

conducting pharmacokinetic (PK) studies in pregnant women and, specifically, on how to assess the influence of pregnancy on the PKs, and where appropriate, the pharmacodynamics (PD) of drugs or biologic products. The goals of this guidance are to recommend a framework for designing and conducting PK studies in pregnant women and stimulate further study and research to assist in rational therapeutics for pregnant patients.

**DATES:** Submit written or electronic comments on the draft guidance by January 3, 2005. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communications, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Kathleen Uhl, Center for Drug Evaluation and Research (HFD-020), Food and Drug Administration, 5515 Security Lane, Rockville, MD 20852, 301-443-5157.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a draft guidance for industry entitled "Draft Guidance for Industry on Pharmacokinetics in Pregnancy—Study Design, Data Analysis, and Impact on Dosing and Labeling." This guidance is intended to provide recommendations to sponsors and investigators on how to design, conduct, and assess studies investigating the influence of pregnancy on the pharmacokinetics, and where appropriate, the pharmacodynamics of drugs or biologic products. During the clinical development of most products, pregnant women are actively excluded from trials, and, if pregnancy does occur during a trial, the usual procedure is to

discontinue treatment and drop the patient from the study. Consequently, at the time of a drug's initial marketing, except for products developed to treat conditions specific to pregnancy, there are seldom meaningful human data on the appropriate dosage and frequency of administration during pregnancy. Even after years of marketing, data in product labels regarding PK and dose adjustments during pregnancy rarely provide more information for appropriate prescribing in pregnancy than what was available at the time of initial marketing.

The information in this guidance is intended to promote an increase in the amount of useful data concerning how drug kinetics are affected by pregnancy and to further encourage the development of appropriate therapeutic treatments for pregnant women. Topics covered include ethical considerations associated with conducting PK studies in pregnant women, study design, data analysis, labeling, and considerations for future research. The agency recommends using this guidance in conjunction with other pharmacological and clinical literature on the design, conduct, and interpretation of PK studies. Because the conduct of studies in pregnant women requires specialized knowledge in a variety of areas, investigators designing such studies are encouraged to obtain advice from experts in fields such as obstetrics, pediatrics, pharmacology, clinical pharmacology, pharmacometrics, statistics, and other applicable disciplines.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

##### **II. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

##### **III. Electronic Access**

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: October 21, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**BILLING CODE 4160-01-S**

#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **Substance Abuse and Mental Health Services Administration**

##### **Funding Opportunity Title: Historically Black Colleges and Universities National Resource Center for Substance Abuse and Mental Health Service System Infrastructure Development (Short Title: HBCU-NRC)**

*Announcement Type:* Initial.

*Funding Opportunity Number:* TI 05-002.

*Catalog of Federal Domestic Assistance (CFDA) Number:* 93.243.

**DATES:** *Due Date for Applications:* January 18, 2005.

(**Note:** Letters from State Single Point of Contact (SPOC) in response to E.O. 12372 are due March 21, 2005.)

**SUMMARY:** The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT) and Center for Mental Health Services (CMHS), announce the availability of FY 2005 funds for a Historically Black Colleges and Universities National Resource Center (HBCU-NRC) for Substance Abuse and Mental Health Service System Infrastructure Development. A synopsis of this Notice of Funding Availability (NOFA), as well as many other Federal government funding opportunities, are also available at the Internet site: <http://www.grants.gov>.

For complete instructions, potential applicants must obtain a copy of SAMHSA's standard Infrastructure Grants Program Announcement, INF-05 PA, and the PHS 5161-1 (Rev. 7/00) application form before preparing and submitting an application. The INF-05 PA describes the general program design and provides instructions for applying for all SAMHSA Infrastructure Grants, including the Historically Black Colleges and Universities National Resource Center for Substance Abuse and Mental Health Service System Infrastructure Development. SAMHSA's Infrastructure Grants provide funds to

increase the capacity of mental health and substance abuse service systems to support effective programs and services. Additional instructions and specific requirements for this funding opportunity are described below.

### I. Funding Opportunity Description

**Authority:** Sections 509 and 520A of the Public Health Service Act, as amended and subject to the availability of funds.

The Historically Black Colleges and Universities National Resource Center for Substance Abuse and Mental Health Service System Infrastructure Development (HBCU-NRC) is one of SAMHSA's Infrastructure Grants. The purpose of the HBCU-NRC cooperative agreement is to provide funds to support an innovative national resource center dedicated to the following 3 goals: (1) Establishing a national network of HBCUs to facilitate collaboration among the 104 HBCU institutions; (2) supporting culturally appropriate substance abuse treatment and mental health disorders prevention and treatment student health services and wellness needs on HBCU campuses; and (3) facilitating the design of accredited courses, minors/majors and undergraduate and graduate degree programs that adapt State requirements and encourage student interest in substance abuse and mental health.

