DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; Investigational Agent Accountability Record Forms in the Conduct of Investigational Trials for the Treatment of Cancer (National Cancer Institute)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

ADDRESSES: 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: Desk Officer for NIH.

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: Charles Hall, Chief, Pharmaceutical Management Branch, Cancer Therapy Evaluation Program, Division of Cancer Diagnosis and Treatment, National Cancer Institute, 9609 Medical Center Drive, Bethesda, Maryland 20892 or call non-toll-free number (240) 276–6575 or Email your request, including your address to: *HallCh@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on October 25, 2018 (83 FR 53885) and allowed 60 days for public comment. One public comment was 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.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection: Investigational Agent Accountability Record Forms in the Conduct of Investigational Trials for the Treatment of Cancer, 0925–0613, Expiration Date 3/31/2019, REVISION, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The U.S. Food and Drug Administration (FDA) holds the National Cancer Institute (NCI), Division of Cancer Treatment and Diagnosis/Cancer Therapy Evaluation Program (NCI/DCTD/CTEP) and the Division of Cancer Prevention (DCP) responsible, as a sponsor of investigational drug trials, to assure the FDA that systems for accountability are being maintained by investigators in its clinical trials program. Data obtained from the Investigational Agent Accountability Record Forms (aka. Drug Accountability Record Forms—DARF) are used to track the dispensing of investigational anticancer agents from receipt from the NCI to dispensing or administration to patients. Requirements for the tracking of investigational agents under an Investigational New Drug Application are outlined in Title 21 Code of Federal Regulations (CRF) part 312. NCI and/or its auditors use this information to ensure compliance with federal regulations and NCI policies. Previously, the investigator registration forms and process were part of this submission. These forms were more appropriately submitted and approved under the CTEP Branch and Support Contracts Forms and Surveys in July 2018 (OMB No. 0925–0753; Expiration Date 7/31/2021). Thus, the investigator registration forms are no longer included in this request.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden are 3,033 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Category of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hours
Individuals (DARF)	2,133	16	4/60	2,275
Individuals (DARF-Oral)	711	16	4/60	758
Total	2,844	45,504		3,033

Patricia M. Busche,

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[FR Doc. 2019–00447 Filed 1–30–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting 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.