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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-day Comment Request; Investigational Agent Accountability Record Forms and International Investigator Statement 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 requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, 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 E-mail your request, including your address to:

HallCh@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: written comments and/or suggestions from the public and affected agencies are invited to address 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 minimizes 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.

Proposed Collection Title: Investigational Agent Accountability Record Forms and International Investigator Statement in the Conduct of Investigational Trials for the Treatment of Cancer, 0925-0613, Expiration Date 3/31/2022, 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. Two additional forms have been added to this submission. The Electronic Agent Accountability Record Form Report (aka electronic Drug Accountability Record Form-eDARF) will be phased into use to replace two of the currently existing forms and will improve tracking and distribution of investigational agents. A second form, the International Investigator Statement (IIS), will ensure compliance of international investigators' participation on CTEP studies.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden are 4,831 hours.

Estimated Annualized Burden Hours

Form Name	Category of Respondent	Number of Respondents	Number of Responses per Respondent	Average Time per Response (in hours)	Total Annual Burden Hours
A1: Investigational Agent Accountability Record Form (DARF)	Individuals	760	20	4/60	1,013
A2: Investigational Agent Accountability Record for Oral Agents Form (DARF-Oral)	Individuals	2,280	20	4/60	3,040
A3: Electronic Agent Accountability Record Form (eDARF)	Individuals	760	20	1/60	253
A4: International Investigator Statement (IIS) (Initial Response)	Individuals	2,100	1	15/60	525
Totals		**5,900**	**78,100**		**4,831**

Dated: September 8, 2021.

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National Cancer Institute,

National Institutes of Health.

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