Applications should reflect a program that achieves these goals and may propose any of the activities listed under Section I-2.1 Allowable Activities of the INF-05 PA. However, the successful applicant must undertake the following required activities:

- Establish and manage a viable structure to serve all 104 HBCU institutions.
- Support the annual Dr. Lonnie E. Mitchell Substance Abuse Conference with tracks on substance abuse and mental health treatment and prevention.
- Establish a database to measure student participation and impact of the Dr. Lonnie E. Mitchell Substance Abuse Conference.
- Develop a strategic plan for the HBCU-NRC.
- Convene the HBCU-NRC steering committee at least twice a year.
- Coordinate technical assistance efforts with SAMHSA's Addiction Technology Transfer Centers (ATTCs), the Mental Health Information Network, and other appropriate SAMHSA-funded activities.
- Establish and maintain a data base of HBCUs with substance abuse and mental health curricula, programs, and faculty.
- Develop assessment models for evaluating substance abuse and mental health curricula and/or programs at HBCUs and in communities at large.
- Disseminate information about effective practices within the mental

health services and substance abuse treatment fields and promote/encourage career opportunities for HBCU students in the substance abuse and mental health fields.

- Conduct on-site and distance learning opportunities to promote awareness of mental health and associated evidence-based practices.
- Pilot campus-based suicide screenings and referrals to appropriate mental health treatment.

**Background:** The National Institute on Drug Abuse (NIDA), in conjunction with the Center for Substance Abuse Treatment (CSAT) and in collaboration with the Morehouse School of Medicine and the Cork Institute-Southeast ATTC, helped to create the National HBCU Substance Abuse Consortium (NHBCUSAC) to address the shortage of qualified, trained, and licensed professionals, especially ethnic minorities, who are capable of treating and preventing substance abuse disorders.

In 1995, CSAT began providing funding to the NHBCUSAC to develop curriculum models and enhance the expansion of college degrees being offered at HBCUs that led to licensure in substance abuse and health-related academic programs. CSAT and the Center for Substance Abuse Prevention (CSAP) supported the initiation of the National Dr. Lonnie E. Mitchell Substance Abuse Conference that brought together researchers, practitioners, faith communities, treatment providers, government officials, and most importantly, students from HBCUs across the country to introduce them to the substance abuse field and stimulate increased awareness and capacity building in substance abuse curricula and services among the faculty. Since that time, CSAT and the NHBCUSAC have expanded their interests to include mental health disorders affecting HBCUs and surrounding communities. Accordingly, CMHS is joining as a cosponsor of this initiative.

Outreach is critical to helping HBCUs develop the capacity to address substance abuse treatment and mental health wellness, as well as improve academic programs and curricula to prepare students to earn degrees and work towards careers in the fields of substance abuse treatment and mental health. For the past several years, CSAT's support for NHBCUSAC activities has been provided on a year-to-year basis under an interagency agreement with various National Institutes of Health. Based on the growing needs within HBCU campuses to develop capacities to address

substance abuse treatment and mental health, formalizing the network of HBCUs with CSAT and CMHS support is expected to improve student access to information and training, thereby furthering support efforts to establish a culturally appropriate workforce.

### II. Award Information

**1. Estimated Funding Available/Number of Awards:** It is expected that up to \$1.075 million will be available to fund one (1) award in FY 2005. The maximum allowable award is \$1.075 million in total costs (direct and indirect) per year for up to 3 years. Proposed budgets cannot exceed the allowable amount in any year of the proposed project. The actual amount available for the awards may vary, depending on unanticipated program requirements and the number and quality of the applications received. Annual continuations will depend on the availability of funds, grantee progress in meeting program goals and objectives, and timely submission of required data and reports.

This is a Category 2—Comprehensive Infrastructure Grant; the total award may be used for infrastructure development and implementation pilots. The allowance of 15 percent of the total grant award for implementation pilots specified in INF-05 PA is not applicable to this program. Funding requested for pilot campus-based suicide screening and referral to appropriate mental health treatment may not exceed \$150,000 per year. Funding requested for the annual Dr. Lonnie E. Mitchell Substance Abuse Conference may not exceed \$500,000 per year. The \$500,000 set aside for the conference includes a contribution from SAMHSA's Center for Substance Abuse Prevention.

