

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents>. Persons unable to download an electronic copy of “Dental Composite Resin Devices—Premarket Notification (510(k)) Submissions (document number GUI00016050)” or “Dental Curing Lights—Premarket Notification (510(k)) Submissions (document number GUI00016017)” may send an

email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While these guidances contain no new collection of information, they do

refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR part or guidance	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
812	Investigational Device Exemption	0910–0078
“Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program”.	Q-submissions and Early Payor Feedback Request Programs for Medical Devices.	0910–0756
800, 801, 809, and 830	Medical Device Labeling Regulations; Unique Device Identification.	0910–0485
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073
50, 56	Protection of Human Subjects and Institutional Review Boards	0910–0130

Dated: July 9, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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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 (NCI)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide an 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 Tali Johnson, 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: tmjohnson@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 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.

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

1/31/2025, REVISION, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information

Collection: This is a request for OMB to approve the revision of the collection titled “Investigational Agent Accountability Record Forms in the Conduct of Investigational Trials for the Treatment of Cancer National Cancer Institute (NCI)” for an additional three years of data 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 investigators in its clinical trials program are maintaining systems for accountability. 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 tracking investigational agents under an Investigational New Drug Application are outlined in title 21 Code of Federal Regulations (CFR) part 312. NCI and/or its auditors use this information to ensure compliance with federal regulations and NCI policies. This revision removes the International Investigator Statement (IIS) form as it was transitioned to the CTEP Branch and Support Contracts Forms and Surveys (OMB#0925–0753) submission.

OMB approval is requested for 3 years. There are no costs to respondents

other than their time. The total estimated annualized burden is 4,166 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	1,000	20	4/60	1,333
A2: Investigational Agent Accountability Record for Oral Agents Form (DARF-Oral).	Individuals	1,500	20	4/60	2,000
A3: Electronic Agent Accountability Record Form (eDARF).	Individuals	2,500	20	1/60	833
Totals	5,000	100,000	4,166

Dated: July 9, 2024.

Diane Kreinbrink,

Project Clearance Liaison, National Cancer Institute, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Joint Meeting of the National Advisory Councils

AGENCY: Substance Abuse and Mental Health Services Administration.

ACTION: Notice.

SUMMARY: Notice is hereby given of the combined (joint) meeting on August 28, 2024, of the Substance Abuse and Mental Health Services Administration's (SAMHSA) national advisory councils: the SAMHSA National Advisory Council (NAC), the Center for Mental Health Services NAC, the Center for Substance Abuse Prevention NAC, the Center for Substance Abuse Treatment NAC; and the two SAMHSA advisory committees: Advisory Committee for Women's Services (ACWS) and the Tribal Technical Advisory Committee (TTAC).

SUPPLEMENTARY INFORMATION: The meeting will include remarks from the Assistant Secretary for Mental Health and Substance Use; follow up from the JNAC meeting of February 28, 2024; updates from the individual council meetings of August 27, 2024; presentations and discussions on the following topics: Youth Engagement Efforts, Criminal Justice, Suicide Prevention, general Council discussion and Public Comments.

The meeting is open to the public and will be held at the Hubert H. Humphrey Building, 200 Independence Ave. SW, Washington, DC 20201, Room 505A.

Attendance by the public will be limited to space availability. Interested persons may present data, information, or views orally or in writing, on issues pending before the Council. Written submissions should be forwarded to the contact person by August 21, 2024. Oral presentations from the public will be scheduled at the conclusion of the meeting. Individuals interested in making oral presentations must notify the contact by August 21, 2024. Up to three minutes will be allotted for each presentation, as time permits.

The meeting may be accessed via telephone and remotely via Zoom platform and callers must register. To attend on site, obtain the call-in number, access code, and/or web access link; submit written or brief oral comments; or request special accommodations for persons with disabilities, please register on-line at: <https://snacregister.samhsa.gov>, or communicate with SAMHSA's Committee Management Officer, Carlos Castillo (see contact information below).

Meeting agenda with call-in information will be posted before the meeting, and additional information may be obtained by accessing the SAMHSA advisory councils web page: <https://www.samhsa.gov/about-us/advisory-councils>.

Council Names:

Substance Abuse and Mental Health Services Administration National Advisory Council
Center for Mental Health Services National Advisory Council
Center for Substance Abuse Prevention National Advisory Council
Center for Substance Abuse Treatment National Advisory Council
Advisory Committee for Women's Services
Tribal Technical Advisory Committee

Date/Time/Type: August 28, 2024, 9:00 a.m. to 4:30 p.m. EDT, Open.

Place: 200 Independence Ave. SW, Washington, DC 20201, Room 505A.

Contact: Carlos Castillo, Committee Management Officer, 5600 Fishers Lane, Rockville, Maryland 20857 (mail), Telephone: (240) 276-2787, Email: carlos.castillo@samhsa.hhs.gov.

SAMHSA's National Advisory Councils were established to advise the Secretary, Department of Health and Human Services (HHS); the Assistant Secretary for Mental Health and Substance Use, SAMHSA; and SAMHSA's Center Directors concerning matters relating to the activities carried out by and through the Centers and the policies respecting such activities.

Under section 501 of the Public Health Service Act, the ACWS is statutorily mandated to advise the SAMHSA Assistant Secretary for Mental Health and Substance Use and the Associate Administrator for Women's Services on appropriate activities to be undertaken by SAMHSA and its Centers with respect to women's substance abuse and mental health services.

Pursuant to Presidential Executive Order No. 13175, November 6, 2000, and the Presidential Memorandum of September 23, 2004, SAMHSA established the TTAC for working with Federally recognized Tribes to enhance the government-to-government relationship, and honor Federal trust responsibilities and obligations to Tribes and American Indian and Alaska Natives. The SAMHSA TTAC serves as an advisory body to SAMHSA.

Authority: Public Law 92-463.

Dated: July 8, 2024.

Carlos Castillo,

Committee Management Officer, SAMHSA.

[FR Doc. 2024-15311 Filed 7-11-24; 8:45 am]

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