

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.*

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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.*

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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**

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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