This program is being announced prior to the annual appropriation for FY 2005 for SAMHSA's programs, with funding estimates based on the President's budget request for FY 2005. Applications are invited based on the assumption that sufficient funds will be appropriated for FY 2005 to permit funding of an award. All applicants are reminded, however, that we cannot guarantee that sufficient funds will be appropriated to permit SAMHSA to fund any applications.

#### **2. Funding Instrument: Cooperative Agreement.**

Because of the complexity of this cross-center initiative, and the anticipation of ongoing involvement of the Federal government in the development of the program guidelines, this award will be made as a cooperative agreement. The grantee will establish a

steering committee for this initiative, and will manage the steering committee's logistical and programmatic needs. The steering committee will consist of the HBCU-NRC Project Director; members of the Executive Board of the NHBCUSAC; two representatives selected by the grantee from among the HBCU institutions that are not current members of the NHBCUSAC; and the CSAT and CMHS Project Officers. All steering committee members will have a vote. Non-voting representatives of professional organizations that have expertise in the fields of substance abuse treatment and mental health may be invited to steering committee meetings on an as-needed basis.

#### *Role of Grantee:*

- Comply with the terms and conditions of the cooperative agreement and collaborate with SAMHSA staff in project implementation.
- Provide SAMHSA with data required to comply with the Government Performance and Results Act (GPRA). The grantee must meet with SAMHSA Project Officers within two months after the award of the cooperative agreement to begin discussing the grantee's evaluation strategy and how it will meet SAMHSA GPRA requirements.
- Participate with SAMHSA staff in any necessary development and refinement of HBCU-NRC policies, evaluation designs, measures, and databases.
- Keep policies consistent with SAMHSA policies on data sharing, access to data and materials, and publications.
- Attend meetings with SAMHSA as typically required of cooperative agreement grantees. These may be conducted in person, electronically, or by conference call.
- Provide funds for HBCU-NRC staff to attend relevant national meetings and conferences.
- Collaborate in planning and participate in any joint learning workshops with the ATTCs and other appropriate SAMHSA-funded activities.

#### *Role of SAMHSA Staff:*

- Work with the HBCU-NRC to help coordinate activities.
- Provide guidance and technical assistance across all the project's components, and conduct site visits as needed.
- Approve project implementation plan.
- Monitor and review progress of the HBCU-NRC project and make recommendations regarding moving through successive stages including its potential continuance.

- Participate in any necessary development and refinement of the HBCU-NRC policies, evaluation designs, measures, and databases.
- Facilitate the coordination of this program with other SAMHSA policies and activities, as appropriate.
- Participate as voting members of the HBCU-NRC steering committee.
- Approve steering committee structure and membership.
- Review and approve products prior to publication and dissemination.
- Approve proposed pilots and subawards.

#### *The HBCU-NRC Steering Committee will:*

- Consist of the HBCU-NRC Project Director, members of the Executive Board of the NHBCUSAC; two representatives selected by the grantee from among the HBCU institutions that are not current members of the NHBCUSAC; and the CSAT and CMHS Project Officers who will participate in but will not chair meetings.
- Meet at least twice annually. The first meeting of the steering committee may be convened at the request of SAMHSA Project Officers; the HBCU-NRC Steering Committee will coordinate with the SAMHSA Project Officers in scheduling, planning, and carrying out future meetings.
- Assist in the development and refinement of HBCU-NRC policies, evaluation designs, measures, and databases.
- Collaborate with SAMHSA in designing and implementing evaluation plans that will include SAMHSA GPRA goals and program specific goals.

### **III. Eligibility Information**

1. *Eligible Applicants* are the 104 nationally recognized Historically Black Colleges and Universities (HBCUs) or a consortium of HBCUs with a lead college/university as the applicant. The recipient of the award will be the entity legally responsible for satisfying the grant requirements. The applicant must agree to involve and serve all 104 HBCUs in the United States.

Eligibility is limited to the nationally recognized HBCUs or a consortium of HBCUs because the target audiences for activities supported under this initiative are HBCUs and HBCU students. Since there is a high concentration of African American students on these campuses, HBCUs are uniquely situated to provide the perspective regarding the substance abuse and mental health needs and issues surrounding the African American population in and around these college campuses. This initiative also supports Executive Orders 12320 and 12876 to "strengthen the capacity of

historically Black colleges and universities to provide quality education, to overcome the effects of discriminatory treatment, and to provide advice to the President regarding the needs in the areas of infrastructure, academic programs, and faculty and institutional development."

