Public Health Service



April 9, 2025

TO: NIH Intramural and Extramural Investigators

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

(OCRECO), Office of Intramural Research

SUBJECT: 2025 Bench-to-Bedside Call for Proposals

Timeline:

Call for Proposals: April 9, 2025

Letter of Intent (LOI) due date: May 16, 2025

Notification of invitation to submit full proposal: June 13, 2025

Application due date: August 5, 2025 **Applications reviewed:** September 2025

Investigators notified of decisions: December 2025

Earliest start date: January/February 2026

We are pleased to announce a call for proposals for the NIH Bench-to-Bedside and Back Program (BtB). This is the 26th 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. The BtB will not accept more than one proposal per applicant.

- Project must include collaborators: an intramural investigator and at least one intramural or extramural co-investigator (collaborator). A single applicant will not be accepted. The primary intramural investigator on the project is responsible for submitting the application; he/she is considered the lead PI.
- Project team must include at least one basic scientist and one clinical researcher.
- Project may exclusively include intramural investigators, but collaborations between intramural and extramural investigators are equally encouraged. Exclusively intramural coinvestigators on a project cannot be from the same branch of an NIH Institute or Center (IC); it is preferred to have co-investigators from different ICs.
- Project may have single or multiple principal investigators (PIs). Extramural co-investigator(s) may lead a project, but the intramural co-investigator must submit the application.

- Extramural investigators may consult the following resources to identify intramural partners:
 - o NIH's database of all current intramural research
 - o <u>Intramural Principal Investigator Directory</u>
 - o "Search the Studies" website to identify investigators on relevant protocols
 - o <u>BtB Program Office</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. Staff clinicians, staff scientists and postdoctoral fellows are also eligible, but must have approval of their lab/branch/section chief or supervisory principal investigator, as indicated on the signature page. All candidates must have at least three years of employment remaining with the NIH Intramural Research Program as award funding is non-transferable, should the recipient leave.

Eligible investigators may apply for multiple intramural award programs, such as Bench-to-Bedside and Back, Director's Challenge Innovation Award, for the same proposal. However, applicants must notify programs of their application status when submitting the full proposal to any of the award programs. Successful applicants will not be able to accept multiple awards and funds from multiple programs for substantially similar scope of proposed work and aims.

Funding:

Each award will be a maximum of \$150,000/year in direct costs for two years. At least half of the funds received must be directed to the intramural investigator(s); the extramural co-investigator(s) cannot receive all or most of the project's direct cost. Year 1 project funds will be distributed in FY 2026 and Year 2 project funds will be distributed in FY 2027.

The extramural co-investigator must have an active NIH grant with sufficient project period, to receive any supplemental funding support. Additionally, the extramural collaborator's role on the BtB proposal must be within scope of the parent grant, and (s)he must be listed as key personnel on the NIH grant (contracts or other mechanisms are unacceptable). This is the responsibility of the extramural collaborator, not the BtB program team.

Any application with high extramural funding requests (greater than 50% of the project's direct cost) will not be funded. All appropriate indirect costs must also be included in the submitted BtB application. Note that the BtB program funds (not our donor offices) may not be able to provide funding for indirect costs; it will be evaluated on a case-by-case basis. Proposals supported by program funds will undergo additional budgetary review to ensure sufficient funding coverage of indirect cost for extramural collaborators.

• <u>Intramural Funds</u>: Intramural funds will be provided to intramural investigators via intraagency 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). Applicants, who do not have their own CAN, must work with their budget and administrative officers to designate a CAN specifically 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, the subject area of the BtB proposal must be closely aligned to and supported by 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. If the BtB extramural partner is NOT the PI on the NIH grant, (s)he 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. 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. 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.

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. Provide a narrative Budget Justification for personnel, collaboration, and other requests to 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. Any projects without budget justification will not be considered for funding.

Research Areas of Interest:

Awards will be available in topics relevant to the research interests and priorities of the funding NIH ICs. If additional award categories are added prior to the LOI due date, these will be highlighted on the BtB Program website.

