Supporting Statement A for:

NIH Information Collection Forms to Support the Genetic Testing Registry (Office of the Director)

OMB Control Number 0925-0651 Expiration Date: January 31, 2025

Date: April 28, 2026

Check off which applies:

☐ New
☐ Revision
☐ Reinstatement with Change
■ Reinstatement without Change
☐ Extension
☐ Emergency
☐ Existing

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A. ABSTRACT

This application is to reinstate, without change, an Office of Management and Budget (OMB) approved collection of information, 0925-0651. The purpose of the reinstatement is to continue the National Institutes of Health (NIH) Genetic Testing Registry (GTR), a public database that health care providers, researchers, and others can search for information submitted voluntarily by genetic test providers. The GTR aims to enhance access to information about the availability and scientific basis of molecular, cytogenetic and biochemical clinical and research genetic tests. In 2020, to support efforts to mitigate the impact of the COVID-19 pandemic, GTR expanded its scope to include molecular and serologic tests for SARS-CoV-2 that causes COVID-19.

The National Center for Biotechnology Information (NCBI), part of the National Library of Medicine at NIH, is responsible for developing and maintaining the GTR, which became publicly available February 29, 2012 (OMB No. 0925-0651; expires January 31, 2025).

NCBI is considered a suitable developer of the GTR because of its experience in building databases of genetic and medical information and its ability to integrate the information with other data, greatly enhancing the GTR's utility for medical professionals and researchers. The GTR is also integrated with other relevant NIH databases to assist these user groups. NIH is, therefore, a natural home for the GTR because of its role in advancing public health through science and its strong expertise in developing databases.

A.1 Circumstances Making the Collection of Information Necessary

The collection of information activities of the GTR set forth herein are conducted under the authorities granted in Section 465 of the Public Health Service Act, 42 U.S.C. 286; and Section 301 of the Public Health Service Act, 42 U.S.C. 241.

Scientific advances have expanded our understanding of the genomic and genetic factors involved in health and disease. This increased knowledge has been accompanied by the development of new technologies and a rise in the number and complexity of genetic tests. Laboratory tests for more than 26,000 genetic phenotypes and 18,000 genes are now available in the GTR. The GTR is the only unbiased, non-commercial, comprehensive public resource that provides detailed information on and about the scientific basis of these tests. Calls for greater transparency of genetic testing through a registry have come from a number of quarters, including the Secretary's Advisory Committee on Genetics, Health, and

Society, which advised the Secretary of Health and Human Services from 2003 to 2011, and the Genetic Alliance, a health advocacy organization.

To address the information gap about genetic tests, NIH developed the GTR, a publicly accessible online resource that provides a centralized location for genetic test developers to submit information voluntarily about genetic tests, including newer types of tests such as exome and pharmacogenomic tests. Enhancing access to detailed test information is important to enable informed decision-making by health care providers and to facilitate research. The GTR may also be of value to other groups such as clinical laboratory professionals, payers, policymakers, regulators and researchers.

A.2 Purpose and Use of the Information Collection

The purpose of the GTR is to provide detailed information about the availability and scientific basis of genetic tests in a centralized resource as well as to facilitate data sharing for research and new scientific discoveries. Participation in the GTR is voluntary, but if a laboratory chooses to participate, it must complete a certain set of data fields (called the "minimal fields"). Information is submitted electronically at the website https://submit.ncbi.nlm.nih.gov/subs/gtr. For details of the information collection, see the Attachment that accompanies this Supporting Statement.

Over the 3-year period of collection, the GTR has provided information about clinical and research tests for heritable variants, biochemical and pharmacogenomic tests, tests for somatic variants, and tests for chromosomal aberrations and copy number variants as well as information about the laboratory offering the test, such as contact information and credentials of the laboratory (e.g., certification and licensure). Test information includes the purpose of the test and its limitations, whether it is a clinical or research test, the test methodology and analytes that are interrogated, performance characteristics such as analytic validity and clinical validity, information on clinical utility, and whether manufactured tests have been cleared or approved by the Food and Drug Administration.

