



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request

Information Program on Clinical Trials: Maintaining a Registry and Results

Databank (National Library of Medicine)

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 recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

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: Vivian Le, Office of Administration, National Library of Medicine, 8600 Rockville Pike, Building 38A, 4N401Q5, Bethesda, Maryland, 20894 or call non-toll-free number 301-827-6328 or E-mail your request, including your address to: vivian.le@nih.gov.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the *Federal Register* on November 26, 2025, page 54340 (90 FR 54340) 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 Library of Medicine (NLM), 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: Information Program on Clinical Trials: Maintaining a Registry and Results Databank, 0925-0586, Expiration Date 03/31/2026, Revision, National Library of Medicine (NLM), National Institutes of Health (NIH).

Need and Use of Information Collection: The National Institutes of Health operates ClinicalTrials.gov, which was established as a clinical trial registry under section 113 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) and was expanded to include a results data bank by Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) and by the Clinical Trials Registration and Results Information Submission regulations at 42 CFR Part 11. ClinicalTrials.gov collects registration and results information for clinical trials and other types of clinical studies (e.g., observational studies and patient registries) with the objectives of enhancing patient enrollment and providing a mechanism for tracking subsequent progress of clinical studies to the benefit of public health. It is widely used by patients, physicians, and medical researchers; in particular those involved in clinical research. While many clinical studies are registered and results information submitted voluntarily, 42 CFR Part 11 requires the registration and submission of results information for certain applicable clinical trials of drug, biological, and device products

whether or not they are approved, licensed, or cleared by the Food and Drug Administration.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 1,411,181.

Estimated Annualized Burden Hours

Submission Type	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hour
Registration - Attachment 2				
Initial	7,400	1	8	59,200
Updates	7,400	8	2	118,400
Triggered, voluntary	182	1	8	1,456
Initial, non-regulated, NIH Policy	1,200	1	8	9,600
Updates, non-regulated, NIH Policy	1,200	8	2	19,200
Initial, voluntary and non-regulated	23,130	1	8	185,040
Updates, voluntary and non-regulated	23,130	8	2	370,080
Results Information Submission - Attachment 5				
Initial	7,400	1	40	296,000
Updates	7,400	2	10	148,000
Triggered, voluntary – also attachment 2	61	1	45	2,745
Initial, non-regulated, NIH Policy	1,200	1	40	48,000
Updates, non-regulated, NIH Policy	1,200	2	10	24,000
Initial, voluntary and non-regulated	2,100	1	40	84,000
Updates, voluntary and non-regulated	2,100	2	10	42,000
Other				
Certification to delay results - attachment 6	5,150	1	30/60	2,575

Extension requests and Appeals - attachment 7	175	1	2	350
Initial, expanded access - attachment 3	213	1	2	426
Updates, expanded access - attachment 3	213	2	15/60	107
Waiver requests and appeals – attachment 10	1	1	2	2
Total		323,878		1,411,181

Vivian K. Le,

Project Clearance Liaison,

National Library of Medicine,

National Institutes of Health.

[FR Doc. 2026-03222 Filed: 2/18/2026 8:45 am; Publication Date: 2/19/2026]