal investigators (tenure, tenure track, senior clinicians, assistant clinical investigators, and senior scientists) are eligible to apply. In addition, staff clinicians, staff scientists and postdoctoral fellows can apply with the approval of their lab/branch/section chief or supervisory principal investigator as indicated on the signature page. All candidates must have at **least two years** of employment remaining with the NIH Intramural Research Program, as the award funding is not transferable should the recipient leave. And remember, the team must include at least one basic scientist and one clinical researcher.

Important Note: Eligible investigators may apply for multiple intramural award programs, such as Bench to Bedside and Back, Director's Challenge Innovation Award, and Research Award for Staff Clinicians (RASCL) for the same proposal. However, applicants must notify those programs of their application status when submitting the full proposal to any of the award programs. Please note that applicants, if successful, will not be able to accept multiple awards and cannot collect funds from multiple programs for substantially similar scope of proposed work and aims. Please note that BtB will not accept more than two proposals per applicant.

Funding:

Each award will be a maximum of \$150,000/year in direct costs for two years. The extramural investigator(s) cannot receive all or most of the project's direct cost and at least half of the funds must be directed to the intramural investigator(s). Year 1 project funds will be distributed in FY 2025 and Year 2 project funds will be distributed in FY 2026. The extramural investigator must have an active, in-scope NIH grant to receive any supplemental funding support. All appropriate indirect costs must be included in the submitted BtB application.

<u>Intramural Funds</u>: Intramural funds will be provided to intramural investigators via intra-agency agreements. At least one intramural investigator on the project must have responsibility for scientific and budgetary oversight (e.g., the investigator must have a budget/assigned CAN and resources). For applicants who do not have their own CAN, they must work with their budget and administrative officers to designate a CAN specific for BtB funds if awarded.

Extramural Funds: Funds to extramural investigators will be provided as an administrative supplement to an eligible NIH grant. To receive funds, **it is mandatory** that the parent grant is aligned closely with the subject area of the proposal so the project can be supported within the aims and objectives of the parent grant. To ensure alignment with the parent grant, a written justification must be included in the budget section of the BtB application describing the scientific relationship.

Please note, if the BtB extramural partner is NOT the PI on the NIH grant, he or she must ensure in writing that the PI of the parent NIH grant is supportive of the use of supplement funds to be used on the BtB project. In addition, the extramural partner must be listed as a key personal on the NIH grant (not any other mechanism such as a contract). Incomplete grant information in the full proposal (e.g., invalid project period dates or lack of scientific alignment) will eliminate the proposal from funding consideration. Indirect costs for extramural investigators will be covered beyond the direct cost limit of \$150,000 if they are included in the budget request in the full proposal. Any application with high extramural funding requests (more than 50% of direct cost) will not be funded.

The extramural collaborator must ensure that his/her role on the BtB proposal is within scope of the parent grant. This is the responsibility of the extramural collaborator, not the BtB program team.

*NOTE: Due to NIH policy, there are no exceptions to the above requirements for receipt of extramural funds. Applications with ineligible extramural components may be eliminated from consideration or may have their funding reduced if awarded. Please contact the Bench-to-Bedside team with any eligibility questions.

Budget Justification:

The budget sheet is an Excel file; fill in each of the fields. You will need the 2-year total for both intramural and extramural (if applicable and including indirect costs) for the budget box. A narrative Budget Justification for personnel, collaboration, and other requests will explain the requested budget. An additional justification must be included to explain why the proposed work is not easily supported by current funds. This portion will be essential for peer reviewers and program officials.

Research Areas of Interest:

Awards will be available in topics relevant to the research interests and priorities of funding NIH Offices Institutes/Centers (ICs). If additional award categories are added prior to the LOI due date, these will be highlighted on the BtB Program website: https://ocreco.od.nih.gov/btb/btb program.html.