The GTR is of value to clinicians by providing information about the availability, accuracy, validity, and usefulness of genetic tests. Furthermore, the GTR highlights evidence gaps where additional research is needed to understand the clinical validity and utility of genetic tests. The inclusion of clinical validity and utility data in the GTR is of value to public and private payers. In addition, the GTR may facilitate collaborations such as laboratory participation in quality assurance exchanges.

A.3 Use of Information Technology and Burden Reduction

The GTR utilizes the latest software and internet technologies for registration and search functions and provides a range of tools to simplify and speed the process of registering tests. The GTR data entry system (manual wizard) has been designed to minimize burden to registrants with a submission user interface augmented by extensive use of pull-down menus and scrolling menus to populate fields, "find as you type" (or "type ahead") functionality, and text fields for those components where submitters might want to cut-and-paste information from their websites and other sources. Where possible, fields are automatically populated for the submitter; for instance, once a submitter fills out the condition for which a test is used, several related fields (e.g., disease identifiers, synonyms, acronyms and disease types) are autopopulated. In addition, a copy function is available to expedite data entry for tests that differ from already submitted tests by just a few data fields (e.g., test order code, test name). Submitters have the opportunity to modify any field that is copied from another test. The copy function is particularly helpful for entering tests based on similar platforms, genes, or conditions.

The GTR also supports mechanisms for the bulk submission of data, which significantly reduces the burden for laboratories that want to provide information on multiple genetic tests. The GTR supports submission via an application programming interface (API), tests can be added, edited or deleted automatically via the API. Submitters can also manage their data via two spreadsheet options: a minimal fields file that has the required test fields and a small number of recommended fields; and a file that incorporates all available data fields. Data submitted via spreadsheets can also be reviewed and updated through the submission user interface.

The GTR has a feature called "Bulk edits" where data submitters in the submission wizard can manually edit a set of fields whose content is the same across a customized set of existing tests. More specifically, in the submission portal, a submitter can select a set of tests and update the content for a set of fields all at once.

The GTR employs a Standard Operating Procedure (SOP) for Resolution of Complaints about Information Submitted to the GTR. The SOP has been tested on two cases, thus far. The GTR enables users to submit complaints, such as breaches of the GTR Code of Conduct,[1] through the "Contact us and provide feedback" link on the GTR homepage.[2] This link opens an email to the GTR team where the user can report information that appears to be inaccurate or misleading and to submit other

[1] Code of Conduct for submitters to the Genetic Testing Registry: http://www.ncbi.nlm.nih.gov/gtr/docs/code/.
[2] Genetic Testing Registry homepage: http://www.ncbi.nlm.nih.gov/gtr/.

comments or questions on the content of the registry. The GTR staff begin working on the complaint within 24 hours. The GTR staff will evaluate and address complaints directly with the data submitter if what is needed is correcting typographical errors or incorrect URLs. For complaints related to the GTR Code of Conduct, the GTR staff will inform the content submitter about the complaint and seek a timely resolution of the matter (e.g., a satisfactory explanation about why the complaint is without foundation or an agreement that the submitter's GTR record will be corrected). More complex cases may need consulting with experts.

A.4 Efforts to Identify Duplication and Use of Similar Information

The GTR is unique because it is unbiased, free to participate in and use, and provides comprehensive public test descriptions like a test's analytical validity. The GTR has a broad range of molecular, cytogenetic and biochemical genetic tests for inherited and somatic variants, pharmacogenomic phenotypes, complex diseases and molecular and serologic microbe tests including pathogen-specific genetic tests; panels to identify pathogens; tests that assess viral load; serologic tests for detection of antibodies and antigens to determine prior exposure. Test providers are able to submit detailed information about these tests.

However, there is another resource that provides limited information for a subset of genetic tests: Concert Genetics (https://www.concert.co/). It is a commercially-funded resource that provides basic test and laboratory information largely gathered from the internet, along with information about price and turn-around time, and the option to order tests through the website.

Another source of duplication and use of similar information is the fact that some GTR data elements, for example analytical validity, are required by the Centers for Medicare & Medicaid Services (CMS) for Clinical Laboratory Improvement Amendments (CLIA) certification and by the Food and Drug Administration (FDA) for the premarket review of manufactured test kits. NIH consults with these agencies on an ongoing basis to minimize reporting burden.

