

investigational new drug (IND) process, points-to-consider documents, resources available from the National Institutes of Health (NIH) to bring gene therapy from the research laboratory to clinical trials, and to conduct a series of workshops on various issues concerning the development, production, and use of viral vectors for gene therapy. FDA believes that the conference will benefit interested parties, including industry, NIH, and FDA, involved in this rapidly advancing and changing field of gene therapy.

**DATES:** The public conference will be held on Thursday and Friday, July 11 and 12, 1996, 8 a.m. to 5 p.m. Preregistration is requested by June 28, 1996. Registration will be held on both days from 7:30 a.m. to 8 a.m.

**ADDRESSES:** The public conference will be held at NIH, Bldg. 45, Natcher Auditorium, 9000 Rockville Pike, Bethesda, MD. There is no registration fee. For a complete description of the conference, agendas, speakers, and session chairs check the FDA Biologics Home Page at <http://www.fda.gov/cber/cberftp.html>. The home page will be updated as the conference gets closer.

**FOR FURTHER INFORMATION CONTACT:**

Regarding information on registration: Margaret Fanning, NCI-FCRDC, P.O. Box B, Frederick, MD 21702-1201, 301-846-5865, or FAX 301-846-5866.

Regarding information on the conference agenda: Bette A. Goldman, Center for Biologics Evaluation and Research (HFM-500), 1401 Rockville Pike, Rockville, MD 20852-1448, 301-594-2860.

**SUPPLEMENTARY INFORMATION:** Gene therapy is a dynamic and rapidly advancing field of scientific study. The purpose of this conference is twofold. On July 11, 1996, FDA hopes to provide the gene therapy community with an education and understanding of the IND review process. Many academic investigators and researchers involved in the research and development of gene therapies are not familiar with the regulatory process for the review of IND's. This lack of knowledge of the IND process may decrease the efficiency of pre-IND meetings and increase the review burden on FDA staff. In order to address this problem, the conference will include a description of the IND process, the use of "points-to-consider" and guideline documents, and resources available from NIH to bring gene therapy from the research laboratory to clinical trials. On July 12, 1996, the conference will serve as an opportunity for FDA to hear concerns, issues, and

ideas from the gene therapy community. There will be presentations of the available scientific data from various groups, followed by discussions, in order to improve understanding of scientific issues that are the foundation of regulatory guidelines. Breakout sessions will address the following: Adenoviral vectors, ancillary products, facilities and manufacturing, information on getting started in gene therapy development, retroviral vectors, pharmacology, toxicology, and the development of new vector systems.

The information obtained from this conference may assist in the development of future scientific and regulatory policy or guidance.

Dated: April 19, 1996.

William K. Hubbard,

*Associate Commissioner for Policy Coordination.*

[FR Doc. 96-10484 Filed 4-26-96; 8:45 am]

**BILLING CODE 4160-01-F**

## **Health Resources and Services Administration**

### **Program Announcement and Proposed Project Requirements and Review Criteria for Cooperative Agreements for Partnerships for Health Professions Education for Fiscal Year 1996**

The Health Resources and Services Administration (HRSA) announces that applications will be accepted for fiscal year (FY) 1996 Cooperative Agreements for Partnerships for Health Professions Education. This model/demonstration program will be jointly funded under sections 738(b) (Minority Faculty Fellowship Program), 739 (Centers of Excellence in Minority Health Professions Education), and 740 (Health Careers Opportunity Program) of the Public Health Service Act, as amended by the Health Professions Education Extension Amendments of 1992, Pub. L. 102-408, dated October 13, 1992. The goal of this program is to establish and test a comprehensive model program in a geographically defined area (e.g., region, state, metropolitan or rural area), that incorporates a variety of educational and community-based entities in a formal continuum of activities to increase the number and quality of: (1) Minority and disadvantaged health professionals to provide health services to underserved populations and (2) minority faculty serving in health professions schools. No comprehensive model currently exists.

## **Rationale**

The rationale for conducting this model project is to:

1. Test the feasibility and effectiveness of executing a comprehensive program in a defined geographic area, which encompasses a dynamic coordinated educational continuum designed to increase the number and quality of minority/disadvantaged health professionals and minority faculty for health professions schools. This program includes formal linkages among several community-based entities and educational institutions.

2. Compare performance outputs of a comprehensive approach versus the output of several independent projects operating in a defined geographic area as is currently practiced.

3. Assess the cost effectiveness of a comprehensive model versus a multiple independent projects approach (testing the hypothesis that approximately one third of the costs for personnel and overhead expenditures would be saved through a comprehensive administrative infrastructure).

4. Determine the potential for several community and educational entities forming a unified, effective, multi-dimensional, comprehensive educational continuum under the umbrella of a single lead institution.

