who fits the definition of clinical investigator for purposes of the financial disclosure rules. Investigators are persons who fit *any* of these criteria: Have *signed* the Form FDA 1572, are identified as an investigator in initial submissions or protocol amendments under an IND, or are identified as an investigator in the NDA/biologic license application (BLA).

The comment raised concerns over ways to minimize the burden of the collection of information on the respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

The comment stated that it is not so much the initial startup costs to develop tracking mechanisms but the ongoing costs of collecting, compiling, verifying and maintaining the information that are high. In the comment, a request was made that FDA limit the scope of people for whom sponsors are required to collect financial information. In addition, the comment recommended streamlining the data collection process by allowing sponsors to use e-mail to communicate with potential investigators; allowing investigators to fax completed forms to the sponsor, rather than requiring that sponsors retain forms with original signatures; and allowing sponsors to collect information at or near the start of each investigator's participation in the trial rather than prior to initiation of the study.

FDA has addressed in detail the definition of clinical investigator earlier in this response and believes it has provided appropriate clarification. The suggested ways of streamlining the data collection process are acceptable. It is permissible to communicate through e-mail or fax machines with investigators. E-mails should be printed and all hard copies of correspondence should be maintained in company files. Finally, as has been stated earlier, information must be collected prior to study start in order to alert the IND/investigational device exemption (IDE) sponsor of the study to any potentially problematic financial interest as early in the drug development process as possible in order to minimize the potential for study bias and to facilitate accurate collection of data that may be submitted many years later.

Dated: February 1, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–3078 Filed 2–7–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: The National Health Service Corps (NHSC) Recruitment and Retention Assistance Application (OMB No. 0915–0230)—Revision

The National Health Service Corps (NHSC) of the Bureau of Health Professions (BHPr), HRSA, is committed to improving the health of the Nation's underserved by uniting communities in need with caring health professionals and by supporting communities' efforts to build better systems of care.

The Application for NHSC Recruitment and Retention Assistance submitted by sites or clinicians requests information on the practice site, sponsoring agency, recruitment contact, staffing levels, service users, site's 5-year infant mortality or low birth rate averages, and next nearest site. Assistance in completing the application may be obtained through the appropriate State Primary Care Offices, State Primary Care Associations and HRSA field offices. The information on the application is used for determining eligibility of sites and to verify the need for NHSC providers. Sites must submit an application annually or when they need a provider.

Estimates of annualized reporting burden are as follows:

Type of report	Number of respondents	Response per respondents	Hours per response	Total burden hours
Application	1200	1	.25	300

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: John Morrall, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: February 4, 2002.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 02–3137 Filed 2–7–02; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)–443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: The National Health Service Corps Uniform Data System (OMB No. 0915–0232)—Revision

The National Health Service Corps (NHSC) of the Bureau of Health Professions (BHPr), Health Resources and Services Administration (HRSA), is committed to improving the health of the Nation's underserved by uniting communities in need with caring health professionals and by supporting

communities' efforts to build better systems of care.

The NHSC needs to collect data on its programs to ensure compliance with legislative mandates and to report to Congress and policymakers on program accomplishments. To meet these objectives, the NHSC requires a core set of information collected annually that is appropriate for monitoring and evaluating performance and reporting on annual trends. The following information will be collected from each site: services offered and delivery method; users by various characteristics; staffing and utilization; charges and collections; receivables, income, and expenses; and managed care.

The estimated burden is as follows:

Type of report	Number of respondents	Responses per respondents	Hours per response	Total burden hours
Universal report	900	1	27	24,300

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: John Morrall, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: February 4, 2002.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 02–3138 Filed 2–7–02; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Privacy Act of 1974; Altered System of Records

AGENCY: National Institutes of Health (NIH), HHS.

ACTION: Notification of altered system of records.