A.5 Impact on Small Businesses or Other Small Entities

The GTR is anticipated to have a minor impact on small businesses. The minimal data that must be submitted to register a clinically available genetic test is similar to existing requirements for CLIA certification, certification by the College of American Pathologists, or other types of certifications or licensure. Thus, much of the information to be submitted to the GTR will have already been compiled by the submitter, significantly reducing the additional burden of this information

collection. Technological tools such as bulk data uploads, copy functions and bulk edits of existing tests (further explained in Section A.3) will also reduce the burden.

The GTR has 31 minimal data fields (which must be completed to register a clinical test in GTR) and 89 optional fields (available for completion at the submitter's discretion). Nineteen of the minimal fields, which consist of contact information for the submitting laboratory and associated staff, are submitted only once. For research tests, the minimal dataset for registration is smaller than for clinically available tests with 12 minimal fields and 36 optional fields.

A.6 Consequences of Collecting the Information Less Frequently

Submitters will provide information on a non-repeating, continual basis, which means they will register a test once and can add new tests on a continual basis. NCBI requests that submitters review their test information at least once every 12 months and update the information as needed or remove the test from GTR if it is no longer offered. Less frequent updating could result in misinformation about genetic tests that compromises the GTR's utility as a resource to enable informed decision-making by health care providers. NCBI removes out-of-date test information from the GTR if submitters fail to review it annually.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This collection fully complies with 5 CFR 1320.5.

A.8.1 Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

The 60-Day Federal Register notice was published on January 22, 2026 (91 FR 2788). No comments were received.

A.8.2. Efforts to Consult Outside Agency

Not applicable at this time.

A.9 Explanation of Any Payment or Gift to Respondents

No gifts or payments are to be offered in regard to this information collection.

A.10 Applicability of the Privacy Act and Privacy Memo

The Privacy Act applies to this collection because GTR is collecting Personally Identifiable Information (PII) including the laboratory's point of contact's credentials, name, email address, phone number, and mailing address. The PII is collected, maintained, or shared within the GTR. Information submitted to the GTR is made available to the public via a website operated and maintained by NIH at http://www.ncbi.nlm.nih.gov/gtr/. However, submitters have the option not to display credentials of personnel or the exact street address of the laboratory. A completed Privacy Impact Assessment is attached (Attachment 1).

A System of Records Notice (SORN), 09-25-0200, Clinical, Basic, and Population-based Research Studies of the National Institutes of Health (NIH) covers this collection and use of the PII as stated in the Privacy Act Memo (Attachment 2).

A.11 Justification for Sensitive Questions

No questions of a sensitive nature are included in this data collection.

A.12 Estimates of Annualized Burden Hours and Costs

Although participation in the GTR is voluntary, to participate, the submitter must provide information for a certain subset of data fields, identified as the "minimal fields" and has the option to add additional information in the "optional fields" (Attachment 3, beginning on page 7). The GTR submitters are also expected to review the submitted tests annually. The GTR clinical test record forms include 31 minimal fields and 89 optional fields. Table 12-1 provides estimated burden hours to submit information for the minimal fields, optional fields, and that annual review.

NIH used current GTR registration data to estimate the annual number of respondents (also referred to as laboratories in this document). As of November 6, 2024, 404 laboratories are active in GTR, 340 of these laboratories maintain 68,687 test submissions and 64 laboratories have not submitted clinical tests. Using data from 2022 to 2024, the average annualized number of new tests submitted per laboratory is 67, on average 16 respondents submitted new test data using bulk submissions and provided minimal fields and optional fields (all new tests submitted in bulk had at least 1 optional field). The average number of respondents that submitted new tests not using bulk submission and provided minimal fields were 51 and 47 respondents provided optional fields. There were 340 laboratories with tests in GTR and the annualized number of tests updated per laboratory is 24.

