before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA'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 respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That are Not Individually Identifiable—(OMB Control Number 0910–0582)—Extension

FDA's investigational device regulations are intended to encourage the development of new, useful devices in a manner that is consistent with public health, safety, and with ethical standards. Investigators should have freedom to pursue the least burdensome means of accomplishing this goal. However, to ensure that the balance is maintained between product development and the protection of public health, safety, and ethical standards, FDA has established human subject protection regulations addressing requirements for informed consent and institutional review board (IRB) review that apply to all FDA-regulated clinical investigations involving human subjects. In particular, informed consent requirements further both safety and ethical considerations by allowing potential subjects to consider both the physical and privacy risks they face if they agree to participate in a trial.

Under FDA regulations, clinical investigations using human specimens conducted in support of premarket submissions to FDA are considered human subject investigations (see 21 CFR 812.3(p)). Many investigational device studies are exempt from most provisions of part 812 (21 CFR part 812), Investigational Device Exemptions, under § 812.2(c)(3), but FDA's regulations for the protection of human subjects (21 CFR parts 50 and 56) apply to all clinical investigations that are regulated by FDA (see 21 CFR 50.1; 21 CFR 56.101; 21 U.S.C. 360j(g)(3)(A), and 21 U.S.C. 360j(g)(3)(D)).

FDA regulations do not contain exceptions from the requirements of informed consent on the grounds that the specimens are not identifiable or that they are remnants of human specimens collected for routine clinical care or analysis that would otherwise have been discarded. Nor do FDA regulations allow IRBs to decide whether or not to waive informed consent for research involving leftover or unidentifiable specimens.

In a level one guidance document issued under the Good Guidances Practices regulation, 21 CFR 10.115, FDA outlines the circumstances in which it intends to exercise enforcement discretion as to the informed consent regulations for clinical investigators, sponsors, and IRBs.

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours	Total Capital Costs	Total Operating and Maintenance Costs
700	1	700	4	2,800	$210,000	420,000

The recommendations of this guidance impose a minimal burden on industry. FDA estimates that 700 studies will be affected annually. Each study will result in one recordkeeping per year, estimated to take 4 hours to complete. This results in a total recordkeeping burden of 2,400 hours (700 x 4 = 2,800). FDA estimates that the cost of developing standard operating procedures for each record keeper is $300 (6 hours of work at $50/hour (h)). This results in a total cost to industry of $210,000 ($300 x 700 recordkeepers). FDA estimates that operating costs for collecting this information is $300 per record keeper (6 hours of work at $50/h). This results in a total operational and maintenance cost to industry of $210,000 ($300 x 700 recordkeepers). The total cost of this recordkeeping, capital plus operational and maintenance cost, is estimated to be $420,000.

Dated: May 12, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–7617 Filed 5–18–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources And Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1891.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Faculty Loan Repayment Program (FLRP) Application (OMB No. 0915–0150)—Extension

Under the Health Resources and Services Administration Faculty Loan Repayment Program, degree-trained health professionals from disadvantaged backgrounds may enter into a contract under which HRSA, with the Department of Health and Human Services, will make payments on eligible health professions educational loans in exchange for a minimum of two years of service as a full-time or part-time faculty member of an accredited health professions college or university. Applicants must complete an application and provide all other required documentation including information on all eligible health professions educational loans.

The estimated response burden is as follows:

Respondent	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Applicants	150	1	150	1	150

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: May 15, 2006.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. E6–7666 Filed 5–18–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information shall have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Proposed Project: Enhanced Performance Measurement System for HRSA Health Professions Education and Training Program Grants: NEW

Following the 1998 reauthorization, HRSA's Health Professions Education and Training Programs have been using a reporting system known as the Comprehensive Performance Management System/Uniform Progress Report (CPMS/UPR) for preparation and submission of applications for continuation grants, and for reporting program outcomes under the Government Performance and Results Act of 1993 (GPRA).

Part I of the CPMS/UPR measures grantee progress toward meeting objectives, and is used for funding decisions. Part II collects information used by program officers to monitor program specific activities. Part III collects information on program results that can be aggregated across multiple programs, and is used for GPRA reporting and OMB initiated performance assessment activities.

The instrument previously approved for OMB for these purposes has been revised for clarity, and modified to better capture outcome information related to Health Professions Education and Training Programs that is increasingly required for evaluating Federal policy and program performance. Some elements have been added to improve measurement capability, while others have been streamlined to reduce burden. Additional validation rules are also being added to improve the quality of the data. Portions of the instrument have also been redesigned to improve reporting consistency among programs. The proposed system will be Web-based, and is planned to include a series of preprogrammed reports to increase access to, and analysis of, the data.

Estimates of annualized reporting burden are as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per respondent	Total hour burden
Enhanced Performance Measurement System	1,550	1	1,550	21.5	33,325