These eligibility criteria supersede the criteria specified in Section III-1 of the INF-05 PA.

2. *Cost Sharing or Matching* is not required.

3. *Other:* Applicants must also meet certain application formatting and submission requirements or the application will be screened out and will not be reviewed. These requirements are described in Section IV-2 below as well as in the INF-05 PA.

### **IV. Application and Submission Information**

1. *Address to Request Application Package:* Complete application kits may be obtained from the National Clearinghouse for Alcohol and Drug Information (NCADI) at 1-800-729-6686, or the National Mental Health Information Center at 1-800-789-2647. When requesting an application kit for this program, the applicant must specify the funding opportunity title "HBCU-NRC" and the funding opportunity number (TI 05-002). All information necessary to apply, including where to submit applications and application deadline instructions, is included in the application kit. The PHS 5161-1 application form is also available electronically via SAMHSA's World Wide Web home page: [http://www.samhsa.gov/Grants/generalinfo/useful\\_Info.aspx](http://www.samhsa.gov/Grants/generalinfo/useful_Info.aspx) and the INF-05 PA is available electronically at <http://www.samhsa.gov/grants/standard/Infrastructure/index.aspx>.

When submitting an application, be sure to type "TI 05-002/HBCU-NRC" in Item Number 10 on the face page of the application form. Also, SAMHSA applicants are required to provide a DUNS Number on the face page of the application. To obtain a DUNS Number, access the Dun and Bradstreet web site at <http://www.dunandbradstreet.com> or call 1-866-705-5711.

2. *Content and Form of Application Submission:* Information including required documents, required application components, and application formatting requirements is available in the INF-05 PA in Section IV-2.

#### *Checklist for Application Formatting Requirements*

SAMHSA's goal is to review all applications submitted for grant

funding. However, this goal must be balanced against SAMHSA's obligation to ensure equitable treatment of applications. For this reason, SAMHSA has established certain formatting requirements for its applications. If you do not adhere to these requirements, your application will be screened out and returned to you without review.

☐ Use the PHS 5161-1 application.  
☐ Applications must be received by the application deadline or have proof of timely submission, as detailed in Section IV-3 of the INF-05 PA.

☐ Information provided must be sufficient for review.

☐ Text must be legible.

• Type size in the Project Narrative cannot exceed an average of 15 characters per inch, as measured on the physical page. (Type size in charts, tables, graphs, and footnotes will not be considered in determining compliance.)  
 • Text in the Project Narrative cannot exceed 6 lines per vertical inch.

☐ Paper must be white paper and 8.5 inches by 11.0 inches in size.

☐ To ensure equity among applications, the amount of space allowed for the Project Narrative cannot be exceeded.

• Applications would meet this requirement by using all margins (left, right, top, bottom) of at least one inch each, and adhering to the page limit for the Project Narrative stated in the INF-05 PA.

• Should an application not conform to these margin or page limits, SAMHSA will use the following method to determine compliance: The total area of the Project Narrative (excluding margins, but including charts, tables, graphs and footnotes) cannot exceed 58.5 square inches multiplied by the page limit. This number represents the full page less margins, multiplied by the total number of allowed pages.

• Space will be measured on the physical page. Space left blank within the Project Narrative (excluding margins) is considered part of the Project Narrative, in determining compliance.

To facilitate review of your application, follow these additional guidelines. Failure to adhere to the following guidelines will not, in itself, result in your application being screened out and returned without review. However, the information provided in your application must be sufficient for review. Following these guidelines will help ensure your application is complete, and will help reviewers to consider your application.

☐ The 10 application components required for SAMHSA applications should be included. These are:

- Face Page (Standard Form 424, which is in PHS 5161-1).
- Abstract.
- Table of Contents.
- Budget Form (Standard Form 424A, which is in PHS 5161-1).
- Project Narrative and Supporting Documentation.
- Appendices.
- Assurances (Standard Form 424B, which is in PHS 5161-1).
- Certifications (a form in PHS 5161-1).

1).  
 • Disclosure of Lobbying Activities (Standard Form LLL, which is in PHS 5161-1).

• Checklist (a form in PHS 5161-1).

☐ Applications should comply with the following requirements:

• Provisions relating to confidentiality, participant protection and the protection of human subjects, as indicated in the INF-05 PA.

• Budgetary limitations as indicated in Sections I, II, and IV-5 of the INF-05 PA.

• Documentation of nonprofit status as required in the PHS 5161-1.