5. Test the relative soundness of a cooperative comprehensive approach versus that of several projects acting independently. This would facilitate tracking, monitoring and retaining targeted individuals through the educational pathway to become health professionals and/or faculty in health professions schools.

This program announcement is subject to reauthorization of the legislative authorities and to the appropriation of funds. Applicants are advised that this program announcement is a contingency action being taken to assure that should authority and funds become available for this purpose, they can be awarded in a timely fashion consistent with the needs of the program as well as to provide for even distribution of funds throughout the fiscal year. At this time, given a continuing resolution and the absence of FY 1996 appropriations for title VII programs, the amount of available funding for this specific cooperative agreement cannot be estimated.

## **Purpose**

The purposes of this program are to: (1) Assist schools in supporting programs of excellence in health

professions education for minority students, (2) assist individuals from disadvantaged backgrounds to undertake education to enter and graduate from a health professions school and (3) to assist schools in increasing the number of underrepresented minority faculty members at such schools. Applicants are required to meet the statutory requirements identified in sections 738(b), 739, and 740. Definitions regarding each of these programs have been published at 60 FR 62097, dated December 4, 1995. In addition, applicants must meet the requirements of regulations as set forth in 42 CFR part 57, subparts S and V. Applicants may request funding for up to three years. In making awards, consideration will be given to an equitable geographic distribution of projects.

#### *Eligibility*

Applicants eligible to apply for this model/demonstration program are accredited schools of allopathic medicine, osteopathic medicine, dentistry, pharmacy, public health, veterinary medicine, optometry, allied health, chiropractic, podiatric medicine, clinical psychology, health administration and other public or private nonprofit health or education entities located in a State as defined in section 799.

#### *Proposed Project Requirements*

The following project requirements are proposed:

1. The Partnerships for Health Professions Education cooperative agreement is to include efforts to increase the numbers and quality of:

- (a) Minority and disadvantaged health professionals who provide health services to underserved populations and
- (b) Minority faculty serving in health professions schools.

This would be accomplished through comprehensive geographically defined cooperative initiatives involving several educational and community-based institutions and organizations. Specifically, the project is to establish and test a model comprehensive program in a defined geographic area (e.g. region, state, metropolitan or rural area). The project would bring together a variety of educational and community entities into a formal educational continuum that addresses:

- (a) The needs of minority and disadvantaged students through graduation from a health professions school, and
- (b) Junior minority faculty aspiring to senior faculty positions in health professions schools.

2. The proposed model must encompass formulation of academic-community educational partnerships including:

(a) Formal linkages among health profession and prehealth profession schools, where both have strong histories and established administrative infrastructures for addressing the types of purposes proposed in this model program;

(b) Linkages among health professions schools and community based health care entities serving underserved populations. This would allow targeted health professions school students to be offered experiences in the delivery of health services in community-based facilities located at sites remote from the institution; and

c. Consortium arrangements (where appropriate) among participating health professions schools.

4. The Partnerships for Health Professions Education Programs shall, for a geographically prescribed area establish:

(a) An educational and non-educational support system designed to improve the quality of the minority applicant pool involving preliminary education, facilitating entry (including post baccalaureate projects where appropriate) and retention activities at the health professions school level. There should be an uninterrupted continuum to assist students through graduation from a health professions school. This would be accomplished through development and implementation of activities related to all the purposes identified in sections 738(b), 739, and 740 of the PHS Act.

(b) Minority faculty development initiatives designed to recruit and provide a formal structured program of preparation in such areas as pedagogical skills, program administration, grant writing and publication skills, research methodology, development of research proposals and community service abilities under a senior faculty mentor. It should involve pre-faculty appointment, faculty fellowship opportunities and retention for junior minority faculty in health professions schools;

(c) Information resources and curricula addressing minority health issues and clinical education at community based sites remote from the health professions school that predominantly serve underserved populations; and

(d) Faculty and student research on health issues particularly affecting minority groups.

5. Measurable, outcome oriented and time framed performance outcome

standards will be used to evaluate the project.

6. All award recipients must agree to maintain institutional expenditures of non-Federal funds in an amount not less than the previous fiscal year.

7. Program activities and experiences related to the establishment of the Partnerships for Health Professions Education Program must be documented in a format that would allow for future duplication by other institutional organizations.

#### *Substantial Federal Programmatic Involvement*

It is anticipated that the Federal government will have substantial programmatic involvement with the planning, development and administration of the Partnerships for Health Professions Education Program and its outputs by:

1. Providing technical assistance, guidance and reviewing changes needed to conduct the project.

2. Reviewing and advising regarding training content and methodologies and formal faculty development regimens.

3. Providing advice regarding formal linkage and consortium arrangements which have been established for the purpose of conducting the Partnerships for Health Professions Education Program.

4. Assisting in the modification of student participant selection criteria and processes.

5. Providing information relative to proven evaluation methods, including data collection methods, data analysis techniques and participant tracking systems.

