

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden per response	Estimated total annual burden hours requested
Total	139.50

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 is necessary for the proper performance of the functions 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 those who are able to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Bryce B. Reeve, Ph.D, Outcomes Research Branch, ARP, DCCPS, National Cancer Institute, 6130 Executive Blvd. MSC 7344, Bethesda, MD 20892-7344. Phone: (301) 594-6574, e-mail: reeveb@mail.nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60-days of this publication.

Dated: July 12, 2004.

Rachelle Ragland-Greene,
NCI Project Clearance Liaison, National Institutes of Health.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notification of Request for Emergency Clearance; "Determination of Location, Capacity, and Status of Existing and Operating BSL-3 Laboratory Facilities Within the United States"

In accordance with section 3507(j) of the Paperwork Reduction Act of 1995, the National Institutes of Health hereby

publishes notification of request for Emergency Clearance for the information collection related to "Determination of Location, Capacity, and Status of Existing and Operating BSL-3 Laboratory Facilities within the United States."

This information collection is essential to the mission of NIAID/NIH (42 U.S.C. 241, 284, and 285f) and is critical to meeting the NIAID's role in the national biodefense effort (42 U.S.C. 285f).

Our nation's ability to detect and counter bioterrorism depends to a large degree on the information generated by biomedical research on dangerous, disease-causing microbes and on the immune system response to these pathogens. Much of this research is supported by the NIH and NIAID. The role of NIAID biodefense research is to develop countermeasures, including vaccines, drugs, and diagnostic tests, necessary to protect civilians from potential agents of bioterrorism. Since the fall of 2001, the NIAID has moved quickly to accelerate basic and clinical research related to the prevention, diagnosis and treatment of diseases caused by potential agents of bioterrorism.

Responsible stewardship of Federal funds in support of the national biodefense effort requires information on the existing capacity of the nation's biosafety level three (BSL-3) laboratories so that informed funding decisions can be made to enhance this national resource. NIAID plans to issue additional awards to develop and to expand the national capacity for biodefense-related research in meeting the objectives of the FY 2005 Presidential Budget (<http://www.whitehouse.gov/omb/budget/fy2005/appendix.html>, pg. 436). Reliable information on the location, size, and operational status of existing facilities is essential for making sound funding decisions. Without this information, NIAID may not be able to ensure appropriate distribution of BSL-3 laboratories when it awards future construction grants.

NIH cannot reasonably comply with the normal clearance procedures for information collection, because the use of normal procedures will delay the collection and hinder the agency in

accomplishing its mission, to the detriment of the public good. Compelling reason exists to collect the required information for successful planning and implementation of the national priority to expand BSL-3 capacity, as described in the FY 2005 Presidential Budget.

This information collection is essential to the effective stewardship of Federal funds. After consultation with scientific experts in the field, other government agencies, and other NIH components, NIAID has determined that the information is not currently available in any single, reliable, accessible source.

The information to be obtained by this survey will provide the NIAID with reliable and current information on the location, size, and operational status of existing BSL-3 laboratory facilities within the United States. This information will enable NIAID to predict the number, size and geographic requirements for additional biosafety laboratories.

Proposed Collection: Title: "Determination of Location, Capacity, and Status of Existing and Operating BSL-3 Laboratory Facilities within the United States." *Type of Information Collection Request:* EMERGENCY. *Need and Use of Information Collection:* To determine the location, capacity, and status of existing and operating BSL-3 laboratory facilities within the United States, in order to make informed funding decisions for awards in FY 2005. *Frequency of Response:* One time. *Affected Public:* Universities, medical research institutions, other Federal agencies, and the private sector (biotechnology and pharmaceutical companies). *Type of Respondent:* Universities, research facilities, other Federal agencies, and the private sector (biotechnology and pharmacological organizations). The annual reporting burden is as follows: *Estimated Number of Respondents:* 1500; *Estimated Number of Responses per Respondent:* One; *Average Burden Hours per Response:* 0.25 hours; and *Estimated Total Annual Burden Hours Requested:* 375 hours. The annualized cost to respondents is estimated at \$20,625 total (\$55/hr x 0.25hr x 1500 respondents). There are no Capital

Costs, Operating Costs, or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate 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) Enhance the quality, utility, and clarity of the information to be collected; and (4) 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(s) 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, DC 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: Deborah Katz, NIAID Office of Biodefense Research Affairs, 6610 Rockledge Drive, Room 5111, Bethesda, MD 20892. Telephone: (301) 402-8539. E-mail: dkatz@niaid.nih.gov.