☐ Pages should be typed single-spaced in black ink with one column per page. Pages should not have printing on both sides.

☐ Please number pages consecutively from beginning to end so that information can be located easily during review of the application. The cover page should be page 1, the abstract page should be page 2, and the table of contents page should be page 3. Appendices should be labeled and separated from the Project Narrative and budget section, and the pages should be numbered to continue the sequence.

☐ The page limits for Appendices stated in the specific funding announcement should not be exceeded.

☐ Send the original application and two copies to the mailing address in the funding announcement. Please do not use staples, paper clips, and fasteners. Nothing should be attached, stapled, folded, or pasted. Do not use heavy or lightweight paper, or any material that cannot be copied using automatic copying machines. Odd-sized and oversized attachments such as posters will not be copied or sent to reviewers. Do not include videotapes, audiotapes, or CD-ROMs.

3. *Submission Dates and Times:* Applications must be received by January 18, 2005. You will be notified by postal mail that your application has been received. Additional submission information is available in the INF-05 PA in Section IV-3.

4. *Intergovernmental Review:* Applicants for this funding opportunity must comply with Executive Order

12372 (E.O.12372). E.O.12372, as implemented through Department of Health and Human Services (DHHS) regulation at 45 CFR part 100, sets up a system for State and local review of applications for Federal financial assistance. Instructions for complying with E.O. 12372 are provided in the INF-05 PA in Section IV-4. A current listing of State Single Points of Contact (SPOCs) is included in the application kit and is available at <http://www.whitehouse.gov/omb/grants/spoc.html>.

5. *Funding Restrictions:* Information concerning funding restrictions is available in the INF-05 PA in Section IV-5.

## V. Application Review Information

1. *Evaluation Criteria:* Applications will be reviewed against the Evaluation Criteria and requirements for the Project Narrative specified in Section V. Application Review Information in the INF-05 PA. The following information describes exceptions or limitations to the INF-05 PA and provides special requirements that pertain only to HBCU-NRC grants. Applicants must discuss the following requirements in their applications, in addition to the requirements specified in the INF-05 PA:

1.1 In "Section A: Statement of Need," the 4th bullet is deleted.

1.2 Performance Measurement: All SAMHSA grantees are required to collect and report certain data so that SAMHSA can meet its obligations under the Government Performance and Results Act (GPRA) and the grantees can meet their requirements to provide quarterly progress reports to SAMHSA as outlined below. All applicants must document their ability to collect and report data using the Knowledge Application Customer Satisfaction GPRA tool in "Section D. Evaluation and Data". This tool can be found at <http://www.csat-gpra.samhsa.gov> (click on 'Data Collection Tools/Instruments'), along with instructions for completing it. GPRA data must be collected at the end of each event and thirty days post-event. GPRA data must be entered into the GPRA Web system within 7 business days of the forms being completed. In addition, 80% of the participants must be followed up on. GPRA data are to be collected and then entered into CSAT's GPRA Data Entry and Reporting System (<http://www.csat-gpra.samhsa.gov>). Training and technical assistance on data collecting, as well as data entry, will be provided by CSAT.

The HBCU–NRC grantee will be required to report quarterly on their progress in meeting the Required Activities in Section I. Funding Opportunity Description of this NOFA as well as any other activities proposed in the application. At present, performance measures for these required activities have not been established. In “Section D. Evaluation and Data,” applicants must describe their current ability to collect and report data on their progress in meeting the Required Activities and any other proposed activities. Applicants may also propose performance measures to be considered by SAMHSA. The HBCU–NRC steering committee will work to build consensus around a common set of performance measures aligned with the Required Activities and program goals in Section I. Funding Opportunity Description of this NOFA. The grantee will be required to report in narrative format on the broad themes around their progress in their quarterly reports. Once SAMHSA has obtained necessary approval from the Office of Management and Budget (OMB), further data requirements will be mandated based on the consensus from the steering committee. The grantee may choose at any time to begin collecting more specific data related to the agreed upon measures to assist in building local support for continued sustainability for their activities once the period of Federal funding ends. SAMHSA will work with the grantee to assist them in building performance measurement systems that will provide needed local policy information.

Program activities may be used to demonstrate SAMHSA’s contribution to the White House Initiative for Historically Black Colleges and Universities.

