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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-day comment request

The Clinical Trials Reporting Program (CTRP) Database (NCI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), 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 March 11, 2016 (Vol. 81, P. 12914) and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Cancer Institute (NCI), 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: Jose Galvez, MD, Office of the Director, National Cancer Institute, 9609 Medical Center Drive, Rockville, MD 20852 or call non-toll-free number

240-276-5206 or E-mail your request, including your address to: jose.galvez@nih.gov. Formal requests for additional plans and instruments must be requested in writing.

PROPOSED COLLECTION: The Clinical Trials Reporting Program (CTRP) Database (NCI), 0925-0600, Expiration Date 05/31/2016 —Revision, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The Clinical Trials Reporting Program (CTRP) is an electronic resource that serves as a single, definitive source of information about all NCI-supported clinical research. This resource allows the NCI to consolidate reporting, aggregate information and reduce redundant submissions. Information is submitted by clinical research administrators as designees of clinical investigators who conduct NCI-supported clinical research. The designees can electronically access the CTRP Web site to complete the initial trial registration. Subsequent to registration, four amendments and four study subject accrual updates occur per trial annually.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The estimated annualized burden hours are 18,000.

Estimated Annualized Burden Hours

Type of Respondents	Form	Number of Respondents	Number of Responses per Respondent	Average Time Per Response (in hours)	Total Annual Burden Hours
Clinical Trials	Initial Registration	3,000	1	1	3,000
	Amendment	1,500	4	1	6,000
	Update	1,500	4	1	6,000
	Accrual Updates	3,000	4	15/60	3000
Total		9,000	27,000		18,000

Dated: May 20, 2016

Karla Bailey

Project Clearance Liaison

National Cancer Institute, NIH

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