

## II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on special controls for the implantable radiofrequency transponder system for patient identification and health information. 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 statute and regulations.

## III. Electronic Access

To receive "Class II Special Controls Guidance Document: Implantable Radiofrequency Transponder System for Patient Identification and Health Information" by FAX, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1541) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

## IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and

Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 USC 3501-3520). The quality system regulation provisions addressed in the guidance have been approved by OMB under OMB control number 0910-0073. The labeling provisions addressed in the guidance have been approved by OMB under OMB control number 0910-0485.

## V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 30, 2004.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

[FR Doc. 04-27078 Filed 12-9-04; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Office of Loan Repayment; Proposed Collection; Comment Request; National Institutes of Health Loan Repayment Programs

*Summary:* In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Office of Loan Repayment, National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

*Proposed Collection: Title:* National Institutes of Health Loan Repayment Programs. *Type of Information Collection Request:* Revision of currently approved collection (OMB No. 0925-0361, expiration date 12/31/04). *Form Numbers:* NIH 2674-1, NIH 2674-2, NIH 2674-3, NIH 2674-4, NIH 2674-5, NIH 2674-6, NIH 2674-7, NIH 2674-8, NIH 2674-9, NIH 2674-10, NIH

2674-11, NIH 2674-12, and NIH 2674-14. *Need and Use of Information Collection:* The NIH makes available financial assistance, in the form of educational loan repayment, to M.D., Ph.D., Pharm.D., D.D.S., D.M.D., D.P.M., D.C., and N.D. degree holders, or the equivalent, who perform biomedical or biobehavioral research in NIH intramural laboratories or as extramural grantees for a minimum of 2 years (3 years for the General Research Loan Repayment Program) in research areas supporting the mission and priorities of the NIH.

The AIDS Research Loan Repayment Program (AIDS-LRP) is authorized by Section 487A of the Public Health Service Act (42 U.S.C. 288-1); the Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds (CR-LRP) is authorized by Section 487E (42 U.S.C. 288-5); the General Research Loan Repayment Program (GR-LRP) is authorized by Section 487C (42 U.S.C. 288-3); the Loan Repayment Program Regarding Clinical Researchers (LRP-CR) is authorized by Section 487F (42 U.S.C. 288-5a); the Pediatric Research Loan Repayment Program (PR-LRP) is authorized by Section 487F (42 U.S.C. 288-6); the Extramural Clinical Research LRP for Individuals from Disadvantaged Backgrounds (ECR-LRP) is authorized by an amendment to Section 487E (42 U.S.C. 288-5); the Contraception and Infertility Research LRP (CIR-LRP) is authorized by Section 487B (42 U.S.C. 288-2); and the Health Disparities Research Loan Repayment Program (HD-LRP) is authorized by Section 485G (42 U.S.C. 287c-33).

The Loan Repayment Programs provide for the repayment of up to \$35,000 a year of the principal and interest of the educational loan debt of qualified health professionals who agree to conduct qualifying research for each year of obligated service. The information proposed for collection will be used to determine an applicant's eligibility for participation in the program.

*Frequency of Response:* Initial application and annual renewal application. *Affected Public:* Applicants, financial institutions, research institutions, recommenders. *Type of Respondents:* Physicians, other scientific or medical personnel, and organizational officials. The annual reporting burden is as follows:

Type of respondents	Number of respondents	Estimated number of responses per respondent	Average burden hours per response	Annual burden hours requested
<i>Intramural LRPs:</i>				
Initial Applicants .....	75	1	9.08	681.00
Recommenders .....	225	1	0.50	112.50
Financial Institutions .....	375	1	0.33	123.75
Subtotal .....	675	.....	.....	917.25
<i>Extramural LRPs:</i>				
Initial Applicants .....	2,000	1	9.83	19,660.00
Recommenders .....	6,000	1 0.50	3,000.00	
Advisors/Supervisors .....	2,000	1	1.50	3,000.00
Financial Institutions .....	10,000	1	0.33	3,300.00
Subtotal .....	20,000	.....	.....	28,960.00
<i>Extramural LRPS:</i>				
Renewal Applicants .....	800	1	7.08	5,664.00
Recommenders .....	2,400	1	0.50	1,200.00
Advisors/Supervisors .....	800	1	1.50	1,200.00
Subtotal .....	4,000	.....	.....	8,064.00
Total .....	24,675	.....	.....	37,941.25

The annualized cost to respondents is estimated at \$1,308,265. There are no capital costs, operating costs, or maintenance costs to report.

*Request for Comments:* Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Stephen J. Boehlert, Director of Operations, Office of Loan Repayment, National Institutes of Health, 6011 Executive Boulevard, Room 206 (MSC 7650), Bethesda, Maryland 20892-7650. (Mr. Boehlert can be contacted via e-mail at [boehlers@od.nih.gov](mailto:boehlers@od.nih.gov) or by calling (301) 451-4465 (not a toll-free number).

*Comment Dates:* Comments regarding this information collection are best assured of having their full effect if

received within 60 days of the date of this publication.

Dated: December 1, 2004.

**Raynard S. Kington,**

*Deputy Director, National Institutes of Health.*

[FR Doc. 04-27116 Filed 12-9-04; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Neurological Disorders and Stroke; 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 meetings.

The meetings 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 grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Neurological Disorders and Stroke Special Emphasis Panel Parkinson's Disease.

*Date:* December 6-7, 2004.

*Time:* 6:30 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

*Contact Person:* Katherine Woodbury, PhD, Scientific Review Administrator, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892-9529, (301) 496-5980, [kw47o@nih.gov](mailto:kw47o@nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* National Institute of Neurological Disorders and Stroke Special Emphasis Panel Huntington's Disease.

*Date:* December 7-8, 2004.

*Time:* 6:30 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

*Contact Person:* Katherine Woodbury, PhD, Scientific Review Administrator, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892-9529, (301) 496-5980, [kw47o@nih.gov](mailto:kw47o@nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS.)

Dated: December 6, 2004.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 04-27108 Filed 12-9-04; 8:45 am]

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