Register of May 17, 1999 (64 FR 26657) amending its regulations by adding provisions that clarify the agency's evaluation and approval of in vivo radiopharmaceuticals used in the diagnosis or monitoring of diseases. The regulation describes the kinds of indications of diagnostic radiopharmaceuticals and some of the criteria that the agency would use to evaluate the safety and effectiveness of a diagnostic radiopharmaceutical under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) and section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262). Information about the safety or effectiveness of a diagnostic radiopharmaceutical enables FDA to properly evaluate the safety and effectiveness profiles of a new diagnostic radiopharmaceutical or a new indication for use of an approved diagnostic radiopharmaceutical.

The rule clarifies existing FDA requirements for approval and evaluation of drug and biological products already in place under the authorities of the act and the PHS Act. The information, which is usually submitted as part of a new drug application or biologics license application or as a supplement to an approved application, typically includes, but is not limited to, nonclinical and clinical data on the pharmacology, toxicology, adverse events, radiation safety assessments, and chemistry, manufacturing, and controls. The content and format of an application for approval of a new drug are set forth in § 314.50 (21 CFR 314.50). Under 21 CFR part 315, information required under the act and needed by FDA to evaluate the safety and effectiveness of in vivo radiopharmaceuticals still needs to be reported.

Based on the number of submissions (that is, human drug applications and/or new indication supplements for diagnostic radiopharmaceuticals) that FDA receives, the agency estimates that it will receive approximately two submissions annually from two applicants. The hours per response refers to the estimated number of hours that an applicant would spend preparing the information required by the regulations. Based on FDA's experience, the agency estimates the time needed to prepare a complete application for a diagnostic radiopharmaceutical to be approximately 10,000 hours, roughly one-fifth of which, or 2,000 hours, is estimated to be spent preparing the portions of the application that would be affected by these regulations. The regulation does not impose any additional reporting burden for safety and effectiveness information on diagnostic radiopharmaceuticals beyond the estimated burden of 2,000 hours because safety and effectiveness information is already required by § 314.50 (collection of information approved by OMB under OMB control number 0910–0001). In fact, clarification in these regulations of FDA's standards for evaluation of diagnostic radiopharmaceuticals is intended to streamline overall information collection burdens, particularly for diagnostic radiopharmaceuticals that may have well established, low risk safety profiles, by enabling manufacturers to tailor information submissions and avoid unnecessary clinical studies. Table 1 of this document contains estimates of the annual reporting burden for the preparation of the safety and effectiveness sections of an application that are imposed by existing regulations. This estimate does not include the actual time needed to conduct studies and trials or other research from which the reported information is obtained.

In the **Federal Register** of April 28, 2008 (73 FR 22955), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.— ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Response	Total Hours
315.4, 315.5, and 315.6	2	1	2	2,000	4,000
Total					

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: August 29, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–20933 Filed 9–9–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Statutorily Mandated Single Source Award; Quentin N. Burdick American Indians Into Nursing Program

AGENCY: Indian Health Service, HHS.

ACTION: Notice of intent to fund a statutorily mandated single source grant award to the University of North Dakota, Quentin N. Burdick American Indians into Nursing Program, also known as the Recruit American Indians Into Nursing (RAIN) Program.

Project Period: August 1, 2008–July 31, 2013.

Amount of Award: $350,000.

Authority: This program is authorized under 25 U.S.C. 1616e(e) as amended, and requires the IETS to provide one grant to establish and maintain a program at the University of North Dakota (UND) to be known as the ''Quentin N. Burdick American Indians into Nursing Program.''

Single Source Justification: The single source award is statutorily mandated under 25 U.S.C. 1616e(e), as amended and shall to the maximum extent feasible, coordinate with the Quentin N. Burdick Indians Into Psychology Program.

Description of the Project: While Indian health programs have need for advance practice nurses who are nurse midwives and nurse practitioners, its greatest need in the field of advance practice nursing is nurse anesthesia. Additional high-need areas are nurse administrators trained at the graduate level and clinical nurses at the bachelor's level. Therefore, UND will maintain or incorporate the following:

A. Provide a preference to Indians,

B. Train nurse anesthetists, nurse midwives, nurse practitioners, nurse administrators and Bachelor's of Science in Nursing (BSN) nurses,

C. Teach curriculum in an interdisciplinary manner with other

health professionals such as pharmacy, medicine, or behavioral health students,

D. Integrate and emphasize an Evidence Based Practice (EBP) curriculum,

E. Have student clinical rotations established with Indian health programs,

F. Provide access to the nursing curriculum using distance learning,

G. Have formal bridge program agreements between Tribal colleges or universities to accommodate License Practical Nurse (LPN) to Associate Degree in Nursing (ADN)/BSN or BSN to Master's of Science in Nursing (MSN)/ Doctorate in Nursing Practice (DNP) students,

H. Have a faculty exchange program between a Tribal college and UND School of Nursing to enhance cultural relevance, competency, and faculty strength,

I. Have an emphasis on transcultural nursing and cultural competency, and

J. Have a rural health focus.

Continuation awards are subject to the availability of funds and satisfactory performance.

