

review activities; copies of all correspondence between investigators and the IRB; (5) statement of significant new findings provided to subjects of the research; and (6) a list of IRB members by name, showing each member's earned degrees, representative capacity, and experience in sufficient detail to describe each member's contributions to the IRB's deliberations, and any employment relationship between each member and the IRB's institution. This information is used by FDA in

conducting audit inspections of IRBs to determine whether IRBs and clinical investigators are providing adequate protections to human subjects participating in clinical research. The recordkeeping requirement burden is based on the following: The burden for each of the paragraphs under 21 CFR 56.115 has been considered as one estimated burden. FDA estimates that there are approximately 2,500 IRBs. The IRBs meet on an average of 14.6 times annually. The Agency estimates

that approximately 100 hours of person-time per meeting are required to meet the requirements of the regulation.

In the **Federal Register** of October 1, 2013 (78 FR 60286), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
56.115	2,500	14.6	36,500	100	3,650,000

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: February 27, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Assessment of DAIDS Training Resources

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 Institute of Allergy and Infectious Diseases (NIAID), 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.

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 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.

To Submit Comments and for Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Jacquelyn Burns, Office for Policy in Clinical Research Operations, DAIDS, NIAID, 6700B Rockledge Drive, Room 4118, Bethesda, MD 20852, or call non-toll-free number 301-402-0143, or Email your request, including your address to: jburns@niaid.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

Comment 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.

Proposed Collection: Assessment of DAIDS Training Resources, 0925-New, National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH).

Need and Use of Information Collection: This is a new data collection in order to assess the efficacy of training resources and their impact on NIAID-supported and/or sponsored research operations. The generic OMB clearance will allow collecting information about the knowledge, attitudes, and behaviors from target audiences (e.g., research staff) to help improve and inform these

training resources. Information collected will be used to determine the future direction for training resources, including which resources should be continued, enhanced, added, or discontinued in order to utilize resources efficiently.

Findings will provide data to inform and guide the optimal development, dissemination, and revisions to improve NIAID trainings and resources. Various types of data will be collected, including post-assessment tests, questionnaires, interviews, and focus groups. Post-assessment tests will be administered at the time of the trainings to assess trainees' immediate knowledge gained, as well as reactions and satisfaction to the content. Select trainees will be queried at later time points (e.g., three-months, six-months) after they have participated in a training to understand if they have been able to apply their knowledge at the workplace, and identify facilitators or hindrances to implementing this new knowledge. The assessment team will conduct repeated data collections for these select trainees to determine any changes throughout time. In order to obtain information beyond self-reported data, select managers and supervisors will also be queried to assess if they have observed any changes in their staff after attending trainings, and if the work environment is conducive for trainees to implement knowledge from trainings.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 847.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Data collection	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annualized burden (in hours)
Investigator	Survey	120	5	10/60	100
	Interviews	12	1	1	12
	Focus Groups ...	4	1	90/60	6
Study Coordinator	Survey	120	5	10/60	100
	Interviews	11	1	1	11
	Focus Groups ...	4	1	90/60	6
Pharmacy Staff	Survey	140	5	10/60	117
	Interviews	9	1	1	9
	Focus Groups ...	4	1	90/60	6
Laboratory Staff	Survey	170	5	10/60	142
	Interviews	11	1	1	11
	Focus Groups ...	4	1	90/60	6
Data Management Staff	Survey	30	3	10/60	15
	Interviews	9	1	1	9
	Focus Groups ...	4	1	90/60	6
Quality Assurance/Quality Control Personnel	Survey	75	5	10/60	63
	Interviews	11	1	1	11
	Focus Groups ...	4	1	90/60	6
Regulatory Coordinator	Survey	75	5	10/60	63
	Interviews	11	1	1	11
	Focus Groups ...	4	1	90/60	6
Community Member	Survey	23	3	10/60	12
	Interviews	6	1	1	6
	Focus Groups ...	4	1	90/60	6
Counselor	Survey	30	3	10/60	15
	Interviews	6	1	1	6
	Focus Groups ...	4	1	90/60	6
IRB Member	Survey	23	3	10/60	12
	Interviews	6	1	1	6
	Focus Groups ...	4	1	90/60	6
Clinical Researcher	Survey	45	5	10/60	38
	Interviews	12	1	1	12
	Focus Groups ...	4	1	90/60	6

Dated: February 20, 2014.

Brandie Taylor,

Project Clearance Liaison, NIAID, NIH.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which

would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; TME Study Section—Special Review.

Date: March 14, 2014.

Time: 11:30 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Angela Y. Ng, MBA, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6200, MSC 7804, Bethesda, MD 20892, 301-435-1715, nga@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Healthcare Delivery and Methodologies.

Date: March 18, 2014.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Ping Wu, Ph.D., Scientific Review Officer, HDM IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3166, Bethesda, MD 20892, 301-615-7401, wup4@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Non-HIV Diagnostics, Food Safety, Sterilization/Disinfection and Bioremediation.

Date: March 27-28, 2014.

Time: 8:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn, 7301 Waverly Street, Bethesda, MD 20814.

Contact Person: Gagan Pandya, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, RM 3200, MSC 7808, Bethesda, MD 20892, 301-435-1167, pandyaga@mai.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Non-HIV Anti-Infective Therapeutics.

Date: March 27-28, 2014.

Time: 8:00 a.m. to 5:00 p.m.