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

- 1. **AIDS (Support from Office of AIDS Research (OAR))** Exemplary HIV/AIDS projects aligned with the overarching HIV/AIDS research priorities will be considered for funding (https://www.oar.nih.gov/hivpolicy-and-research/research-priorities).
- 2. Behavioral and Social Sciences (Support from Office of Behavioral and Social Sciences Research (OBSSR)): OBSSR will consider funding projects that facilitate the <u>translation</u> of research findings into effective interventions to prevent or treat disease with the aim of

promoting and optimizing health. The work must incorporate basic or applied behavioral or social sciences (BSS) theory, research, principles, or strategies. Of particular interest are interdisciplinary research projects on factors that influence prevention and health outcomes. Research in which scientists and practitioners work together to accelerate the translation, implementation, dissemination of BSS research findings or that employ BSS theory or principles or evaluate BSS strategies or components are of high priority to OBSSR. The Office has strong interests in the development of behavioral interventions for prevention and health improvement, including studies in the areas of gene-environment interactions, adherence (at the patient and provider levels), behavior change and maintenance, measurement harmonization, areas of and causes of health outcome disparities, primary care, mobile health, and shared medical decision-making, among other areas.

- 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 optimize health for all. Research projects must focus on 1) improving our understanding of ways to reduce health disparities among persons of less privileged socioeconomic status, underserved rural residents, or racial and/or ethnic minority populations; or 2) health determinants and mechanisms of health outcomes in racial and/or ethnic minority populations as defined by the US Census.
- 5. Office of Research on Women's Health (Support from the Office of Research on Women's Health (ORWH)): Applications seeking funding from ORWH should focus on efforts to improve the health of women through biomedical and behavioral research, and ensure that the proposed work is aligned with at least one goal and objective outlined in the NIH-Wide Strategic Plan for Research on the Health of Women 2024-2028 (https://www.nih.gov/women/strategicplan). 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 on health and disease is of particular interest. 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 16, 2025):

The LOI process allows investigators to describe the project idea for pre-submission approval. The lead PI will receive a decision letting him/her 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 PI through ProposalCentral. See BtB LOI Tip Sheet and review the requirements below:

- Project title and all applicable BtB categories
- If a resubmission, indicate when the proposal was previously submitted.
- Contact information and IC(s)/institution(s) of all intramural and extramural investigators.
- Estimated budget, showing annual total costs for each investigator receiving funds.
- Summary of Project to include overall summary, specific project's aims, approach, and a brief explanation of the contributions of each project collaborator.

The lead PI can enable colleagues to access the LOI online during development; however, the lead PI must submit the completed LOI, which will be reviewed by his/her Scientific Director(s) and Clinical Director(s). The lead PI will be notified about the approval of the LOI.

Full Application (Due August 5, 2025):

Once endorsement from the Scientific Director has been received, PIs can access <u>ProposalCentral</u> to develop and submit the full proposal (see <u>application instructions</u>). For first time applicants, it is strongly recommended to view the interactive BtB Overview & Application Tips on the program website for guidelines on a well-written, well-formatted application. 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:** Amendable section automatically pre-populated by summary provided in LOI.
- 3. **Research Proposal:** No more than 9 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: hypotheses, preliminary results, experimental plan, and milestones. If proposal involves a clinical trial, please include a separate protocol synopsis as a separate download; limit 2 pages. This is not part of the 9-page limit.
 - Budget justification
 - Resubmission status: 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:** Also available in ProposalCentral. If applicable, extramural partners must include existing extramural grant number to receive supplement and indirect costs (<u>more information</u>).
- 5. **NIH Biosketch:** For all principal and associate investigators. Also available in ProposalCentral.
- 6. **Checklist:** Also available in ProposalCentral. The lead PI must submit the full proposal via **ProposalCentral**; see <u>BtB Proposal Tip Sheet</u>. Email <u>ProposalCentral Customer Support</u> or call 800-875-2562 for online assistance; Monday through Friday, 8:30am 5:00pm ET.

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 and explain why the current funds are not able to cover the proposed work/funding request.

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.

^{*}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.

For awards involving extramural collaborator, (s)he needs 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-24-180 which will be renewed this summer with updated available dates.

Contact:

Please feel free to contact Hana Smith (BenchtoBedside@mail.nih.gov) with program questions. Additional information may be found on the Bench-to-Bedside program website.

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Nina F. Schor, M.D., Ph.D.

Deputy Director for Intramural Research

4/7/2025

Ahmed M. Gharib, M.D.

Program Director, Office of Clinical Research

Education and Collaboration Outreach

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