6. Reviewing and advising on program evaluation methods, including data collection activities, data analysis techniques and participant tracking systems.

7. Reviewing and advising on the documentation of the activities and experiences related to establishment of the Partnerships for Health Professions Education Program.

8. Providing data and information about Federal programs that may impact the Partnerships for Health Professions Education Program.

9. Participating in the review of subcontracts awarded under the Cooperative Agreement.

#### *Proposed Review Criteria*

The following criteria are proposed for review of applications for this program:

1. The relationship of the applicants proposal to the purposes stated for the Partnerships for Health Professions Education Program, the

comprehensiveness and geographic base of the proposed project, the extent to which linkages with community entities and institutions are documented, and the degree to which the proposed project plans are transferable to other institutions.

2. The extent, institutional commitment and outcomes of past efforts and activities of the institution in conducting minority/disadvantaged programs, the extent to which applicant data indicate trends, the numbers and type (race/ethnicity, gender) of individuals that can be expected to benefit from the project, and suitability of participant eligibility requirements, selection criteria, and process.

3. The relevance of objective(s) to the stated problem and need, and to model purposes; their measurability and attainability within a specific time frame; and the extent to which they represent outcome measures.

4. The scope of specific activities and their relevance to the stated objectives and projected outcomes; their appropriateness for a Partnership for Health Professions Education Program; their soundness in terms of the extent and nature of the academic content and non-academic services; and their validity as to the methodologies, logic and sequencing proposed.

5. The administrative and managerial capability of the applicant to conduct the project, qualifications of the staff and faculty, their academic and experiential background and time commitment, the nature and degree of their involvement, and their experience in working with the proposed target group.

6. The appropriateness of the budget for assuring effective utilization of cooperative agreement funds and the institutional or organizational plan for phasing-in income from other sources and developing self-sufficiency for continuing the program after Federal funding.

7. The degree to which the applicant has made significant efforts to increase the number of minority individuals serving in faculty or administrative positions at the health professions school.

8. Techniques and methods to be employed in evaluating the project.

#### *National Health Objectives for the Year 2000*

The Public Health Service urges applicants to submit work plans that address specific objectives of *Healthy People 2000*. Potential applicants may obtain a copy of *Healthy People 2000* (Full Report; Stock No. 017-001-00474-0) or *Healthy People 2000* (Summary

Report; Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402-9325 (Telephone 202-783-3238).

#### *Education and Service Linkage*

As part of its long-range planning, HRSA will be targeting its efforts to strengthening linkages between U.S. Public Health Service education programs and programs which provide comprehensive primary care services to the underserved.

#### *Smoke-Free Workplace*

The Public Health Service strongly encourages all grant recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products and Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

#### *Additional Information*

Interested persons are invited to comment on the proposed project requirements and review criteria. The comment period is 30 days. All comments received on or before May 29, 1996 will be considered before the final project requirements and review criteria are established. Written comments should be addressed to Dr. Ciriaco Q. Gonzales, Director, Division of Disadvantaged Assistance, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Room 8A-09, 5600 Fishers Lane, Rockville, Maryland 20857. All comments received will be available for public inspection and copying at the Division of Disadvantaged Assistance, Bureau of Health Professions, at the above address, weekdays (Federal holiday excepted) between the hours of 8:30 a.m. and 5:00 p.m.

#### *Application Availability*

Application materials are available on the World Wide Web at address: <http://www.os.dhhs.gov/hrsa/bhpr>. Click on the file name you want to download to your computer. It will be saved as a self-extracting WordPerfect 5.1 file. Once the file is downloaded to the applicant's PC, it will still be in a compressed state. To decompress the file, go to the directory where the file has been downloaded and type in the file name followed by a <return>. The file will expand into a WordPerfect 5.1 file. Applicants are strongly encouraged to obtain application materials from the World Wide Web via the Internet.

However, for applicants who do not have Internet capability, application materials are also available on the Bureau of Health Professions (BHP) Bulletin Board. Use your computer and modem to call (301) 443-5913. Set your modem parameters to 2400 baud, parity to none, data bits to 8, and stop bits to 1. Set your terminal emulation to ANSI or VT-100.

Once you have accessed the BHP Bulletin Board, you will be asked for your first and last name. It will also ask you to choose a password. *Remember Your Password!* The first time you logon you "register" by answering a number of other questions. The next time you logon, BHP's Bulletin Board will know you.

Press (F) for the (F)iles Menu and (L) to (L)ist Files. Press (L) again to see a list of numbered file areas. To see a list of files in any area, type the number corresponding to that area. Competitive application materials for grant programs administered by the Bureau of Health Professions are located in the File Area item "B" titled Grants Announcements.

