

associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory Agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In November 2012, the ICH Steering Committee agreed that a draft guidance entitled "S10 Photosafety Evaluation of Pharmaceuticals" should be made available for public comment. The draft guidance is the product of the S10 Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the S10 Expert Working Group.

The ICH S10 draft guidance provides guidance on when photosafety testing is warranted, and on possible testing strategies. It represents the consensus that exists regarding assessment of photosafety to support clinical development and marketing authorization of pharmaceuticals. It supplements the ICH M3(R2) guidance,<sup>1</sup>

which (1) provides certain information regarding timing of photosafety testing relative to clinical development and (2) recommends that an initial assessment of photoreactive potential be conducted and, if appropriate, an experimental evaluation be undertaken before exposure of large numbers of subjects. However, the ICH M3(R2) guidance does not address testing strategies.

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**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management (see **ADDRESSES**) 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.regulations.gov> or <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

Dated: January 29, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Indian Health Service

#### Loan Repayment Program for Repayment of Health Professions Educational Loans

*Announcement Type:* Initial  
*CFDA Number:* 93.164

*Key Dates:* February 15, 2013 first award cycle deadline date; August 16, 2013 last award cycle deadline date; September 13, 2013 last award cycle

Pharmaceuticals," available on the Internet at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

deadline date for supplemental loan repayment program funds; September 30, 2013 entry on duty deadline date.

## I. Funding Opportunity Description

The Indian Health Service (IHS) estimated budget request for Fiscal Year (FY) 2013 includes \$20,179,074 for the IHS Loan Repayment Program (LRP) for health professional educational loans (undergraduate and graduate) in return for full-time clinical service as defined in the IHS LRP policy clarifications at [http://www.ihs.gov/loanrepayment/documents/LRP\\_Policy\\_Updates.pdf](http://www.ihs.gov/loanrepayment/documents/LRP_Policy_Updates.pdf), in Indian health programs.

This program announcement is subject to the appropriation of funds. This notice is being published early to coincide with the recruitment activity of the IHS, which competes with other Government and private health management organizations to employ qualified health professionals.

This program is authorized by 25 U.S.C. Section 1616a.

## II. Award Information

The estimated amount available is approximately \$20,179,074 to support approximately 455 competing awards averaging \$44,270 per award for a two year contract. One year contract continuations will receive priority consideration in any award cycle. Applicants selected for participation in the FY 2013 program cycle will be expected to begin their service period no later than September 30, 2013.

## III. Eligibility Information

### 1. Eligible Applicants

Pursuant to Section 108(b), to be eligible to participate in the LRP, an individual must:

(1) (A) Be enrolled—

(i) In a course of study or program in an accredited institution, as determined by the Secretary, within any State and be scheduled to complete such course of study in the same year such individual applies to participate in such program; or

(ii) In an approved graduate training program in a health profession; or  
(B) Have a degree in a health profession and a license to practice in a state; and

(2) (A) Be eligible for, or hold an appointment as a Commissioned Officer in the Regular Corps of the Public Health Service (PHS); or

(B) Be eligible for selection for service in the Regular Corps of the PHS; or

(C) Meet the professional standards for civil service employment in the IHS; or

(D) Be employed in an Indian health program without service obligation; and

<sup>1</sup> See the ICH guidance "M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for

(E) Submit to the Secretary an application for a contract to the LRP. The Secretary must approve the contract before the disbursement of loan repayments can be made to the participant. Participants will be required to fulfill their contract service agreements through full-time clinical practice at an Indian health program site determined by the Secretary. Loan repayment sites are characterized by physical, cultural, and professional isolation, and have histories of frequent staff turnover. Indian health program sites are annually prioritized within the Agency by discipline, based on need or vacancy. The IHS LRP's ranking system gives high site scores to those sites that are most in need of specific health professions. Awards are given to the applications that match the highest priorities until funds are no longer available.

Any individual who owes an obligation for health professional service to the Federal Government, a State, or other entity is not eligible for the LRP unless the obligation will be completely satisfied before they begin service under this program.

Section 108 of the IHCA, as amended, authorizes the IHS LRP and provides in pertinent part as follows:

(a)(1) The Secretary, acting through the Service, shall establish a program to be known as the Indian Health Service Loan Repayment Program (hereinafter referred to as the Loan Repayment Program) in order to assure an adequate supply of trained health professionals necessary to maintain accreditation of, and provide health care services to Indians through, Indian health programs.

