section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)). This guidance document will serve as the special control for RNA preanalytical systems.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification. Because of the timeframes established by section 513(f)(2) of the act, FDA has determined, under § 10.115(g)(2) (21 CFR 10.115(g)(2)), that it is not feasible to allow for public participation before issuing this guidance as a final guidance document. Therefore, FDA is issuing this guidance document as a level 1 guidance document that is immediately in effect. FDA will consider any comments that are received in response to this notice to determine whether to amend the guidance document.

II. Significance of Guidance

This guidance is being issued consistent with FDA's GGP regulation (21 CFR 10.115). The guidance represents the agency's current thinking on RNA preanalytical systems. 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: RNA Preanalytical Systems (RNA Collection, Stabilization and Purification Systems for RT–PCR used in Molecular Diagnostic Testing)'' by fax call the Center for Devices and Radiological Health (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 (1563) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

To receive ''Class II Special Controls Guidance Document: RNA Preanalytical Systems (RNA Collection, Stabilization and Purification Systems for RT–PCR used in Molecular Diagnostic Testing),'' you may either send a fax request to 301–443–8818 to receive a hard copy of the document, or send an e-mail request to *gwa@cdrh.fda.gov* to receive a hard copy or an electronic copy. Please use the document number (1563) to identify the guidance you are requesting.

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 U.S.C. 3501–3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910–0120). The labeling provisions addressed in the guidance have been approved by OMB under OMB control number 0910–0485.

V. Comments

Interested persons may submit written or electronic comments regarding this document to the Division of Dockets Management (see **ADDRESSES**). 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 9, 2005.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 05–16913 Filed 8–24–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Research and Demonstration Projects for Indian Health

AGENCY: Indian Health Service, HHS.

ACTION: Notice of single source cooperative agreement with the National Council of Urban Indian Health.

SUMMARY: The Indian Health Service (IHS) announces the award of a cooperative agreement to the National Council of Urban Indian Health (NCUIH) for demonstration project for urban Indian health care education, consultation, health care data dissemination, training, and technical assistance to determine the unmet health care needs of urban Indians and to assist the Secretary in assessing the health status and health care of urban Indians. The project is for a three year project period effective September 1, 2005 to August 31, 2008. Annual funding for the project is $417,000.

The award is issued under the authority of the Public Health Service Act, Section 301 and the Indian Health Care Improvement Act, Public Law 94–437, Sections 503, 504, and 511, and is listed under Catalog of Federal Domestic Assistance number 93–933.

The specific objectives of the project are:

1. NCUIH will keep the Urban Indian health programs and the IHS informed of items of interest pertaining to the health status and unmet needs of urban Indians and the federal budget process by reviewing activities that have taken place in regard to Indian health care.

2. To disseminate information relative to Title V, local Urban Indian health issues, training opportunities, research instruments, data, budget, NCUIH activities and various forms of technical assistance to the Urban Indian health programs, keeping IHS informed of activities taking place.

3. To disseminate information and respond to all inquiries relative to Title V, local Urban Indian health issues, training opportunities, research instruments, data, budget, NCUIH

activities and will issue a quarterly newsletter and develop a web page.

4. To coordinate meetings for the Urban Indian health programs to provide training, technical assistance, and/or updated information addressing the health care needs of Urban Indians.

Reporting Requirements:

1. Monthly Activity Report: The organization will provide to the IHS program office a monthly report detailing activities performed for the organization. These activity reports will include:

- Trip reports for travel in connection to the organization
- Information on meetings attended by NCUIH regarding Indian health care education activities, and any documentation provided by NCUIH at these meetings
- Information relative to health status and health care needs of urban Indians in urban centers

2. Program Progress Report: Program progress reports are required semi-annually. These reports will include brief comparison of actual accomplishments to the goals established for the period, reasons for slippage (if applicable), and other pertinent information as required. A final report is to be submitted within 90 days of expiration of the budget/project period.

3. Financial Status Report: Financial status reports are required semi-annually. Standard Form 269 (long form) will be used for financial reporting. A final report must be submitted within 90 days of expiration of the budget/project period.

4. Financial Audit: A financial audit, conducted by an independent auditor will be completed annually for each year within the project period (three).