To (R)ead a file or (D)ownload a file, you need to know its exact name as listed on BHP's Bulletin Board. Press (R) to (R)ead a file and type the name of the file. Press (D) to (D)ownload a file to your computer. You need to know how your communications software accomplishes downloading.

When you have completed your tour of BHP's Bulletin Board for this session, press (G) for (G)oodbye and press <enter>.

If you have difficulty accessing the BHP Bulletin Board, please try the Internet address listed above. If you do not have Internet capability and need assistance in accessing the BHP Bulletin Board or technical assistance with any aspect of the BHP Bulletin Board, please call Mr. Larry DiGiulio, Systems Operator for the BHP Bulletin Board at (301) 443-2850 or "ldigiuli@hrsa.ssw.dhhs.gov".

Questions regarding grants policy and business management issues should be directed to Ms. Wilma Johnson, Acting Chief, Centers and Formula Grants Section ([wjohnson@hrsa.ssw.dhhs.gov](mailto:wjohnson@hrsa.ssw.dhhs.gov)), Grants Management Branch, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Room 8C-26, 5600 Fishers Lane, Rockville, Maryland 20857. If you are unable to obtain the application materials electronically, you may obtain application materials in the mail by sending a written request to the Grants Management Branch at the address above. Written requests may also be sent via FAX (301) 443-6343 or via the Internet listed above. Completed

applications should be returned to the Grants Management Branch at the above address.

If additional programmatic information is needed, please contact Dr. Ciriaco Q. Gonzales, Director, Division of Disadvantaged Assistance, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Room 8A-17, 5600 Fishers Lane, Rockville, Maryland 20857.

#### *Paperwork Reduction Act*

The standard application form PHS 6025-1, HRSA Competing Training Grant Application, and General Instructions have been approved by the Office of Management and Budget under the Paperwork Reduction Act. The OMB Clearance Number is 0915-0060.

The deadline date for receipt of applications is July 12, 1996. Applications will be considered to be "on time" if they are either:

- (1) *Received on or before* the established deadline date, or
- (2) *Sent on or before* the established deadline date and received in time for orderly processing. (Applicants should request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

Late applications not accepted for processing will be returned to the applicant. In addition, applications

which exceed the page limitation and/or do not follow format instructions will not be accepted for processing and will be returned to the applicant.

This program is not subject to the provisions of Executive Order 12372, Intergovernmental Review of Federal Programs (as implemented through 45 CFR part 100). This program is also not subject to the Public Health System Reporting Requirements.

Dated: April 17, 1996.

Ciro V. Sumaya,

*Administrator.*

[FR Doc. 96-10483 Filed 4-26-96; 8:45 am]

BILLING CODE 4160-15-P

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

##### **Agency Information Collection Activities: Proposed Collection; Comment Request**

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, contact the SAMHSA Reports Clearance Officer on (301) 443-0525.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

#### **Proposed Project**

National Household Survey on Drug Abuse—Revision—The National Household Survey on Drug Abuse (NHSDA) is a survey of the civilian, noninstitutionalized population of the United States, age 12 and over. The data are used to determine the prevalence of use of cigarettes, alcohol, and illicit substances, and illicit use of prescription drugs. The results are used by SAMHSA, ONDCP, Federal government agencies, and other organizations and researchers to establish policy, direct program activities, and better allocate resources. For 1997, the core NHSDA questionnaire will remain unchanged; however, several special topic modules are expected to change. The total annual burden estimate is 30,220 hours as shown below:

	Number of respondents	Number of responses per respondent	Average burden per response (hrs.)	Total burden (hrs.)
Household screener .....	53,082	1	0.05	2,654
NHSDA questionnaire .....	23,320	1	1.18	27,566

Send comments to Deborah Trunzo, SAMHSA Reports Clearance Officer, Room 16-105, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: April 23, 1996.

Richard Kopanda,

*Executive Officer, SAMHSA.*

[FR Doc. 96-10501 Filed 4-26-96; 8:45 am]

BILLING CODE 4162-20-P

#### **DEPARTMENT OF THE INTERIOR**

##### **Fish and Wildlife Service**

##### **Endangered and Threatened Species Permit Application**

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of receipt of application.

The following applicant has applied for a permit to conduct certain activities with endangered species. This notice is provided pursuant to section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

PRT-813910

*Applicant:* Dr. Michael I. Kelrick, Northeast Missouri State University, Kirksville, Missouri.

The applicant requests a permit to take (collection of seed, stems, leaves) Missouri bladderpod (*Lesquerella filiformis*) at the Wilson's Creek National Battlefield, Republic, Missouri, for the purpose of enhancement of species through propagation and scientific research.

Written data or comments should be submitted to the Regional Director, U.S. Fish and Wildlife Service, Division of Endangered Species, 1 Federal Drive, Fort Snelling, Minnesota 55111-4056, and must be received within 30 days of the date of this publication.