Section 1603(10) of the IHCA provides that:

"Health Profession" means allopathic medicine, family medicine, internal medicine, pediatrics, geriatric medicine, obstetrics and gynecology, podiatric medicine, nursing, public health nursing, dentistry, psychiatry, osteopathy, optometry, pharmacy, psychology, public health, social work, marriage and family therapy, chiropractic medicine, environmental health and engineering, an allied health profession, or any other health profession.

For the purposes of this program, the term "Indian health program" is defined in Section 108(a)(2)(A), as follows:

(A) The term Indian health program means any health program or facility funded, in whole or in part, by the Service for the benefit of Indians and administered—

(i) Directly by the Service;  
(ii) By any Indian Tribe or Tribal or Indian organization pursuant to a contract under—

(I) The Indian Self-Determination Act, or

(II) Section 23 of the Act of April 30, 1908, (25 U.S.C. 47), popularly known as the Buy Indian Act; or

(iii) By an urban Indian organization pursuant to Title V of this act.

Section 108 of the IHCA, as amended, authorizes the IHS to determine specific health professions for which IHS LRP contracts will be awarded. Annually, the Director, Division of Health Professions Support sends a letter to the Director, Office of Public Health, tribal leaders, and urban Indian health programs directors to request a list of positions for which there is a need or vacancy. The list of priority health professions that follows is based upon the needs of the IHS as well as upon the needs of American Indians and Alaska Natives.

(a) Medicine: Allopathic and Osteopathic.

(b) Nurse: Associate, B.S., and M.S. Degree.

(c) Clinical Psychology: Ph.D. and Psy.D.

(d) Counseling Psychology: Ph.D.

(e) Social Work: Masters level only.

(f) Chemical Dependency Counseling: Baccalaureate and Masters level.

(g) Counseling: Masters level only.

(h) Dentistry: DDS and DMD.

(i) Dental Hygiene.

(j) Dental Assistant: Certified.

(k) Pharmacy: B.S., Pharm.D.

(l) Optometry: O.D.

(m) Physician Assistant: Certified.

(n) Advanced Practice Nurses: Nurse Practitioner, Certified Nurse Midwife, Doctor of Nursing, Registered Nurse Anesthetist (Priority consideration will be given to Registered Nurse Anesthetists.)

(o) Podiatry: D.P.M.

(p) Physical Rehabilitation Services: Physical Therapy, Occupational Therapy, Speech-Language Pathology, and Audiology: M.S. and D.P.T.

(q) Diagnostic Radiology Technology: Certificate, Associate, and B.S.

(r) Medical Laboratory Scientist, Medical Technology, Medical Laboratory Technician: Associate, and B.S.

(s) Public Health Nutritionist/Registered Dietitian.

(t) Engineering (Environmental): B.S. (Engineers must provide environmental engineering services to be eligible.)

(u) Environmental Health (Sanitarian): B.S. and M.S.

(v) Health Records: R.H.I.T. and R.H.I.A.

(w) Certified Professional Coder: AAPC or AHIMA.

(x) Respiratory Therapy.

(y) Ultrasonography.

(z) Chiropractors: Licensed.

(aa) Naturopathic Medicine: Licensed.

(bb) Acupuncturists: Licensed.

## 2. Cost Sharing or Matching

Not applicable.

## 3. Other Requirements

Interested individuals are reminded that the list of eligible health and allied health professions is effective for applicants for FY 2013. These priorities will remain in effect until superseded.

## IV. Application and Submission Information

### 1. Content and Form of Application Submission

Each applicant will be responsible for submitting a complete application. Go to <http://www.ihs.gov/loanrepayment> for more information on how to apply electronically. The application will be considered complete if the following documents are included:

- Employment Verification—Documentation of your employment with an Indian health program as applicable:
  - Commissioned Corps orders, Tribal employment documentation or offer letter, or notification of Personnel Action (SF-50B)—For current Federal employees.

- License to Practice—A photocopy of your current, non-temporary, full and unrestricted license to practice (issued by any state, Washington, DC or Puerto Rico).

- Loan Documentation—A copy of all current statements related to the loans submitted as part of the LRP application.

- If applicable, if you are a member of a Federally recognized Tribe or Alaska Native (recognized by the Secretary of the Interior), provide a certification of Tribal enrollment by the Secretary of the Interior, acting through the Bureau of Indian Affairs (BIA) (Certification: Form 4432 Category A—Members of Federally-Recognized Indian Tribes, Bands or Communities).