Failure to submit required reports within the time allowed may result in suspension or termination of the active cooperative agreement, withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in the imposition of special award provisions, or cause other eligible projects or activities involving the grantee organization not to be funded.

Justification for Single Source: This project has been awarded on a non-competitive single source basis. NCUIH is the only nationwide Indian organization that is specifically established to address the health needs of American Indians and Alaska Natives living in urban areas with membership consisting of Urban Indian health organizations funded under Title V of the Indian Health Care Improvement Act, Public Law 93–437, as amended, and under authority 25 U.S.C. 1652. Furthermore, it is the only nationwide organization for urban American Indians and Alaska Natives supporting the growth of the Urban Indian health care delivery system.

Use of Cooperative Agreement: A cooperative agreement has been awarded because of anticipated substantial Programmatic involvement by IHS staff in the project. Substantial programmatic involvement is as follows:

1. IHS staff will participate in the Board of Director meetings. Purposes will be to present the IHS prospectus on current health care issues affecting the Urban Indian people and allow IHS the opportunity to hear the continuing unmet needs of Urban Indians.

2. IHS staff may, at the request of NCUIH, participate on study groups and may recommend topics for consideration.

3. IHS will be involved in the selection and approval process for hiring key personnel. Key personnel are the Executive Director, the Office Administrator, and may include the hiring of major consultants. NCUIH must submit the Executive Director and Office Administrator selection criteria to IHS for approval when there becomes a change in staffing.;

4. IHS will be involved in meetings held by NCUIH.

Contacts: For program information, contact Ms. Danielle Steward, Program Specialist, Office of Urban Indian Health Programs, Office of the Director, Indian Health Service, Reyes Building, 801 Thompson Avenue, Rockville, MD, 20852, (301) 443–4680. For grants management information, contact Lois Hodge, Grants Management Officer, Division of Grants Operations, Reyes Building, 801 Thompson Avenue, Rockville, MD, 20852, (301) 443–5204.

Dated: August 19, 2005.

Mary Lou Stanton,

Deputy Director for Indian Health Policy Indian Health Service.

[FR Doc. 05–16912 Filed 8–24–05; 8:45 am]

BILLING CODE 4156–16–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Privacy Act of 1974; Report of Modified or Altered System

AGENCY: Indian Health Service (IHS), HHS.

ACTION: Notice of proposed modification or Alteration to a System of Records (SOR).

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, we are proposing to modify or alter an SOR, ''Health, Medical and Billing Records (formerly known as the Health and Medical Records Systems),'' System No. 09–17–0001. We propose to include contract health service records, as an additional category of individuals covered by the system, which consists of medical records to eligible American Indians and Alaska Native (AI/AN) people that supplements the health care resources available with the purchase of medical care and services that are not available within the IHS direct care system which may include, but not limited to, basic and specialty health care services from local and community health care providers, including hospital care, physician services, outpatient care, laboratory, dental, radiology, pharmacy, and transportation services. Under the Purpose of the system, we propose to include several new purposes that are in line with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule provisions which were incorporated into the published IHS Notice of Privacy Practices (NPP) and to include debt collection activities. We are proposing to modify/alter/delete several published routine uses, as explained, to accommodate for program and statutory changes as indicated: Number 1 is modified/altered by separating the medical treatment, payment and health care operations into two separate routine uses 1 and 2 to include payment, billing, third-party reimbursement and debt collection activities; numbers 3, 4 and 11 are to include business associate agreement language to comply with HIPAA Privacy standards and renumbered as 5, 6 and 12 respectively; number 5 is to include a special requirement notice for sensitive protected health information (PHI) such as alcohol/drug abuse, HIV/AIDS, STD or mental health patient information and renumbered as 7; number 6 is to reflect changes in research disclosures to comply with HIPAA Privacy standards and renumbered as 8; number 7 is to include various cases of abuses, neglect, sexual assault and domestic violence and emphasis on meeting the requirements of 42 CFR part 2 and renumbered as 9; number 8 is to clarify the disclosures regarding suspected cases of child abuse and renumbered as 10; number 9 is modified to include legal proceedings related to administrative claims and the inclusive provision of the Department of Health and Human Services (DHHS)/Office of General Counsel (OGC)