



[BILLING CODE 4140-01-P]

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  
(NLM)

**SUMMARY:** In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for 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. This summary describes the existing information collection at ClinicalTrials.gov, for which an extension is requested; it does not include any changes to the information collection that were proposed in the Notice of Proposed Rulemaking on Clinical Trial Registration and Results Submission that was issued on November 21, 2014 (79 FR 225, Nov. 21, 2014).

Written comments and/or suggestions from the public and affected agencies are invited on 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.

**TO SUBMIT COMMENTS AND FOR FURTHER INFORMATION:** To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, 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) 402-9680, or E-mail your request, including your address to: sharlipd@mail.nih.gov  
Formal requests for additional plans and instruments must be requested in writing.

**COMMENT DUE DATE:** Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

**PROPOSED COLLECTION:** Information Program on Clinical Trials: Maintaining a Registry and Results Databank (NLM), 0925-0586, Expiration Date: 08/31/2015,  
**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). 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, FDAAA requires the registration of certain applicable clinical trials of drugs and devices and the submission of results information for completed applicable clinical trials of drugs and devices that are approved, licensed, or cleared by the Food and Drug Administration. Beginning in 2009, results information was required to include information about serious and frequent adverse events.

This extension request does not include any changes to the information submission requirements for ClinicalTrials.gov that were proposed in the Notice of Proposed Rulemaking on Clinical Trial Registration and Results Submission that was issued on November 21, 2014 and for which the public comment period closed on March 23, 2015 (79 FR 225, Nov. 21, 2014). The NIH is continuing to review submitted public comments as it prepares the final rule. The NIH will make any corresponding changes to the ClinicalTrials.gov information collection via separate procedure.

OMB approval is requested for 3 years. The total estimated annualized cost to

respondents is \$49,399,851. The total estimated annualized burden hours are 682,535.

### Estimated Annualized Burden Hours

<b>Submission Type</b>	<b>Number of Respondents</b>	<b>Number of Response per Respondent</b>	<b>Average Time per Response</b>	<b>Annual Hour Burden</b>
PRS Account	5,700	1	15/60	1,425
<i>Initial Registration</i>	<i>23,000</i>	<i>1</i>	<i>7</i>	<i>161,000</i>
<i>Updates</i>	<i>23,000</i>	<i>8</i>	<i>2</i>	<i>368,000</i>
<i>Initial Results</i>	<i>3,700</i>	<i>1</i>	<i>25</i>	<i>92,500</i>
<i>Updates</i>	<i>3,700</i>	<i>2</i>	<i>8</i>	<i>59,200</i>
<i>Certification to Delay Results</i>	<i>700</i>	<i>1</i>	<i>30/60</i>	<i>350</i>
<i>Extension Request</i>	<i>30</i>	<i>1</i>	<i>2</i>	<i>60</i>
<b>Total</b>	<b>33,130</b>			<b>682,535</b>

Dated: June 4, 2015.

David Sharlip,

Project Clearance Liaison,

NLM, NIH.

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