### 2. Submission Dates and Address

Applications for the FY 2013 LRP will be accepted and evaluated monthly beginning February 15, 2013, and will continue to be accepted each month thereafter until all funds are exhausted for FY 2013. Subsequent monthly deadline dates are scheduled for Friday of the second full week of each month until August 16, 2013.

Applications shall be considered as meeting the deadline if they are either: (a) Received on or before the deadline date; and

(b) All documentation as describe above are submitted on or before the deadline date. (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 are not acceptable as proof of timely mailing).

Applications submitted after the monthly closing date will be held for consideration in the next monthly funding cycle. Applicants who do not receive funding by September 30, 2013, will be notified in writing.

Application documents should be sent to: IHS Loan Repayment Program, 801 Thompson Avenue, Suite 120, Rockville, Maryland 20852.

### 3. Intergovernmental Review

This program is not subject to review under Executive Order 12372.

### 4. Funding Restrictions

Not applicable.

### 5. Other Submission Requirements

New applicants are responsible for using the online application. Applicants requesting a continuation must do so in writing as early in the fiscal year in which they are reapplying.

## V. Application Review Information

### 1. Criteria

The IHS has identified the positions in each Indian health program for which there is a need or vacancy and ranked those positions in order of priority by developing discipline-specific prioritized lists of sites. Ranking criteria for these sites may include the following:

(a) Historically critical shortages caused by frequent staff turnover;

(b) Current unmatched vacancies in a health profession discipline;

(c) Projected vacancies in a health profession discipline;

(d) Ensuring that the staffing needs of Indian health programs administered by an Indian Tribe or Tribal health organization or urban Indian organization receive consideration on an equal basis with programs that are administered directly by the Service; and

(e) Giving priority to vacancies in Indian health programs that have a need for health professionals to provide health care services as a result of individuals having breached LRP contracts entered into under this section.

Consistent with this priority ranking, in determining applications to be approved and contracts to accept, the IHS will give priority to applications made by American Indians and Alaska Natives and to individuals recruited

through the efforts of Indian Tribes or Tribal or Indian organizations.

### 2. Review and Selection Process

Loan repayment awards will be made only to those individuals serving at facilities which have a site score of 70 or above during the first quarter of FY 2013, if funding is available.

One or all of the following factors may be applicable to an applicant, and the applicant who has the most of these factors, all other criteria being equal, will be selected.

(a) An applicant's length of current employment in the IHS, Tribal, or urban program.

(b) Availability for service earlier than other applicants (first come, first served).

(c) Date the individual's application was received.

### 3. Anticipated Announcement and Award Dates

Not applicable.

## VI. Award Administration Information

### 1. Award Notices

Notice of awards will be mailed on the last working day of each month. Once the applicant is approved for participation in the LRP, the applicant will receive confirmation of his/her loan repayment award and the duty site at which he/she will serve his/her loan repayment obligation.

### 2. Administrative and National Policy Requirements

Applicants may sign contractual agreements with the Secretary for two years. The IHS may repay all, or a portion of the applicant's health profession educational loans (undergraduate and graduate) for tuition expenses and reasonable educational and living expenses in amounts up to \$20,000 per year for each year of contracted service. Payments will be made annually to the participant for the purpose of repaying his/her outstanding health profession educational loans. Payment of health profession education loans will be made to the participant within 120 days, from the date the contract becomes effective. The effective date of the contract is calculated from the date it is signed by the Secretary or his/her delegate, or the IHS, Tribal, urban, or Buy Indian health center entry-on-duty date, whichever is more recent.

In addition to the loan payment, participants are provided tax assistance payments in an amount not less than 20 percent and not more than 39 percent of the participant's total amount of loan repayments made for the taxable year

involved. The loan repayments and the tax assistance payments are taxable income and will be reported to the Internal Revenue Service (IRS). The tax assistance payment will be paid to the IRS directly on the participant's behalf. LRP award recipients should be aware that the IRS may place them in a higher tax bracket than they would otherwise have been prior to their award.

### 3. Contract Extensions

Any individual who enters this program and satisfactorily completes his or her obligated period of service may apply to extend his/her contract on a year-by-year basis, as determined by the IHS. Participants extending their contracts may receive up to the maximum amount of \$20,000 per year plus an additional 20 percent for Federal withholding.

## VII. Agency Contact

Please address inquiries to Ms. Jacqueline K. Santiago, Chief, IHS Loan Repayment Program, 801 Thompson Avenue, Suite 120, Rockville, Maryland 20852, Telephone: 301/443-3396 [between 8:00 a.m. and 5:00 p.m. (EST) Monday through Friday, except Federal holidays].

