



August 10, 2010

TO: NIH Intramural Investigators
FROM: Deputy Director for Intramural Research
Director, NIH Clinical Center
SUBJECT: FY 2011 Bench-to-Bedside Awards

We are pleased to announce a call for proposals for the FY 2010 intramural bench-to-bedside program. This is the 13th cycle of funding for two-year awards designed to seed new projects that propose to translate basic science to human subjects. Criteria for success of a proposal include the following:

- although projects can be exclusively among intramural investigators preferably from more than one IC, collaborations between intramural and extramural investigators will receive priority review
- high quality of science
- promise to evolve into an active clinical protocol should be clearly articulated
- a well defined plan for involvement of patients (not just tissue specimens)
- patients being seen at the NIH Clinical Center
- the potential to result in understanding an important disease process or lead to new therapeutic intervention
- proposals with bench and bedside components clearly related in a translational sense – the components should complement each other – one should lead logically to the next, and both should be strongly developed; a bench-to-bedside – and – back concept should be considered
- the work should be a truly new initiative, not a funding request for work in progress; collaborations with NIH-funded extramural investigators must be within the approved scope of the extramural grant

The award amount will be a maximum of \$135,000/year for two years. Funding is anticipated from the Food & Drug Administration (FDA), the NIH Office of Behavioral and Social Sciences Research (OBSSR), the Office of AIDS Research (OAR), the Office of Rare Diseases Research (ORDR), the Office of Research on Women's Health (ORWH), the National Center on Minority Health and Health Disparities (NCMHD), and the National Center for Research Resources (NCRR). Categories for awards:

- (1) **Pharmacogenomics (FDA):** Up to two clinical projects will be funded that identify genetic factors that contribute to inter-individual response to medicines, including efficacy, safety and optimal dosing. The results of such research are intended to be translated into clinical practice to eventually help healthcare providers optimize treatments for individual patients or patient groups.
- (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 promote and improve 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. See *The Contributions of Behavioral and Social Sciences Research to Improving the Health of the Nation: A Prospectus for the Future* for a complete description of the Office's strategic priorities (http://obssr.od.nih.gov/pdf/OBSSR_Prospectus.pdf).

- (3) **Rare Diseases (ORDR):** ORDR will co-fund with institutes up to six projects for two years. 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>.
- (4) **AIDS (OAR):** Up to four exemplary AIDS-related projects for two years will be funded.
- (5) **Minority Health & Health Disparities (NCMHD):** NCMHD will co-fund with institutes up to four projects that promote outreach, recruitment, and retention of under-represented minorities, rural and medically underserved populations, women, low socio-economic groups and persons with disabilities in research and/or clinical trials. These projects must focus on an area of science/research that supports the overall NIH effort to reduce and ultimately eliminate health disparities.
- (6) **Women's Health (ORWH):** One project for two years 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.
- (7) **General:** As in the past, additional meritorious projects will be considered in the 'general' category to be funded by the sponsoring institutes. NCRR will provide extramural funds to help support the general category.

Both intramural and extramural NIH investigators will be able to initiate applications for Bench-to-Bedside 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 are invited to initiate proposals in one of two ways:

1. First, 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>. Extramural investigators may also consult the Bench-to-Bedside Program Office (BenchtoBedside@mail.nih.gov) for assistance in identifying an intramural partner.
2. New this cycle is an invitation for extramural investigators to 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. On behalf of the lead extramural PI, 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 Wednesday, September 22, 2010**. Project investigators 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 original proposal and should be labeled as a resubmission. Investigators who receive LOI approval are required to submit completed proposals electronically **no later than Tuesday, November 23, 2010**. 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 pharmacogenomics, behavioral and social sciences, rare diseases, AIDS, women's health and minority research.

For projects selected for awards, extramural funds will be directed as an administrative supplement to an existing 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 be in a position to receive supplements for two years. ARRA-funded grants are ineligible for bench-to-bedside supplements. Incomplete grant information in the submission packet will eliminate the proposal for funding consideration. Principal investigators for all awarded projects will be required to submit annual progress reports.

Please feel free to contact us by email (BenchtoBedside@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>



Michael M. Gottesman, M.D.



John I. Gallin, M.D.

Attachment

cc: Institute Directors
Scientific Directors
Clinical Directors
Barbara Alving, M.D., Director, NCRR
Stephen C. Groft, Pharm.D, Director, ORDR
Deborah H. Olster, Ph.D., Acting Director, OBSSR
Vivian W. Pinn, M.D., Director, ORWH
John Ruffin, Ph.D., Director, NCMHD
Jack Whitescarver, Ph.D., Director, OAR
Janet Woodcock, M.D., Director, CDER, FDA

DEADLINES FOR SUBMISSION/TIMELINE

August 10, 2010	Call for proposals
September 22, 2010	Letter of Intent (LOI) submitted online by intramural investigator
October 11, 2010	Investigators notified of SD(s) decision to support submission of full proposal
November 23, 2010	Full proposals submitted online by intramural investigator
December 7, 2010	Investigators notified of review decision(s) by Scientific & Clinical Director to submit proposal for central review
January 2011	Recommendations by review team; intramural investigator(s) notified of decision within two weeks of review session

INSTRUCTIONS FOR FY 2011 BENCH-TO-BEDSIDE PROPOSALS

Requirements for Letter of Intent (LOI): (Due September 22nd)

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, Minority Health 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.

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
 - biosketch(es) (*optional*)

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.