

staff. CDER seeks to significantly enhance review efficiency and review quality by providing the staff with a better understanding of the pharmaceutical industry and its operations. To this end, CDER is continuing its training program to give regulatory project managers the opportunity to tour pharmaceutical facilities. The goals are to provide the following: (1) First hand exposure to industry's drug development processes and (2) a venue for sharing information about project management procedures (but not drug-specific information) with industry representatives.

## II. The Site Tours Program

In this program, over a 2- to 3-day period, small groups (five or less) of regulatory project managers, including a senior level regulatory project manager, can observe operations of pharmaceutical manufacturing and/or packaging facilities, pathology/toxicology laboratories, and regulatory affairs operations. Neither this tour nor any part of the program is intended as a mechanism to inspect, assess, judge, or perform a regulatory function, but is meant rather to improve mutual understanding and to provide an avenue for open dialogue. During the Site Tours Program, regulatory project managers will also participate in daily workshops with their industry counterparts, focusing on selective regulatory issues important to both CDER staff and industry. The primary objective of the daily workshops is to learn about the team approach to drug development, including drug discovery, preclinical evaluation, tracking mechanisms, and regulatory submission operations.

The overall benefit to regulatory project managers will be exposure to project management, team techniques, and processes employed by the pharmaceutical industry. By participating in this program, the regulatory project manager will grow professionally by gaining a better understanding of industry processes and procedures.

## III. Site Selection

All travel expenses associated with the site tours will be the responsibility of CDER; therefore, selection will be based on the availability of funds and resources for each fiscal year. Firms interested in offering a site tour or learning more about this training opportunity should respond by (see **DATES**) by submitting a proposed agenda to Beth Duvall-Miller (see **FOR FURTHER INFORMATION**).

Dated: December 22, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

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**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Part C Early Intervention Services Grant

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice of Non-competitive Program Expansion Supplemental Award.

**SUMMARY:** HRSA will be providing temporary critical HIV medical care and treatment services through the Medical Center of Louisiana at New Orleans to avoid a disruption of HIV clinical care to clients in Orleans Parish in Louisiana.

#### SUPPLEMENTARY INFORMATION:

*Intended recipient of the award:* Medical Center of Louisiana at New Orleans, Louisiana.

*Amount of the award:* \$186,664 to ensure ongoing clinical services to the target population.

**Authority:** Section 2651 of the Public Health Service Act, 42 U.S.C. 300ff-51.

*CFDA Number:* 93.918.

*Project period:* July 1, 2006 to June 30, 2011. The period of supplemental support is from November 1, 2008, to June 30, 2009.

*Justification for the Exception to Competition:* Critical funding for HIV medical care and treatment services to clients in Orleans Parish in Louisiana will be continued through a non-competitive program expansion supplement to an existing grant award to Medical Center of Louisiana at New Orleans, New Orleans, Louisiana. This is a temporary award because the previous grant recipient serving this population notified HRSA that it would not be able to continue participating in the program after the fiscal year (FY) 2008 award was made. Medical Center of Louisiana at New Orleans is the best qualified grantee for this supplement since it serves many of the former grantee's patients and is the closest Part C Program to the former grantee. Further funding beyond June 30, 2009, for this service area will be competitively awarded during the Part C HIV Early Intervention Service (EIS) competing application process for FY 2009.

#### FOR FURTHER INFORMATION CONTACT:

Kathleen Treat, through e-mail [ktreat@hrsa.gov](mailto:ktreat@hrsa.gov), or via telephone, 301-443-0493.

Dated: December 19, 2008.

**Elizabeth M. Duke,**

*Administrator.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Center for Research Resources; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Center for Research Resources Special Emphasis Panel; SBIR Contracts.

*Date:* February 26, 2009.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate contract proposals.

*Place:* Hilton Hotel Gaithersburg, 620 Perry Parkway, Gaithersburg, MD 20877.

*Contact Person:* Guo Zhang, Ph.D., MD, Scientific Review Officer, National Center for Research Resources; or, National Institutes of Health, 6701 Democracy Blvd., 1 Democracy Plaza, Room 1064, MSC 4874, Bethesda, MD 20892-4874, 301-435-0812, [zhanggu@mail.nih.gov](mailto:zhanggu@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.371, Biomedical Technology; 93.389, Research Infrastructure, 93.306, 93.333, National Institutes of Health, HHS)

Dated: December 24, 2008.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

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