



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

February 5, 2013

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

We are pleased to announce a call for proposals for the intramural Bedside-to-Bench Program. This is the 15th cycle of 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, which can involve either intramural investigators from different laboratories or intramural and extramural investigators.

Criteria for success of a proposal include the following:

- 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.
- Promise to evolve into an active clinical protocol to take place either during the award period or within the next 3 to 4 years;
- A well-defined plan for involvement of patients (not just tissue specimens) with patient involvement at the Clinical Center a strong preference but not a requirement;
- 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.

The award will be a maximum of \$135,000/year for two years. Year 1 project funds will be distributed in FY 2014, and Year 2 project funds will be distributed in FY 2015. Funding is anticipated from the Office of Rare Diseases Research in the National Center for Advancing Translational Sciences (NCATS), the NIH Office of Behavioral and Social Sciences Research (OBSSR), the NIH Office of AIDS Research (OAR), the NIH Office of Research on Women's Health (ORWH), the Office of Intramural Research (OIR) and the NIH Center for Regenerative Medicine (CRM). Categories for awards will be in the following research areas:

- (1) **AIDS (OAR):** Up to four exemplary AIDS-related projects will be funded.
- (2) **Behavioral and Social Sciences (OBSSR):** 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. Additional information about OBSSR's strategic priorities can be found at http://obsr.od.nih.gov/about_obsr/strategic_planning/strategicPlanning.aspx.

- (3) **General:** Additional meritorious projects will be considered in the 'general' category. Funding for projects in this category is restricted to intramural IC funding with potential funding support from the Office of Intramural Research. **There are no funds to support extramural projects in the "general" category.**
- (4) **Rare Diseases (NCATS):** NCATS will co-fund with institutes at least two projects. 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?PageIC=1>.
- (5) **Regenerative Medicine (NIH CRM):** One project will be funded that supports efforts to accelerate the clinical translation of stem cell-based technologies, and to develop widely available resources to be used as standards in stem cell research. See mission of the NIH Center for Regenerative Medicine: <http://crm.nih.gov/aboutCRM/index.asp>
- (6) **Women's Health (ORWH):** 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. Additional information about ORWH's strategic priorities can be found here: http://orwh.od.nih.gov/research/strategicplan/ORWH_StrategicPlan2020_Vol1.pdf

Eligibility:

Both intramural and extramural NIH investigators will be able to initiate applications for Bedside-to-Bench research projects. As in prior years, intramural investigators in all institutes/centers are eligible to serve as project leaders on proposals. 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 principal investigators (PIs) with an existing NIH grant may initiate proposals in one of two ways:

- (1) Extramural investigators may seek an intramural partner at NIH who would function as the project leader and serve as the point of contact. To identify an intramural collaborator, extramural investigators can consult the
 - 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
 - Bedside-to-Bench Program Office (BedsidetoBench@mail.nih.gov) for assistance in identifying intramural partners.
- (2) Extramural investigators can initiate proposals and serve as project leaders. In this scenario, extramural investigators are required to identify an intramural collaborator on the project. In this role, extramural principal investigators will develop letters of intent and if approved, may develop full proposals.

In either scenario, the intramural investigator will be responsible to submit both the letter of intent and full proposal electronically using proposalCentral.

Application Process:

The first step in the application process requires the intramural investigator to submit a letter of intent (LOI) electronically via proposalCentral. LOIs are reviewed by the Scientific Director for each intramural investigator on a project. The LOI allows Scientific Directors an opportunity to advise principal investigators regarding the proposal

prior to formal submission. Letters of intent must be submitted electronically no later than **April 17, 2013**. The intramural investigator submitting the LOI will be notified via email whether or not the LOI is approved by the Scientific Director(s).

Investigators may re-submit proposals from prior cycles that were not selected for funding. Resubmissions must clearly identify revisions from the original proposal and should be labeled as a resubmission. Investigators who receive LOI approval are required to submit completed proposals electronically no later than **June 14, 2013**. The electronic submission process is detailed in Attachment 1.

