This technology describes modified T cell therapeutics that have reduced expression of one or a combination of transmembrane adaptor proteins SIT1, LAX1 and TRAT1. T cell-based therapeutics such as ex vivo expanded tumor infiltrating lymphocytes (TIL) and chimeric antigen receptor T-cells (CAR–T) have clinical utility against a limited number of solid tumor types, most notably, melanoma. However, to date, efficacy in patients has been limited due to several factors. The subject invention potentially addresses the limited efficacy of T cell therapeutics by reducing expression of SIT1, LAX1 and/or TRAT1 which leads to enhanced T cell cytotoxic activity against tumor cells.

This Notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute, representing the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Complete applications for a license that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent license. In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: December 18, 2025.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2025–23691 Filed 12–22–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; the Clinical Trials Reporting Program (CTRP) Database (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 Melissa Park, PRA Liaison, Office of Management Policy and Compliance, National Cancer Institute, 9609 Medical Center Drive, Room 2E196, Bethesda, MD 20892 or call non-toll-free number (240) 276–5717 or email your request, including your address to: *melissa.park@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: The Clinical Trials Reporting Program (CTRP) Database, 0925–0600, Expiration Date 02/28/2026–REVISION, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The Clinical Trials Reporting Program (CTRP) Database 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 website 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

Form name	Type of respondents	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hours
Initial Registration	Individuals	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	3,000
Totals		9,000	27,000		18,000

Dated: December 19, 2025.

Melissa Park,

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

[FR Doc. 2025–23713 Filed 12–22–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer at (240) 276–0361.

Project: Mandatory Guidelines for Federal Workplace Drug Testing Programs Federal Drug Testing Custody and Control Form (CCF) (OMB No. 0930–0158) and National Laboratory Certification Program (NLCP) Information Collection Tools—Revision

SAMHSA will request OMB approval for revision of the Federal Drug Testing Custody and Control Form (CCF) for federal agency and federally regulated drug testing programs which must comply with the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG) dated October 12, 2023 (88 FR 70768) and using Oral Fluid (OFMG) dated October 12, 2023 (88 FR 70814), and OMB approval for information provided by test facilities (laboratories and Instrumented Initial Test Facilities, IITFs) for the National Laboratory Certification Program (NLCP).

The CCF is used by all federal agencies and by employers regulated by the Department of Transportation (DOT) and the Nuclear Regulatory Commission (NRC) to document the collection and chain of custody of a urine or oral fluid specimen at the collection site, for HHS-certified test facilities to document chain of custody and report results, and for Medical Review Officers (MROs) to document and report a verified result. SAMHSA allows the use of the CCF as a paper or electronic form.

The current OMB-approved CCF has an August 31, 2026 expiration date. SAMHSA has resubmitted the CCF with revisions to the form for OMB approval. During 60-day public comment, 7 commenters submitted comments on the proposed changes to the CCF. Commenters were comprised of individuals, organizations, and private sector companies. All comments were reviewed and taken into consideration in preparation of the revised CCF. The issues and concerns raised in the public comments are set out at *www.reginfo.gov/public/do/PRAMain.*

The revisions are listed below:

Copies 1–5

Revised Step 1

1. Removed drug analytes and checkboxes from Item F and changed ''Drug Tests to be Performed'' to ''Other tests to be performed (specify):''.

Copy 1

Revised Step 4

1. Moved the ''Split Specimen Device Expiration Date'' field to the right.

Copies 2–5

Revised Step 5

1. Lengthened the email address line and moved it to the right.

2. Replaced the 2 date fields for ''Daytime Phone No.'' and ''Evening Phone No.'' with a single field ''Phone No.'' and moved it to the left.

3. Moved the ''Date of Birth'' field to the left, reworded as ''Birthdate'' and moved the text under the line.

Laboratories and IITFs seeking HHS certification under the NLCP must complete and submit the NLCP application form. The NLCP application form has been updated in accordance with the current UrMG and OFMG. The revisions enable provision of information for analytes in the Authorized Testing Panels now published separately from the Mandatory Guidelines, and enable applicant test facilities to submit information on new technologies/instruments.

Prior to an inspection, an HHS-certified laboratory or IITF is required to submit specific information regarding its procedures. Collecting this information prior to an inspection allows the inspectors to thoroughly review and understand the testing procedures before arriving for the onsite inspection. The NLCP information checklist has been updated in accordance with the current UrMG and OFMG. The revisions enable provision of information for analytes in the Authorized Testing Panels now published separately from the Mandatory Guidelines, and enable certified test facilities to submit information on new technologies/instruments.

The annual total burden estimates for the CCF, the NLCP application, the NLCP information checklist, and the NLCP recordkeeping requirements are shown in the following table.

Form/respondent	Number of respondents	Responses per respondent	Total number of responses	Burden per response (hours)	Annual burden (hours)	Hourly wage rate ($)	Total cost ($) [3]
Custody and Control Form: [1]							
Donor	6,726,610	1	6,726,610	0.08	538,129	25	13,453,225
Collector	6,726,610	1	6,726,610	0.07	470,683	15	7,060,245
Laboratory	6,726,610	1	6,726,610	0.05	336,331	35	11,771,585
IITF	1	0	0	0.05	0	35	0
Medical Review Officer	6,726,610	1	6,726,610	0.05	336,331	150	50,449,650
NLCP Application Form: [2]							
Laboratory	20	1	20	3	60	35	2,100
IITF	0	0	0	3	0	35	0
Sections B and C—NLCP Information Checklist:							
Laboratory	19	1	19	1	19	35	665
IITF	1	1	1	1	1	35	35
Record Keeping:							
Laboratory	19	1	19	250	4,750	35	166,250
IITF	0	0	0	250	0	35	0