## VIII. Other Information

IHS Area Offices and Service Units that are financially able are authorized to provide additional funding to make awards to applicants in the LRP, but not to exceed \$35,000 a year plus tax assistance. All additional funding must be made in accordance with the priority system outlined below. Health professions given priority for selection above the \$20,000 threshold are those identified as meeting the criteria in 25 U.S.C. 1616a(g)(2)(A) which provides that the Secretary shall consider the extent to which each such determination:

(i) Affects the ability of the Secretary to maximize the number of contracts that can be provided under the LRP from the amounts appropriated for such contracts;

(ii) Provides an incentive to serve in Indian health programs with the greatest shortages of health professionals; and

(iii) Provides an incentive with respect to the health professional involved remaining in an Indian health program with such a health professional shortage, and continuing to provide primary health services, after the completion of the period of obligated service under the LRP.

Contracts may be awarded to those who are available for service no later than September 30, 2013, and must be in compliance with any limits in the

appropriation and Section 108 of the IHCA not to exceed the amount authorized in the IHS appropriation (up to \$32,000,000 for FY 2013). In order to ensure compliance with the statutes, Area Offices or Service Units providing additional funding under this section are responsible for notifying the LRP of such payments before funding is offered to the LRP participant.

Should an IHS Area Office contribute to the LRP, those funds will be used for only those sites located in that Area. Those sites will retain their relative ranking from the national site-ranking list. For example, the Albuquerque Area Office identifies supplemental monies for dentists. Only the dental positions within the Albuquerque Area will be funded with the supplemental monies consistent with the national ranking and site index within that Area.

Should an IHS Service Unit contribute to the LRP, those funds will be used for only those sites located in that Service Unit. Those sites will retain their relative ranking from the national site-ranking list. For example, Whiteriver Service Unit identifies supplemental monies for nurses. The Whiteriver Service Unit consists of two facilities, namely the Whiteriver PHS Indian Hospital and the Cibecue Indian Health Center. The national ranking will be used for the Whiteriver PHS Indian Hospital (Score = 79) and the Cibecue Indian Health Center (Score = 95). With a score of 95, the Cibecue Indian Health Center would receive priority over the Whiteriver PHS Indian Hospital.

Dated: January 28, 2013.

**Yvette Roubideaux,**  
Director, Indian Health Service.

[FR Doc. 2013-02356 Filed 2-1-13; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 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 Cancer Institute Initial Review Group; Subcommittee J—Career Development.

*Date:* March 5–6, 2013.

*Time:* 4:30 p.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications

*Place:* Westin Alexandria, 400 Courthouse Square, Alexandria, VA 22314.

*Contact Person:* Ilda F. S. Melo, Ph.D. Scientific Review Officer, Resources and Training Review Branch, Division Of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Boulevard, Room 8111, Bethesda, MD 20892-8328, 301-496-7481, [mckennai@mail.nih.gov](mailto:mckennai@mail.nih.gov).

Information is also available on the Institute's/Center's home page: <http://deainfo.nci.nih.gov/advisory/irg/irg.htm>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: January 29, 2013.

**Melanie J. Gray,**  
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-02281 Filed 2-1-13; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 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:* Arthritis and Musculoskeletal and Skin Diseases Initial

Review Group; Arthritis and Musculoskeletal and Skin Diseases Special Grants Review Committee.

*Date:* March 7–8, 2013.

*Time:* 6:00 p.m. to 2:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

*Contact Person:* Helen Lin, Ph.D., Scientific Review Officer, NIH/NIAMS/RB, 6701 Democracy Blvd., Suite 800, Plaza One, Bethesda, MD 20817, 301-594-4952, [linh1@mail.nih.gov](mailto:linh1@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: January 29, 2013.

**Carolyn Baum,**  
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-02275 Filed 2-1-13; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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:* Center for Scientific Review Special Emphasis Panel; Skeletal Biology Structure and Regeneration Overflow.

*Date:* February 22, 2013.

*Time:* 1:00 p.m. to 2:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* The Westin St. Francis, 335 Powell Street, San Francisco, CA 94102.

*Contact Person:* Daniel F McDonald, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4110, MSC 7814, Bethesda, MD 20892, (301) 435-1215, [mcdonald@csr.nih.gov](mailto:mcdonald@csr.nih.gov).

*Name of Committee:* Vascular and Hematology Integrated Review Group; Hemostasis and Thrombosis Study Section.

*Date:* February 25, 2013.

*Time:* 8:00 a.m. to 5:00 p.m.