



NATIONAL INSTITUTES OF HEALTH CLINICAL CENTER

Public Health Service

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May 10, 2016

TO: NIH Intramural and Extramural Investigators
FROM: Deputy Director for Intramural Research, NIH
Director, NIH Clinical Center
SUBJECT: Next Cycle of Bench-to-Bedside Awards

Timeline:

Call for Proposals: May 10, 2016
Meeting to Address Applicant Questions: May 24, 2016
LOI due date: June 16, 2016
Notification of invitation to submit full proposal: July 1, 2016
Application due date: August 12, 2016
Applications reviewed: October 2016
Investigators notified of decisions: December 2016
Earliest start date: January/February 2017

We are pleased to announce a call for proposals for the intramural Bench-to-Bedside (BtB) Program. This is the 18th cycle of BtB funding for two-year awards designed to seed new projects that propose to translate clinical observations to the laboratory and then back to the patient. 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 small/pilot research projects designed to translate basic scientific findings into therapeutic interventions for patients and to increase understanding of important disease processes.

Every project must include an intramural investigator who is responsible for submitting the application, and he or she must have at least one intramural and/or extramural co-investigator. Preference is shown for projects involving extramural partners, though this is not required. Projects may have single or multiple Principal Investigator(s). Extramural investigators may 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 (Benchtobedside@mail.nih.gov) for assistance in identifying intramural partners.

Funding: Awards will be a maximum of \$135,000/year in direct costs for two years. The extramural investigator(s) cannot receive all project funds, and at least some funds must be directed to the intramural investigator(s). Year 1 project funds will be distributed in FY 2017, and Year 2 project funds will be distributed in FY 2018.

Intramural Funds: 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).

Extramural Funds: Funds to extramural investigators will be provided as an administrative supplement to an existing NIH grant. To receive funds, it is essential 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. Please note, if the BtB extramural partner is NOT the PI on the NIH grant, he or she must ensure in writing that the parent NIH grant PI is supportive of the use of supplement funds to be used on the BtB project. The active grant must have monetary commitments for FY 2017 and 2018, must be active through May 31, 2019, and may not be in a no cost extension. Incomplete grant information in the full proposal (e.g., invalid project period dates or lack of scientific alignment) will eliminate the proposal for funding consideration. Indirect costs for extramural investigators will be covered beyond the direct cost limit of \$135,000, if they are included in the budget request in the full proposal.

*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.

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 (<http://www.cc.nih.gov/ccc/btb/index.html>).

- (1) **AIDS {Support from Office of AIDS Research}** Up to four exemplary HIV/AIDS projects aligned with the new overarching HIV/AIDS research priorities will be funded.
- (2) **Behavioral and Social Sciences {Support from Office of Behavioral and Social Sciences Research}:** Up to two projects will be funded that facilitate the translation of basic behavioral and social science research findings into effective interventions to prevent disease and to promote and optimize health. Of particular interest are interdisciplinary research and systems thinking and modeling approaches that integrate multiple levels of analysis - from cells to society - of factors that influence health. Key problems in population health where scientists, practitioners, and decision-makers can work together to accelerate the translation, implementation, dissemination, and adoption of behavioral and social sciences research findings are of high priority to OBSSR. The Office has strong interests in the development of behavioral interventions to improve health, studies of gene-environment interactions, adherence (at the patient and provider levels), measurement harmonization, primary care, mobile health, health disparities, shared medical decision-making, the exposome, and 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., these ingredients are usually defined as including plant extracts, enzymes, vitamins, minerals amino acids, and hormonal products that are available without prescription and are consumed in addition to the regular diet.
- (4) **General:** Additional meritorious projects will be considered in the 'general' category; however, this category is restricted to partnerships involving intramural investigators only.
- (5) **Minority Health: {Support from the National Institute on Minority Health & Health Disparities}:** NIMHD will fund projects that promote the science of understanding behavioral, biological, environmental and health system factors that are unique to the minority groups in the US (defined by the US Census). NIMHD will also fund projects that advance the science of understanding the factors that lead to adverse outcomes or health disparities in minority groups and persons of low socioeconomic status. These projects must focus on an area of science/research that supports the overall NIH effort to reduce health disparities.

- (6) **Rare Diseases {Support from Office of Rare Diseases Research in the National Center for Advancing Translational Sciences}**: ORDR/NCATS will provide funding in this category. Projects must focus on an area of science/research directly related to a rare disease. An orphan or rare disease is generally considered to have a prevalence of less than 200,000 affected individuals in the United States. Certain diseases with more than 200,000 affected individuals are included but subpopulations of these conditions may be less than the prevalence standard for a rare disease. A comprehensive list of rare diseases, updated regularly, is available at <http://rarediseases.info.nih.gov/RareDiseaseList.aspx?PageID=1>.
- (7) **Women's Health {Office of Research on Women's Health}**: One project will be funded that focuses on efforts to improve the health of women through biomedical and behavioral research on the roles of sex and gender in health and disease with particular interest in comparing and contrasting female and male data from cells, animals, tissues in the context of a range of research questions relevant to diseases that affect women. Additional information about ORWH's strategic priorities can be found here: http://orwh.od.nih.gov/research/strategicplan/ORWH_StrategicPlan2020_Vol1.pdf

Application Process

Meeting to Address Applicant Questions (May 24, 2016 9:30-11:00 AM, CRC Medical Board Room 10/4-2551)

An information session will be held in the Clinical Center Medical Board Room (10/4-2551) to address any questions applicants may have about the application process and the BtB program overall. Please contact Julie Orlando at (301) 402-0102 with questions about this session.

Letter of Intent (LOI): (Due June 16, 2016). The LOI process allows investigators to describe the project idea and will let them know if the Scientific Director(s) consider 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 <http://www.cc.nih.gov/cc/btb/deadlines.html#letterofintent>.

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 her/his 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) have approved the project.

Full Application: (Due August 12, 2016). 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 program website: <http://www.cc.nih.gov/ccc/btb/deadlines.html>. 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 program website: <http://www.cc.nih.gov/ccc/btb/deadlines.html>

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) or +1 703 964 5840 (direct dial international): from 8:30am - 5:00pm Eastern time, Monday through Friday.

Review of Applications: A review team, appointed by the Director, NIH Clinical Center, will review and rank the proposals. The team will include both intramural and extramural basic and clinical scientists representing multiple institutes and centers and will include expertise in the funded research categories. Considerations for review will include:

- High quality of science (to be evaluated by the NIH Enhanced Review Criteria for Research Grants and Cooperative Agreements) 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*.
- Although projects can be exclusively among intramural investigators preferably from more than one IC, collaborations between intramural and extramural investigators will receive priority review;
- The work should be a truly new initiative, not a funding request for work in progress.

**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 final progress report, you will be contacted to provide the final report before your new application is considered.

Contact: Please feel free to contact us by email (BenchttoBedside@mail.nih.gov) with program questions. Additional information may be found on the Bench-to-Bedside program website: <http://www.cc.nih.gov/ccc/btb/awards.shtml>.



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