Response: Once. *Affected Public:* Registered members of the CTSU and Clinical Trials Cooperative Group staff. *Type of Respondents:* The Online Information Survey will survey registered CTSU users and Cooperative Group staff. The Online Data Submission Survey will survey registered CTSU users and Cooperative Group staff. The annualized cost to respondents is estimated at $10,400. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report. *Estimated Number of Respondents:* 520. *Estimated Number of Responses per Respondent:* 1. *Average Burden per Response:* 0.50 Hours. *Estimated Total Annual Burden Hours Requested:* 260.

The total burden estimate per respondent is shown below:

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden per response	Estimated total annual burden hours requests
Online Information System Survey—registered CTSU users and Cooperative Group staff ..	290	1	0.50	145
Online Data Submission Survey—registered CTSU users and Cooperative Group staff	230	1	0.50	115
Total	.....	.....	.....	260

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 the date of this publication.

Dated: July 12, 2004.

Rachelle Ragland-Greene,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 04–16315 Filed 7–16–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Evaluation of National Cancer Institute's Central Institutional Review Board To Improve Cancer Clinical Trials System

SUMMARY: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: Evaluation of National Cancer Institute's Central Institutional Review Board To Improve Cancer Clinical Trials System. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* This study will evaluate the success of the Central Institutional Review Board (CIRB), a pilot project designed to streamline the protocol activation process by conducting human subject protection reviews that can be utilized by local Institutional Review Boards (IRBs) for facilitated approval of multi-institutional, NCI-sponsored phase III clinical trails. This evaluation includes two surveys that will be made available online to minimize respondent burden. The CIRB Survey will assess acceptance level and satisfaction of local IRB chairs, coordinators, and principal investigators with the CIRB. The Cooperative Group Staff survey will assess the opinions and experiences of the operations and regulations staff of the nine Clinical Trials Cooperative Groups about CIRB operations, office processes, and procedures. The findings will provide valuable information concerning whether the CIRB is meeting its intended goals and will provide recommendations for change and further study. *Frequency of Response:* Once. *Affected Public:* Registered members of the CIRB and Clinical Trials Cooperative Group staff. *Type of Respondents:* IRB chairs, IRB coordinators, principal investigators, and the operations and regulations staff of Clinical Trials Cooperative Groups. The annualized cost to respondents is estimated at $5,500. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report. *Estimated Number of Respondents:* 279. *Estimated Number of Responses per Respondent:* 1. *Average Burden per Response:* 0.50 Hours. *Estimated Total Annual Burden Hours Requested:* 139.50.

The total burden estimate per respondent is shown below:

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden per response	Estimated total annual burden hours requested
IRB chairs, IRB coordinators, principal investigators	225	1	0.50	112.50
Clinical Trials Cooperative Group operations and regulations staff	54	1	0.50	27

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.

[FR Doc. 04–16316 Filed 7–16–04; 8:45 am]

BILLING CODE 4140–01–M

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 × 0.25hr × 1500 respondents). There are no Capital