

Dated: December 10, 1997.

**Joanne Lanahan,**

*Director, Health Care Administrative Sanctions, Office of Inspector General, OI.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Office for Protection From Research Risks; Submission for OMB Review; Comment Request; Protection of Human Subjects: Assurance Identification/Certification Declaration**

**SUMMARY:** Under the provisions of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office for Protection from Research Risks (OPRR), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** of August 22, 1997 (62 FR 44701) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

**Proposed Collection**

*Title:* Protection of Human Subjects: Assurance Identification/Certification/Declaration. *Type of Information Collection Request:* Extension. *OMB Control Number:* 0925-0418. *Expiration Date:* 12/31/97. *Need and Use of Information Collection:* The Federal Policy for the Protection of Human Subjects was promulgated on June 18, 1991 (56 FR 28003) and requires applicant and awardee institutions receiving Federal funds to initiate procedures to report, disclose, and keep required records for the protection of human subjects of research. Optional Form 310, Protection of Human Subjects: Assurance Identification/Certification/Declaration is necessary for the implementation and administration of the reporting and recordkeeping requirements set forth in the Federal Policy. *Frequency of Response:* On occasion. *Affected Public:* Individuals or households; Business or

other for-profit; Not for-profit institutions; Federal Government; State, local or tribal government. *Type of Respondents:* Researchers. The annual reporting burden is as follows: Estimated number of Respondents: 3,831. *Estimated Number of Responses per Respondent:* 56.8. *Average burden hours per response:* 0.755; and *Estimated total Annual Burden Hours Requested:* 164,428. The annualized cost to respondents is estimated at: \$2,096. There are not Capital Costs to report. There are no Operating or Maintenance Costs to report.

**Request for Comments**

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information will have the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency'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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

**Direct Comments to OMB**

Written comments and/or suggestions regarding the item contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, D.C. 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Michele Russell-Einhorn, Director of Regulatory Affairs, Office for Protection from Research Risks, 6100 Executive Blvd., Suite 3B-01, Rockville, MD. 20892-7507, or call non-toll-free-number (301) 435-5649 or E-mail your request, including your address to: <einhornm@od.nih.gov>.

**Comments Due Date**

Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: December 10, 1997.

**Gary B. Ellis,**

*Director, OPRR.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Substance Abuse and Mental Health Services Administration**

**Agency Information Collection Activities: Proposed Collection; Comment Request**

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed information requests, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of each proposed collection of information. To request a copy of these documents, contact the SAMHSA Reports Clearance Officer on (301) 443-8005.

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:* The 1997 Sample Survey of Mental Health Organizations and General Hospitals with Separate Psychiatric Services—Revision of the Inventory of Mental Health Organizations and General Hospital Mental Health Services (IMHO/GHMHS). The survey will be conducted in two phases. Phase I will be a brief two page inventory consisting of two forms—one for all organizations that provide mental health treatment services and the other for all managed behavioral health care organizations. Phase II will be a sample survey of 3,800 organizations drawn from the universe of organizations providing mental health treatment services identified in the first phase. The sample survey will use a more comprehensive, but very similar form to the one used in the 1994 IMHO/GHMHS. The organizational data to be collected include ownership and management, client/patient