



[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection; 60-day comment request

Process Assessment Review of the Division of Acquired Immunodeficiency Syndrome (DAIDS) Critical Events Policy Implementation (CEPI) Program (NIAID)

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: Lyndi Lahl, RN, MS, Office for Policy in Clinical Research Operations, DAIDS, NIAID, 6700B Rockledge Drive, Room 4254, Bethesda, MD 20852, or call non-toll-free number 301-435-3756, or E-mail your request, including your address to: Lynda.Lahl@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: Process Assessment Review of the Division of Acquired Immunodeficiency Syndrome (DAIDS) Critical Events Policy Implementation (CEPI) Program, 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 to assess the CEPI program's progression to fulfillment of its program goals and will assess

whether the CEPI program is implemented and functioning as intended. The program goals for CEPI are: 1) Awareness & Accessibility - The target populations (DAIDS Staff, extramural researchers, external stakeholders) are aware of the DAIDS Critical Events (CE) policy and manual and associated documents and whether the policy and associated documents are readily accessible.; 2) Understandability – The Critical Events policy and manual clearly articulate DAIDS expectations for CE policy implementation by the target populations. The CE policy and manual should establish a common base of understanding and promote positive attitudes towards event reporting; and 3) Applicability – Target populations are able to correctly identify which Critical Events have occurred at their sites and are able to apply the CE policy and manual to their events.

Findings will provide data to inform DAIDS and Protection of Participants, Evaluation and Policy (ProPEP) leadership regarding further policy deployment decisions. Information collected will be used to determine how effectively the CEPI Program meets extramural researchers' needs. By assessing the CEPI Program, DAIDS will determine how successfully it is reaching its goals - to facilitate and improve the quality of clinical research conducted within the division. In addition, the CEPI Program assessment will determine whether previously recommended improvements included in the DPIP assessment were successfully incorporated into the policy rollout process. The results may be used as a model for policy development to facilitate compliance in reporting certain incidents and implementation in other National Institutes of Health (NIH) Institutes and Centers (ICs) and will be shared with all interested divisions and institutes within the NIH. There are no plans to share this information with the public.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 386.

Estimated Annualized Burden Hours

Type of Respondents	Data collection	Number of Respondents	Number of Responses per Respondent	Average Time Per Response	Total Annual Burden Hours
DAIDS Staff, ER/ES	Survey	500	1	30/60	250
	Focus Group-IC Review	81	1	10/60	14
	Focus Group	81	1	90/60	122

Dated: April 3, 2014.

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[FR Doc. 2014-07960 Filed 04/08/2014 at 8:45 am; Publication Date: 04/09/2014]