To obtain application instructions please click on the following link and go to the funding opportunities: *http://www.ihs.gov/NonMedicalPrograms/gogp/index.cfm?rnodule=gogp_funding.*

Criteria

A. Methodology (40 Points)

Applicants must train nurses at the graduate level in nurse anesthesia, nurse midwifery, nurse practitioners, nursing healthcare administration, or undergraduate level at the BSN degree level and should provide this training in an interdisciplinary manner. The applicant's curriculum should be available via a distance learning model and emphasize and integrate EBP, transcultural nursing, and include a rural health focus. Applicants must define how they will locate and recruit American Indian and Alaska Native (AI/AN) students and provide support services to AI/AN students who are recruited to facilitate their success in the nursing program and to track their progress. Applicants must define how they will assist the graduate nurse with job placement and track their payback status to ensure that the obligees comply with the terms of their service obligation. Applicants should have a mechanism in place to provide their students with clinical rotations in AI/AN health programs, have a bridge program agreement between Tribal colleges or universities so as to accommodate LPN to ADN/BSN or BSN to MSN/DNP and have a faculty exchange program with a Tribal college or university and a university school of nursing.

B. Capacity (20 Points)

Applicants must provide verification of accreditation and show that they are capable of conducting the project from a technical and business standpoint by providing the qualifications and credentials of key personnel and a sound fiscal plan using the grant funds. Applicants for the Graduate or Bachelor's level grants must submit verifying documentation of National League of Nursing Accreditation Commission or American Association of Colleges of Nursing Commission on Collegiate Nursing Education accreditation. All programs must submit verifying documentation of State approval.

C. Need (15 Points)

Applicants must justify the need for their project and provide a plan for the methodology they will use for recruiting AI/AN students nationwide as well as how they will actively assist nursing graduates with job placement. Applicants must recruit and train AI/AN individuals to be nurses at the graduate and undergraduate level and provide scholarships to those AI/AN individuals enrolled in the school of nursing to pay tuition, books, fees, and stipends for living expenses; provide a program that encourages AI/AN nurses at the graduate and undergraduate level to provide or continue to provide, health care services in AI/AN health care programs; and provide a program that increases the skills of, and provides continuing education, to AI/AN nurses at the graduate and undergraduate level.

D. Evaluation (15 Points)

Applicants must present a plan for evaluating their success in carrying out the project and on an annual basis conduct a quantitative and qualitative evaluation of their year's activities, identifying what areas of the project need to be improved and how they will make those improvements. Applicants must identify how they will meet on an annual basis with the other project directors and staff under this grant program to share successes and challenges and to receive Federal grant training.

E. Prior Experience (10 Points)

The UND must identify their experience with other similar projects, including the results of those projects and provide evidence of their past or potential cooperation and experience with AI/AN communities and Tribes and how UND Works with the Center for Gifted and Talented Indian Students established under section 5324(a) of the Indian Education Act of 1988.

Agency Contacts(s):

For program-related information, contact Ms. Sandra L. Haldane, BSN, RN, MS, Director, Division of Nursing Services, Office of Clinical and Prevention Services, Indian Health Service, 801 Thompson Avenue, Reyes Building, Suite 300, Rockville, MD 20852, (301) 443–1840.

For grants-related information, contact Ms. Norma Jean Dunne, Grants Management Specialist, Division of Grants Operations, Indian Health Service, 801 Thompson Avenue, TMP 360, Rockville, MD 20852, (301) 443–5204. (The telephone numbers are not toll-free numbers).

Dated: September 2, 2008.

Robert G. McSwain,

Director, Indian Health Service.

[FR Doc. E8–20907 Filed 9–9–08; 8:45 am]

BILLING CODE 4165–16–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Molecular and Integrative Signal Transduction Study Section, October 2, 2008, 8 a.m. to October 3, 2008, 5:30 p.m., Sheraton Delfina Santa Monica Hotel, 530 West Pico Boulevard, Santa Monica, CA 90405 which was published in the **Federal Register** on August 18, 2008, 73 FR 48219–48220.

The meeting will be held one day only October 2, 2008. The meeting time and location remain the same. The meeting is closed to the public.

Dated: September 3, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–20908 Filed 9–9–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice