Billing Code 4140-01-P

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/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: Desk Officer for NIH.

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: David Sharlip, Office of Administrative and Management Analysis Services, National Library of Medicine, Building 38A, Room B2N12, 8600 Rockville Pike, Bethesda, MD 20894, or call non-toll-free number (301) 827-6361, or E-mail your request, including

your address to: sharlipd@mail.nih.gov.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the Federal Register on November 19, 2019, pages 63884-5 (84 FR 63884) 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 02/29/2020—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 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 1,072,306.

Estimated Annualized Burden Hours

Submission Type	**Number of respondents**	**Number of responses per respondent**	**Average time per response (in hours)**	**Total annual burden hours**
Registration – attachment 2				
Initial	7,400	1	8	59,200
Updates	7,400	8	2	118,400
Triggered, voluntary	88	1	8	704
Initial, non-regulated, NIH Policy	657	1	8	5,256
Updates, non-regulated, NIH Policy	657	8	2	10,512
Initial, voluntary and non-regulated	11,244	1	8	89,952
Updates, voluntary and non-regulated	11,244	8	2	179,904
Results Information Submission – attachment 5				
Initial	7,400	1	40	296,000
Updates	7,400	2	10	148,000
Triggered, voluntary – also attachment 2	30	1	45	1,350

Initial, non-regulated, NIH Policy	657	1	40	26,280
Updates, non-regulated, NIH Policy	657	2	10	13,140
Initial, voluntary and non-regulated	2,000	1	40	80,000
Updates, voluntary and non-regulated	2,000	2	10	40,000
Other				
Certification to delay results – attachment 6	5,150	1	30/60	2,575
Extension request – attachment 7	250	1	2	500
Initial, expanded access – attachment 3	213	1	2	426
Updates, expanded access – attachment 3	213	2	15/60	107
Total	**64,660**	**210,037**		**1,072,306**

Dated: January 21, 2020.

David H. Sharlip,

Project Clearance Liaison,

National Library of Medicine,

National Institutes of Health.

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