Outcome measures expected from the HBCU–NRC:

- Program reports and evaluations that include client satisfaction and performance with relevant Government Performance and Results Act (GRPA) measures.
- Practice changes resulting from participating in the substance abuse and HIV prevention, substance abuse treatment, and mental health wellness tracks at the Dr. Lonnie E. Mitchell Substance Abuse Conference.
- An increase in the number of HBCUs that will make substance abuse and mental health a major part of their student orientations by 25% in year 2 and 50% in year 3 relative to the baseline estimate in year 1 of the project.
- An increase in the number of HBCUs that offer courses,

concentrations, minors and/or majors in the fields of substance abuse and/or addiction and mental health by 15% in year 2 and 30% in year 3 relative to the baseline estimate in year 1 of the project.

- Number of referrals to mental health treatment as a result of suicide screenings.

#### 2. Review and Selection Process:

Information about the review and selection process is available in the INF–05 PA in Section V–2.

### VI. Award Administration Information

Award administration information, including award notices, administrative and national policy requirements, and reporting requirements are available in the INF–05 PA in Section VI. SAMHSA’s standard terms and conditions are available at [http://www.samhsa.gov/Grants/generalinfo/grants\\_management.aspx](http://www.samhsa.gov/Grants/generalinfo/grants_management.aspx).

The HBCU–NRC program requires reporting in addition to that outlined in Section VI–3 Reporting Requirements of the INF–05 PA. The HBCU–NRC is expected to provide the following types of reports:

- Quarterly progress reports.
- Annual progress and fiscal reports.
- Final summary report at the end of the 3-year cycle.
- Periodic delivery of electronic copies of contact and service data.

Additional reports may be required on special projects and activities (e.g., collaborative services delivered with supplemental funding by another Federal agency partnering with SAMHSA in this program).

### VII. Agency Contacts for Additional Information

For questions concerning program issues contact:

CSAT: Shannon Taitt, SAMHSA/CSAT/OPAC, 1 Choke Cherry Road, Room 5–1037, Rockville, MD 20857. 240–276–1691; e-mail: [shannon.taitt@samhsa.hhs.gov](mailto:shannon.taitt@samhsa.hhs.gov).

CMHS: Roslyn Holliday Moore, SAMHSA/CMHS/OPAC, 1 Choke Cherry Road, Room 6–1077, Rockville, MD 20857. 240–276–1825; e-mail: [roslyn.moore@samhsa.hhs.gov](mailto:roslyn.moore@samhsa.hhs.gov).

For questions on grants management issues contact: Kimberly Pendleton, SAMHSA/Division of Grants Management, 1 Choke Cherry Road, Room 7–1097, Rockville, MD 20857. 240–276–1421; e-mail: [kimberly.pendleton@samhsa.hhs.gov](mailto:kimberly.pendleton@samhsa.hhs.gov).

Dated: October 22, 2004.

**Daryl Kade,**

*Director, Office of Policy Planning and Budget, Substance Abuse and Mental Health Services Administration.*

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BILLING CODE 4162–20–P

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

#### Open Meeting of the Federal Interagency Committee on Emergency Medical Services (FICEMS)

**AGENCY:** Federal Emergency Management Agency (FEMA), Emergency Preparedness and Response Directorate, Department of Homeland Security.

**ACTION:** Notice of open meeting.

**SUMMARY:** FEMA announces the following open meeting.

*Name:* Federal Interagency Committee on Emergency Medical Services (FICEMS).

*Date of Meeting:* December 2, 2004.

*Place:* Room 2029, National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161.

*Times:* 10:30 a.m.—Main FICEMS Meeting; 1 p.m.—FICEMS Counter-Terrorism Subcommittee and Ambulance Safety Subcommittee.

*Proposed Agenda:* Review and submission for approval of previous FICEMS Committee Meeting Minutes; Ambulance Safety Subcommittee and Counter-terrorism Subcommittee report; Action Items review; presentation of member agency reports; and reports of other interested parties.

**SUPPLEMENTARY INFORMATION:** This meeting will be open to the public with limited seating available on a first-come, first-served basis. See the Response and Security Procedures below. For those driving, parking is complimentary. If you are interested in taking METRO, blue line, and need shuttle service from/to METRO/NTIS, please notify Ms. Patti Roman when following the response procedures below.

*Response Procedures:* Committee Members and members of the general public who plan to attend the meeting should contact Ms. Patti Roman, on or before Tuesday, November 30, 2004, via mail at NATEK Incorporated, 21355 Ridgetop Circle, Suite 200, Dulles, Virginia 20166–8503, or by telephone at (703) 674–0190, or via facsimile at (703) 674–0195, or via e-mail at [proman@natekinc.com](mailto:proman@natekinc.com). This is