All applications are automatically considered for "general category" funding through the Office of Clinical Research Education and Collaboration Outreach, BtB funds in addition to any funding consideration by the donor offices listed below:

- **1. AIDS** (Support from Office of AIDS Research) Exemplary HIV/AIDS projects aligned with the overarching HIV/AIDS research priorities and NIH OAR signature programs (Women's health & HIV; HIV and Aging) will be considered for funding (https://www.oar.nih.gov/hiv-policy-and-research/research-priorities).
- 2. Behavioral and Social Sciences (Support from Office of Behavioral and Social Sciences Research): Projects will be considered for funding that facilitate the translation of basic behavioral and social science research findings into effective interventions and those that meet

the mission of OBSSR. Topics of interest include research on the initiation and maintenance of health-promoting behaviors and the mechanisms (basic behavioral and physiologic) underlying behavioral interventions that promote health; research that examines the role of social relationships and interactions (e.g., in dyads, families, and other social groups) on health, including the mechanisms through which social isolation or connectedness accelerate or impede biologic and other disease processes and impact overall health and well-being; research that examines the interaction of behavioral and social influences on health; research that examines the effects of health communication on behavior and health outcomes, both at the individual and group levels and; research that integrates behavioral and social sciences research into biomedical research projects (e.g. methods, measurement, and behavioral and/or social sciences related outcomes). Projects that help accelerate the translation, implementation, dissemination, and adoption of behavioral and social sciences research findings are of interest to OBSSR.

- 3. Dietary Supplements (Support from the Office of Dietary Supplements): Awards in this funding category are designed to promote scientific study of the benefits of dietary supplements in maintaining health and preventing chronic disease and other health-related conditions but not in disease treatment. In the U.S., dietary supplement ingredients are usually defined as including vitamins, minerals, amino acids, and herbs or other botanicals, that are intended to be taken by mouth, and are consumed in addition to the regular diet.
- 4. Health Disparities & Minority Health (Support from the National Institute on Minority Health & Health Disparities): NIMHD will fund projects that support the overall NIH effort to reduce and ultimately eliminate health disparities, improve minority health, and promote health equity. Research projects must focus on 1) improving our understanding of ways to reduce health disparities among racial and ethnic minorities, persons of less privileged socioeconomic status, sexual and gender minorities, underserved rural residents, or persons with disabilities; or 2) health determinants and mechanisms of health outcomes in racial and ethnic minority populations as defined by the US Census. NIMHD is especially interested in intersectional issues between race and ethnicity and SES and other populations.
- 5. Women's Health (Support from the Office of Research on Women's Health): One project may be funded that focuses on efforts to improve the health of women through biomedical and behavioral research. Broadly defined, women's health includes female specific conditions (e.g., endometriosis, gynecologic cancers, menopause), conditions that disproportionately affect women (e.g., mental health conditions, migraine), and conditions that present and progress differently in women (e.g., cardiovascular disease, HIV). The influence of sex as a biological variable and/or gender as a social and structural variable on health and disease is of particular interest as well. For information on the NIH-wide Strategic Plan for Women's Health Research, see: www.nih.gov/women/strategicplan.

The Office of Autoimmune Disease Research in the Office of Research on Women's Health (OADR-ORWH) is seeking applications to support bench-to-bedside research in autoimmune

disease. The portfolio of the Office of Autoimmune Disease research encompasses more than 140 diseases and conditions and encompasses basic and translational science and is seeking applications that focus on either autoimmune aspects of the specific disease or diseases being studied, and/or autoimmunity pathogenesis in more general terms. This may include studies investigating basic immunology, gene expression, pathophysiology, diagnostic imaging, environmental exposures, biomarkers, sex influences, co-occurring autoimmune diseases, mechanistic pathways as therapeutic targets, animal models, systems biology, health outcomes research, symptom science, and translational research as they related to autoimmune disease and conditions.

Letter of Intent (LOI) (Due May 12, 2024):

The LOI process allows investigators to describe the project idea for pre-submission approval. PIs will receive a decision letting them know if the Scientific Director(s) consider(s) the concept appropriate for consideration as a full proposal. LOIs will be submitted online by the lead intramural PI at https://proposalcentral.altum.com/default.asp?GMID=68. Tips for LOI submission can be found at https://ocr.od.nih.gov/btb/btb program.html.

The following content is required:

- 1. Project title and all applicable BtB categories
- 2. If a resubmission, indicate when the proposal was previously submitted.
- 3. Contact information and IC(s)/institution(s) of all intramural and extramural investigators.
- 4. Estimated budget, to show an estimate of annual total costs for each investigator receiving funds.
- 5. Summary of Project, to include overall summary, specific project's aims, approach, and a brief explanation of the contributions of each project collaborator. The character limit is 5,000 including spaces.

