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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-day comment request

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

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health, has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the Federal Register on April 9, 2013, page 19633 and allowed 60-days for public comment. No comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute of Allergy and Infectious Diseases (NIAID), 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.

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, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: NIH Desk Officer.

COMMENT 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.

FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments, or request more information on the proposed project, contact: Lynda Lahl, RN, MS, Office for Policy in Clinical Research Operations, DAIDS, NIAID, 5601 Fishers Lane, 9B25, Rockville, MD 20852, or call non-toll-free number 240-292-

4887, 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.

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 470.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Frequency of Response	Average Time Per Response	Annual Hour Burden
DAIDS staff surveys IC review	Webpage Study Details and Informed Consent DAIDS Staff screenshots	100	1	5/60	8
DAIDS staff surveys	DAIDS Staff Survey screenshots	100	1	30/60	50
ER/ES- web surveys IC review	Webpage Study Details and Informed Consent for Extramural Researchers and External Stakeholders screenshots	400	1	5/60	33
ER/ES- web surveys	Extramural Researcher External Stakeholder Survey screenshots	400	1	30/60	200
DAIDS staff - web survey reminder	Reminder email to T2 web-survey participants	100	1	5/60	8
ER/ES- web survey reminder	Reminder email to T2 web-survey participants	400	1	5/60	33
DAIDS staff focus group IC review	DAIDS staff focus group consent form	18	1	10/60	3
ER/ES- focus group IC review	Extramural researcher external stakeholders focus group consent form	63	1	10/60	11
ER/ES- focus group	Incentive distribution log for focus group participants	63	1	2/60	2

DAIDS staff focus groups	Focus group opening script and questions	18	1	90/60	27
ER/ES- focus groups	Focus group opening script and questions	63	1	90/60	95
Totals		1162			470

Dated: September 12, 2014

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Dione Washington

Project Clearance Liaison, NIAID, NIH

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