A review team, appointed by the Director, NIH Clinical Center, will review and rank the proposals. Preference will be given to those applications that address the criteria previously noted. The team will include both intramural and extramural basic and clinical scientists representing multiple institutes and centers and will include expertise in behavioral and social sciences, rare diseases, AIDS, women's health, and regenerative medicine.

Requirements for Extramural Funds:

For projects selected for awards, extramural funds will be directed as an administrative supplement to an existing NIH grant and, if indicated, the amounts of funds to extramural investigators may be increased to cover indirect costs. All funds for extramural partners will come from the contributors described above. To receive funds, it is essential that the grant is aligned closely to the subject area of the proposal so the project can be supported within the aims and objectives of the extramural grant. The grant must have commitments for FY 2014 and 2015 and be active through September 2015. ARRA-funded grants are ineligible for Bedside-to-Bench supplements. Incomplete grant information in the submission packet will eliminate the proposal for funding consideration. Please note, if the B2B extramural partner is NOT the PI on the NIH grant, he or she must ensure in writing that the PI is supportive of the use of supplement funds to be used on the B2B project.

Projects with all funds directed to the extramural site(s) will not be considered.

Progress Reports: Principal investigators for awarded projects will be required to submit annual progress reports.

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

/s/

Michael M. Gottesman, M.D.

/s/

John I. Gallin, M.D.

Attachment

Cc: Institute Directors
Scientific Directors
Clinical Directors
Christopher P. Austin, M.D., Director, NCATS
Janine Clayton, M.D., Director, ORWH
Stephen Groft, Pharm.D, Director, ORDR/NCATS
Robert M. Kaplan, Ph.D., Director, OBSSR
Mahendra Rao, M.D., Ph.D., Director, CRM
Jack Whitescarver, Ph.D., Director, OAR

DEADLINES FOR SUBMISSION/TIMELINE - REVISED

February 5, 2013	Call for proposals
April 17, 2013	Letter of Intent (LOI) submitted online by intramural investigator
May 6, 2013	Investigators notified of SD(s) decision to support submission of full proposal
June 14, 2013	Full proposals submitted online by intramural investigator
July 5, 2013	Investigators notified of review decision(s) by Scientific & Clinical Director to submit proposal for central review
Early FY 2014	Notification to awardees

INSTRUCTIONS FOR CURRENT CYCLE BEDSIDE-TO-BENCH PROPOSALS**Requirements for Letter of Intent (LOI): (Due April 17, 2013)**

The LOI will provide investigators initial feedback on the concept/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 via an online database at <https://proposalcentral.altum.com/default.asp?GMID=68>. The following content is required:

- Project title
- Contact information for lead principal investigator
- Institute/center of lead principal investigator for proposed project
- Project summary information (summary of overall project; estimated budget; proposed collaborators). Remember: the LOI is a brief conceptual 'snap-shot' of the formal proposal. It should be specific and to the point. The budget estimate can be very general, but should include how resources likely would be shared among collaborators if the project is funded. Please check all categories for which proposal might be considered. This will assist Scientific Directors in recognizing those proposals that would require IC co-funding (Rare Diseases and General categories).

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.

Requirements for Online Submission of Proposal: To submit a full proposal, principal investigators will use the same online site used for the LOI <https://proposalcentral.altum.com/default.asp?GMID=68>. Once endorsement from the Scientific Director has been received, the system can be accessed for development of the full proposal.

This online tool will require the following information be entered accurately and completely:

- complete name, ICs or institutions, contact information for all principal and associate investigators
- abstract
- proposal
- budget information
- existing extramural grant number (*if applicable*)
- references (*optional*)
- biosketch(es)

Customer support with online submissions for LOIs and/or full proposals will be provided by *proposalCentral*. Contact information is 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.