SUMMARY: In accordance with the requirements of the Privacy Act, the National Institutes of Health is publishing a notice of a proposal to alter the system of records 09–25–0165, ''National Institutes of Health Office of Loan Repayment and Scholarship (OLRS) Records System, HHS/NIH/OD.'' The main purposes of the major alteration include: (1) Addition of three new programs, (2) addition of the National Center on Minority Health and Health Disparities to ''System Location,'' (3) addition of grant numbers to ''Categories of Records in the System,'' and (4) two modified routine uses and one new routine use.

DATES: The NIH invites interested parties to submit comments on the proposed uses on or before March 11, 2002. The NIH will send a Report of the Altered System to the Congress and to the Office of Management and Budget (OMB). The alteration of this system of records will be effective 40 days from the date submitted to the OMB, unless NIH receives comments that would result in a contrary determination.

ADDRESSES: Please address comments to: NIH Privacy Act Officer, 6011 Executive Boulevard, Room 601, MSC 7669, Rockville, Maryland 20892, (301) 496–2832 (This is not a toll-free number).

Comments received will be available for inspection at this same address from 9 a.m. to 3 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Marc S. Horowitz, J.D., Director, Office of Loan Repayment and Scholarship, National Institutes of Health, 2 Center Drive, Room 2E30, Bethesda, Maryland 20892–0230, (800) 528–7689 (toll-free number).

For the loan repayment program administered by the National Center on Minority Health and Health Disparities (NCMHD), the contact is: John Ruffin, Ph.D., Director, National Center on Minority Health and Health Disparities, 6707 Democracy Boulevard, Suite 800, Bethesda, Maryland 20892–5465, (301) 402–1366.

SUPPLEMENTARY INFORMATION: Sections 487A–C, E and F of the Public Health Service (PHS) Act (42 U.S.C. 288–1, 2, 3, 5, 5a, and 6), Section 103 of the Minority Health and Health Disparities Research and Education Act (Pub. L. 106–525) as amended, and section 223 of Public Law 106–554 (114 Stat. 2763A–30) authorizes the Secretary or the Director, National Center on Minority Health and Health Disparities to implement and establish programs of entering into agreements with appropriately qualified health professionals under which such health professionals agree to conduct research, as employees or extramural grantees of the NIH or to conduct research with respect to contraception or infertility as employees or affiliates of the National Institute of Child Health and Human Development (NICHD) Intramural Laboratories and NICHD Extramural sites, in consideration of the Federal Government agreeing to repay, for each year of service, not more than $35,000 of the principal and interest of the educational loans of such health professionals. These programs include the following: (1) The NIH AIDS Research Loan Repayment Program, (2) the NIH General Research Loan Repayment Program, (3) the NIH Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds, (4) the NIH Contraceptive and Infertility Research Loan Repayment Program, (5) the NIH Loan Repayment Program Regarding Clinical Researchers, (6) the NIH Pediatric Research Loan Repayment Program, and (7) the NIH Loan Repayment Program for Minority Health Disparities Research.

Section 487D of the PHS Act (42 U.S.C 288–4) authorizes a scholarship program for individuals who agree to pursue, as undergraduates, academic programs appropriate for careers in professions needed by the NIH and who agree to serve as NIH employees in exchange for receipt of the scholarship. This program is known as the NIH Undergraduate Scholarship Program (UGSP) for Individuals from Disadvantaged Backgrounds.

The NIH is recommending this proposed major alteration to expand system coverage for three new programs: (1) The Loan Repayment Program Regarding Clinical Researchers, (2) the Pediatric Research Loan Repayment Program, and (3) the Loan Repayment Program for Minority Health Disparities Research.

NIH is proposing to include grant numbers in the ''Categories of Records in the System.'' In addition, two modified routine uses and one new routine use are proposed: (a) Modified Routine Use No. 4—the disclosure of records to HHS contractors and subcontractors for the purposes of collecting, compiling, aggregating, analyzing, or refining records in the system, and for the purposes of evaluating NIH programs; Modified