

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Tribal Leaders .....	40	1	1	40
Program Managers and Front Line Workers .....	120	1	1	120
Funding Officials .....	20	1	1	20
Child Welfare/Human Service Collaborators .....	60	1	1	60
Court Officials .....	20	1	1	20

*Estimated Total Annual Burden Hours: 260.*

In compliance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments 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) 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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: March 26, 2002.

**Bob Sargis,**

*Reports Clearance, Officer.*

[FR Doc. 02-7907 Filed 4-1-02; 8:45 am]

**BILLING CODE 4184-01-M**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Office of Planning, Research, and Evaluation, Grant to the University of Georgia**

**AGENCY:** Office of Planning, Research and Evaluation, ACF, DHHS.

**ACTION:** Award announcement.

**SUMMARY:** Notice is hereby given that a noncompetitive grant award is being made to the University of Georgia to conduct a study to identify rural counties in the Southern Black Belt experience persistent poverty and to examine their social, demographic, and economic conditions.

As a Congressional setaside, this one-year project is being funded noncompetitively. The university has several facilities and resources on campus for undertaking the feasibility study. The university also will rely upon several outside sources with specialized expertise to conduct various activities related to the project. The cost of this one-year project is \$250,000.

**FOR FURTHER INFORMATION CONTACT:** Hossein Faris, Administration for Children and Families, Office of Planning, Research And Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Phone: 202-205-4922.

Dated: March 22, 2002.

**Howard Rolston,**

*Director, Office of Planning, Research, and Evaluation.*

[FR Doc. 02-7906 Filed 4-1-02; 8:45 am]

**BILLING CODE 4184-01-M**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. 02D-0095]**

**Draft Guidance for Industry on Exposure-Response Relationships: Study Design, Data Analysis, and Regulatory Applications; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Exposure-Response Relationships: Study Design, Data Analysis, and Regulatory Applications." The guidance is intended to provide

recommendations for sponsors of investigational new drug applications (INDs) and applicants submitting new drug applications (NDAs) or biologics license applications (BLAs) on the use of exposure-response information in the development of drugs, including therapeutic biologics.

**DATES:** Submit written or electronic comments on the draft guidance by June 3, 2002. 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 Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, 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 Dockets Management Branch (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:** Lawrence J. Lesko, Office of Clinical Pharmacology and Biopharmaceutics, Center for Drug Evaluation and Research (HFD-850), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5690, or David Green, Center for Biologics Evaluation and Research (HFM-579), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-5349.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a draft guidance for industry entitled "Exposure-Response Relationships: Study Design, Data Analysis, and

Regulatory Applications.” This guidance provides recommendations on the use of exposure-response information in the development of drugs, including therapeutic biologics. The guidance describes: (1) The uses of exposure-response studies in regulatory decisionmaking, (2) the important considerations in exposure-response study designs to ensure valid information, (3) the strategy for prospective planning and data analyses in the exposure-response modeling process, (4) the integration of assessment of exposure-response relationships into all phases of drug development, and (5) the format and content of reports of exposure-response studies.

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 study design, data analysis, and regulatory applications of exposure-response relationships. 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 Dockets Management Branch (address above) written or electronic comments on the draft guidance. Two copies of any 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 guidance and received comments are available for public examination in the Dockets Management Branch 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 <http://www.fda.gov/cder/guidance/index.htm>, <http://www.fda.gov/cber/guidelines.htm>, or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: March 25, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 02-7883 Filed 4-1-02; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Fiscal Year 2002 Competitive Cycle for the Graduate Psychology Education Program 93.191a

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

**ACTION:** Notice.

**SUMMARY:** The Health Resources and Services Administration (HRSA) announces that applications will be accepted for the Graduate Psychology Education Program (GPEP) for Fiscal Year 2002.

*Authorizing Legislation:* These applications are solicited under section 755(b)(1)(J) of the Public Health Service Act as amended, and the FY 2002 Appropriations Act, Public Law 107-116 which provides \$2 million to support graduate psychology education programs to train health service psychologists in accredited psychology programs.

*Purpose:* Grants will be awarded to assist eligible entities in meeting the costs to plan, develop, operate, or maintain graduate psychology education programs to train health service psychologists to work with underserved populations including children, the elderly, victims of abuse, the chronically ill or disabled and in areas of emerging needs, which will foster an integrated approach to health care services and address access for underserved populations. The Graduate Psychology Education Program addresses interrelatedness of behavior and health and the critical need for integrated health care services. Funding is available to doctoral programs or doctoral internship programs as defined and accredited by the American Psychological Association (APA). Funding may not be used for post-doctoral residency programs.

*Eligible Applicants:* Eligible entities are accredited health profession schools, universities, and other public or private nonprofit entities. Each Graduate Psychology Education Program must be accredited by the American Psychological Association (APA). As provided in section 750, to be eligible to receive assistance, the eligible entity must use such assistance in collaboration with two or more disciplines.

*Funding Preference:* A funding preference is defined as the funding of a specific category or group of approved applications ahead of other categories or

groups of applications. This statutory general preference will only be applied to applications that rank above the 20th percentile of applications recommended for approval by the peer review group.

As provided in section 791(a) of the Public Health Service Act, preference will be given to any qualified applicant that: (1) Has a high rate for placing graduates in practice settings having the principal focus of serving residents of medically underserved communities; or (2) during the 2-year period preceding the fiscal year for which such an award is sought, has achieved a significant increase in the rate of placing graduates in such settings. “High Rate” refers to a minimum of 20 percent of graduates in academic year 1999-2000 or academic year 2000-2001, whichever is greater, who spend at least 50 percent of their worktime in clinical practice in the specified settings.

“Significant Increase in the Rate” means that, between academic years 1999-2000 and 2000-2001, the rate of placing graduates in the specified settings has increased by a minimum of 50 percent.

*Estimated Amount of Available Funds:* \$1,900,000.

*Estimated Number of Awards:* 15-19.

*Estimated Average Size of Each Award:* \$100,000-\$130,000.

*Estimated Funding Period:* One year.

*Application Requests, Availability, Date and Addresses:* Application materials will be available for downloading via the Web on March 29, 2002. Applicants may also request a hardcopy of the application material by contacting the HRSA Grants Application Center, 901 Russell Avenue, Suite 450, Gaithersburg, Maryland, 20879, by calling at 1-877-477-2123, or by fax at 1-877-477-2345. In order to be considered for competition, applications must be received by mail or delivered to the HRSA Grants Application Center by no later than May 22, 2002. Applications received after the deadline date may be returned to the applicant and not processed.

*Projected Award Date:* August 30, 2002.

**FOR FURTHER INFORMATION CONTACT:** LCDR Young Song, Division of State, Community and Public Health, Bureau of Health Professions, HRSA, Room 8C-09, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857; or e-mail at [ysong@hrsa.gov](mailto:ysong@hrsa.gov). Telephone number is (301) 443-3353.

*Additional Information:* A Technical Assistance Videoconference Workshop is being planned for sometime in April, 2002. Detailed information regarding this workshop will be in the application