



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### **Proposed Collection; 60-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 requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Library of Medicine (NLM), National Institutes of Health (NIH) 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: 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](mailto:vivian.le@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:* Information Program on Clinical Trials: Maintaining a Registry and Results Databank, 0925-0586, Expiration Date: 03/31/2026, Extension, 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 submit results information voluntarily, 42 CFR Part 11 requires the registration of certain applicable clinical trials of drug, biological, and device products and the submission of results information for completed 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

<b>Submission Type</b>	<b>Number of Respondents</b>	<b>Number of Responses per Respondent</b>	<b>Average Burden Per Response (in hours)</b>	<b>Total Annual Burden Hour</b>
<b>Registration - Attachment 2</b>				
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
<b>Results Information Submission - Attachment 5</b>				
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
<b>Other</b>				
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	1	1	2	2
<b>Total</b>		<b>323,878</b>		<b>1,411,181</b>

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