



BILLING CODE 4167-05-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 30-Day Comment Request

NIH Information Collection Forms to Support the Genetic Testing Registry (OD)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institutes of Health Office of the Director (OD) 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 by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

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 obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Ellen Wann, Acting Director, Division

of Scientific Data Sharing Policy, Office of Science Policy, Office of the Director, NIH, 6705 Rockledge Dr., Suite 631, Bethesda, MD 20892, non-toll-free number (301) 496-9838; *SciencePolicy@mail.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 from 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: NIH Information Collection Forms to Support the Genetic Testing Registry - 0925-0651 – Expiration Date January 31, 2025 - REINSTATEMENT WITHOUT CHANGE – Office of the Director (OD), National Institutes of Health (NIH).

Need and Use of Information Collection:

Clinical laboratory tests are available for more than 18,000 genetic conditions. The Genetic Testing Registry (GTR) provides a centralized, online location for test developers, manufacturers, and researchers to voluntarily submit detailed information about the availability and scientific basis of their genetic tests. The GTR is of value to

clinicians by providing information about the accuracy, validity, and usefulness of genetic tests. The GTR also highlights evidence gaps where additional research is needed. The GTR also has tests for microbes like for SARS-CoV-2 to diagnose COVID-19. OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 5,217 hours.

Estimated Annualized Burden Hours

Type of Respondent	Type of Form	Estimated Annual Number of Respondents	Number of Responses per Respondent	Average Time per Response (in hours)	Total Annual Burden Hours
Laboratory Personnel Using Bulk Submission (new tests)	Minimal Fields	16	67	18/60	322
	Optional Fields	16	67	17/60	304
Laboratory Personnel Not Using Bulk Submission (new tests)	Minimal Fields	51	67	30/60	1,709
	Optional Fields	47	67	29/60	1,522
Laboratory Personnel (updated tests)	Annual Review	340	24	10/60	1,360
Total		470	16, 870	-	5,217

Dated: June 25, 2026.

Matthew J. Memoli,

Principal Deputy Director,

National Institutes of Health.

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