By publication of this request of this request for emergency review, the NIH is requesting the approval for this collection. In view of the urgent public priority to meet the required levels of preparedness for possible bioterrorist actions against the United States and its citizens, NIAID requests that the collection of information be approved within 10 days of the publication of the **Federal Register** notice. This will allow sufficient time for public comment.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 10 days of the date of this publication.

Dated: July 12, 2004.

Lynn C. Hellinger,

Associate Director for Management and Operations, NIAID (Executive Officer), National Institutes of Health.

[FR Doc. 04-16317 Filed 7-16-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

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

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443-7978.

Substance Abuse Prevention and Treatment Block Grant (SAPTBG) Regulations (45 CFR part 96) and FY2005-2007 Application Format— (OMB No. 0930-0080, Revision)—Sections 1921 through 1935 of the Public Health Service Act (U.S.C. 300x-21 to 300x-35) provide for annual allotments to assist States to plan, carry out, and evaluate activities to prevent and treat substance abuse and for related activities. Under the provisions of the law, States may receive allotments only after an application is submitted and approved by the Secretary, DHHS. For the Federal fiscal year 2005-2007 SAPT Block Grant application cycles, the Substance Abuse and Mental Health Services Administration (SAMHSA) will provide States with revised application guidance and instructions to implement changes made by 42 U.S.C. 290kk and 42 U.S.C. 300x-65, implemented by 45 CFR part 54 and 45 CFR 96.122(f)(5), and the recommendations of the Office of Management and Budget's Program Assessment Rating Tool (PART) analysis of the SAPT Block Grant program.

Revisions to the previously-approved application resulting from the authorizing legislation, new regulation, and PART analysis reflect the following changes: (1) In Section I, the Funding Agreements/Certifications (Form 3) are being amended to include the requirement of 42 U.S.C. 300x-65 and 45 CFR part 54; (2) In Section II.2, the annual report and plan includes a new reporting requirement, Goal #17, "Services Provided By Non-Governmental Organizations," and Attachment J, "Charitable Choice Notice to Program Beneficiaries." In Section II.4, the "Treatment Utilization Matrix (Form 7)," is being replaced with the "Treatment Utilization Matrix (Form 7A)," which includes clarification in its column headings to improve collection of number of persons served and the

average cost of services for each modality. A column has been added to collect information on the number of State approved facilities in each level or category of service to facilitate understanding of the States' capacities. The information on number of persons served and treatment costs is being collected in response to the OMB PART analysis of the SAPT Block Grant. Form 7A replaces "Number of Persons Served (Form P1)," that appeared in Section IV-A, "Voluntary Treatment Performance Measures." A new Form 7B, "Number of Persons Served (Unduplicated Count) of Persons Served for Alcohol and Other Drug Use in State Funded Services," has been added to collect treatment utilization data by age, gender, and race/ethnicity in order to facilitate comparisons with the currently collected Forms 8 and 9. In Section III.7, the "Purchasing Services Checklist(s)" has been revised to include information on competitive and non-competitive contracts as well as information on the estimated percent of clients served and estimated percent of SAPT Block Grant expenditures. In prior year applications for SAPT Block Grant funds, Form 7, "Treatment Utilization Matrix," and Form 12, "Treatment Capacity Matrix," the States were required to provide 2 or more sub-State planning area utilization and capacity reports and a Statewide utilization and capacity report. SAMHSA has deleted the sub-State planning area reporting requirements for Form 7 and Form 12. SAMHSA has also deleted Form 10, "State Use of Needs Assessment Information Items," and the Form 11 Supplement.

In Section IV-A, "Voluntary Treatment Performance Measures," the "Number of Persons Served (Form P1)" has been revised and renamed as described in Section II.4. Form P2, "Employment Status," Form P3, "Living Status," Form P4 "Criminal Activity," and Form P5, "Alcohol Use," have been renamed Form T1 through T4, respectively. Form P6, "Marijuana Use," Form P7, "Cocaine Use," Form P8, "Amphetamine Use," and P9, "Opiate Use," have been replaced by Form T5, "Other Drug Use." Form T-6, "Infectious Disease Performance Measure," is a checklist to determine the degree to which the Single State Agency provides and/or coordinates delivery of appropriate infection control practices within its service system for substance abuse treatment and prevention services.

Form T-7, "Social Support for Recovery," and Form T-8, "Retention," were added to encourage States to report performance and outcome data