The lead PI can enable colleagues to access the LOI online during development; however, the lead intramural PI must submit the completed LOI, which will be reviewed by his/her Scientific Director and the Scientific Directors of the other intramural investigators listed on the project. The lead intramural PI will be notified via email as to whether or not the Scientific Director(s) has/have approved the project.

Full Application (Due July 14, 2024):

Once endorsement from the Scientific Director has been received, the system can be accessed for development of the full proposal. Full proposals must be submitted online at https://proposalcentral.altum.com/default.asp?GMID=68.

The following information must be entered accurately and completely:

- 1. Investigator(s) name(s), IC(s) or institution(s), contact information, and roles.
- 2. **Abstract:** This section will be automatically pre-populated by summary provided in LOI and may be amended.
- 3. **Research Proposal:** No more than 6 pages of 11-point Arial text with 0.5-inch margins, including tables and figures, excluding references. The following format is suggested:
 - Significance and background
 - Specific Aims

- Research strategy, including hypotheses, preliminary results, experimental plan, and milestones {Note: if proposal involves a clinical trial, please include a separate protocol synopsis (limit 2 pages.)}
- Budget justification.
- Resubmission status {Note: if proposal is a resubmission, reviewer feedback from a prior cycle may be included, with an explanation of changes to the proposed project.}
- 4. **Budget Form:** download from https://ocreco.od.nih.gov/btb/application_instructions.html or ProposalCentral website.
 - If applicable, budget requests for extramural partners **must** include existing extramural grant number to receive supplement and **must** include the indirect costs.
- 5. NIH Biosketch for all principal and associate investigators
- 6. **Checklist:** download from: https://ocreco.od.nih.gov/btb/application_instructions.html or Proposal Central website.

Customer support with online submissions for LOIs and/or full proposals will be provided by *ProposalCentral*. Contact information is as follows: e-mail: pcsupport@altum.com; phone: 800-875-2562 (toll-free) from 8:30am - 5:00pm Eastern time, Monday through Friday.

Review of Applications:

A review team with subject matter expertise will review and rank the proposals. The team includes both intramural and extramural basic and clinical scientists representing multiple institutes and centers. Applications with an extramural component will be subject to further review prior to funding to ensure scientific alignment with the parent grant. Considerations for review will include:

- High quality of science (to be evaluated by the <u>NIH Enhanced Review Criteria for Research Grants and Cooperative Agreements</u>) with the potential to result in understanding an important disease process or lead to new therapeutic intervention*.
- Strong translational science, with the bedside and bench components clearly related; one should lead logically to the next, and both should be strongly developed*.
- The proposed translational work has the **promise** to evolve into an active clinical protocol with patient involvement in **the future***. **Applicants should emphasize how results from the proposed work will lead to clinical projects.**
- Although projects can be exclusively among intramural investigators **preferably from more than one IC**, collaborations between intramural and extramural investigators **will not** receive preference or priority review.
- The work should be a truly new initiative, not a funding request for work in progress. Applications with work that would broaden approaches in ways not easily supported by his/her current funds would be encouraged, however, applicants must elaborate on the need for BtB funding.

^{*}Translational component: Applicants must explain how the proposed project will involve clinical work with direct patient contact OR how the proposal results will lead to next steps involving clinical work (ultimately with direct patient contact). Involvement at the Clinical Center is a preference but not a requirement.

Requirements for Funded Projects:

Principal Investigators for awarded projects will be required to submit annual progress reports. Please note that if you were previously the intramural lead on a BtB project and failed to provide a progress report we will not be able to release any additional funds for continuation of the award (i.e., year 2 funds) and will not be able to make any future awards until the reporting requirements are met.

For **awards** involving extramural collaborator, he/she need to complete a request in IMPACII for an administrative supplement in response to the special announcement specific for Bench to Bedside, Notice Number: NOT-OD-24-027. which will be renewed this summer with updated available dates.

Contact:

Please feel free to contact Hana Smith by email (<u>BenchtoBedside@mail.nih.gov</u>) with program questions. Additional information may be found on the Bench-to-Bedside program website: https://ocreco.od.nih.gov/btb/btb program.html

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cc: NIH Institute, Scientific, and Clinical Directors Diana Finzi, Ph.D., Acting Director, OAR, NIH Eliseo J. Perez-Stable, M.D., Director, NIMHD Stefan Pasiakos, Ph.D., Director, ODS, NIH Janine Clayton, M.D., Director, ORWH, NIH Jane Simoni, Ph.D., Director, OBSSR, NIH