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September 3, 2008

TO: NIH Intramural Investigators
FROM: Deputy Director for Intramural Research
Director, NIH Clinical Center
SUBJECT: FY 2009 Bench-to-Bedside Awards

We are pleased to announce a call for proposals for the FY 2009 intramural bench-to-bedside program. These two-year awards are designed to seed new projects that propose to translate basic science to human subjects. Criteria for success of a proposal include the following:

- o collaborations between intramural and extramural investigators will receive priority review
- o inter-institute collaborations involving investigators from more than one IC are encouraged
- o quality of science should be high
- o promise to evolve into an active clinical protocol should be clearly articulated
- o the plan for use of patients (not just tissue specimens) in the bedside component should be defined
- o preference will be given to projects that result in patients being seen at the NIH Clinical Center
- o the potential to result in understanding an important disease process or lead to new therapeutic intervention should be explained
- o proposals should have 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
- o the work should be a truly new initiative, not a funding request for a work in progress; however, collaborations proposed with NII-funded extramural investigators must be within the approved scope of the extramural grant

Four major changes will be introduced to the program this year as follows: (1) two new program sponsors; (2) expanded opportunity for extramural investigators to partner with intramural investigators; (3) requirement for letter of intent; (4) electronic submission of proposals. These changes will allow program expansion and ease the submission process as we embark on the 11th cycle of bench-to-bedside awards.

I. New Sponsors: As a pilot effort, the Food & Drug Administration (FDA) and the NIH Office of Behavioral and Social Sciences Research (OBSSR) will join our list of program donors: the Office of AIDS Research (OAR), the Office of Rare Diseases (ORD), 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). As in FY 2008, the award amount will be a maximum of \$135,000/year for two years. The categories for awards supported by each of these donors follow:

- (1) **Pharmacogenomics**: Within this new category the FDA will fund clinical projects that identify genetic factors contributing 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 will support projects 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://www.thehillgroup.com/OBSSR Prospectus.pdt](http://www.thehillgroup.com/OBSSR_Prospectus.pdt)).
- (3) **Rare Diseases**: The ORD will co-fund, with institutes' intramural programs, projects that 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: The OAR will fund exemplary AIDS-related projects.
- (5) Minority Health & Health Disparities: The NCMHD will co-fund, with institutes' Intramural programs, projects that improve outreach, recruitment, and retention of minorities, women, and persons with disabilities. These projects must focus on an area of science/research that promotes minority health and supports the NIH effort to reduce and ultimately eliminate health disparities.
- (6) Women's Health: The ORWH will fund projects that focus 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. NCCR will provide extramural funds to help support the general category.

II. Extramural Expansion: New this year is an Invitation to extramural principal investigators, through the CTSA consortium, to identify intramural partners who will lead the study. In this scenario, the intramural PI will function as the project leader and serve as point-of-contact. To identify an intramural collaborator, extramural investigators are encouraged to consult the database of all current intramural research at <http://intramural.nih.gov/search/index.tml>. 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.

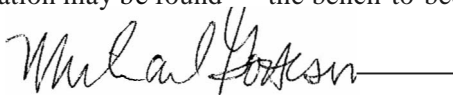
III. Letter of Intent (LOI): The first step in the application process is new and requires the intramural investigator who serves as the project leader to submit a letter of intent electronically (see attachment 1). Upon submission, the Scientific Director for each institute involved in the project will review the LOI electronically. The LOI will allow Scientific Directors an opportunity to advise principal investigators regarding the project prior to formal submission of the full proposal. Letters of intent must be submitted electronically **no later than October 10, 2008**. Scientific Directors are asked to provide review/approval by October 24, 2008. The principal intramural investigator will be notified via email whether or not the LOI is approved.

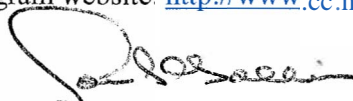
IV. Electronic Submission of Proposals: Principal intramural investigators who receive LOI approval will submit completed proposals electronically **no later than December 15, 2008**. The website for submission will allow multiple investigators to review and edit the proposal, but the principal intramural investigator will submit the final version. The electronic submission process is detailed in Attachment 1

A review group appointed by the Director, NIH Clinical Center will review and rank the proposals. The group 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. Preference will be given to those applications that address the criteria previously noted.

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. Principal investigators for all awarded projects will be required to submit annual progress reports on the project's status.

Please feel free to contact us if you have any questions about the bench-to-bedside program. Additional information may be found on the bench-to-bedside program website: <http://www.cc.nih.gov/cc/btb/awards.shtml>.


Michael M. Gottesman, M.D.


John I. Gallin, M.D.

Attachment

cc: Institute Directors
Scientific Directors
Clinical Directors

Stephen C. Gofft, Pharm.D, Director, ORD
Vivian W. Pinn, M.D., Director, ORWH

Janet Woodcock, M.D., Deputy Commissioner, Chief Medical Officer, FDA

John Ruffin, Ph.D., Director, NCMHD
Barbara Alving, M.D., Director, NCCR
Christine Bachrach, Ph.D., Acting Director, OBSSR
Jack Whitescarver, Ph.D., Director, OAR