Based on simulated trials of entering test information in the GTR, NIH projected that it would take submitters an average of 0.5 hours (30/60 minutes) to provide

test information for the minimal fields. Nineteen of the 31 minimal fields request laboratory data and contact information, which the submitter completes only once. These data auto-populate new test records, leaving 12 minimal fields that require completion. NIH estimated that it would take submitters 2.5 hours to provide information for all 89 optional fields. Of the 404 registered laboratories, 340 completed 1 or more optional fields, and on average, 17 optional fields were completed per test. The estimated average time to complete 17 optional fields is 0.48 hour (29/60 minutes).[3]

The estimated hour burdens reflect the average time for submitters who are familiar with their tests and know where to find test information. It is assumed that test submitters will have already gathered much of the information requested for these data fields as part of laboratory certification and licensure. Submitters will likely become more efficient in data entry as they gain experience with the GTR. In addition, the GTR provides some time-saving features. For example, a copy (clone) function is available to expedite entry for tests that differ by just a few data fields (e.g., test order code, test name), which is especially helpful for entering tests based on a similar platform. Submitters can modify any of the copied data.

The GTR also has mechanisms for the bulk submission of data, which significantly reduces the burden for laboratories that want to provide information on multiple genetic tests (Attachment 3, page 50). The GTR supports bulk submission from spreadsheets and API. The expectation is that large laboratories will have their tests already stored electronically and will have the computational support to use bulk submission to the GTR. In practice, the observed proportion of tests submitted using bulk submission is 46 percent. NIH estimated that bulk submission reduces burden by 40 percent. Therefore, completion of minimal fields by bulk submission is estimated to take 0.3 hours (18/60 minutes) instead of 0.5 hours (30/60 minutes), and completion of 17 optional fields by bulk is estimated to take 0.28 hours (17/60 minutes) rather than 0.48 hours (29/60 minutes). Taking into consideration the proportion of new tests submitted individually versus bulk submission, the total annual hour burden to complete minimal and an average of 17 optional fields is 3,857 hours.

The GTR implemented the Annual Review which is the requirement that, once a year, respondents review their information and confirm their data is current (Attachment 3, page 48). The goal is to provide access to current and accurate test information. Test data in the GTR can be updated at any time. Existing test records can be edited, and the relevant fields updated. Records can be updated using the manual wizard, in bulk via spreadsheet or by using a feature to edit a set of fields for a customized set of existing tests (bulk edits). The average time to update 1 field

[3] Estimated average time to complete 6 optional fields: (2.5/89) = (x/17) =0.48 hr. or 10 minutes

per test is 3 mins (3/60 hours). The average time to submit the annual review form is 1 minute (1/60 hours). The annualized number of tests updated per laboratory is 24 and the average number of fields updated per test is 3. The average time to update 3 fields is 9 mins plus 1 minute to submit the annual review, so a total of 10 mins (10/60 hours). The total annual hour burden to update tests and complete the Annual Review is 1,360.

Table 12-1 Estimates of Hour Burden

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

To estimate the annualized cost to respondents, NIH used the mean hourly wage of a genetic counselor from the National Society of Genetic Counselors 2024 Professional Status Survey: Salary & Benefits.[4] Table 12-2 provides the estimated annualized cost for respondents. Based on a mean hourly wage of $51.13, the total estimated cost for all respondents is $266,745. Laboratories can reduce costs by using time-saving features such as the copy function and bulk upload feature.

[4] National Society of Genetic Counselors. (2024) 2024 Professional Status Survey. https://www.nsgc.org/Policy-Research-and-Publications/Professional-Status-Survey.

Table 12-2 Annualized Cost to Respondents

Type of Respondent	Type of Form	Total Annual Burden Hours	Hourly Wage Rate	Respondent Cost
Laboratory Personnel Using Bulk Submission	Minimal Fields	322	$51.13	$16,464
	Optional Fields	304	$51.13	$15,543
Laboratory Personnel Not Using Bulk Submission	Minimal Fields	1,709	$51.13	$87,381
	Optional Fields	1,522	$51.13	$77,820
Laboratory Personnel	Annual Review	1,360	$51.13	$69,537
Total		5217	-	$266,745

A.13 Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There is no capital costs associated with this collection.

A.14 Annualized Cost to the Federal Government

The estimated annualized cost to the Federal Government to support this information collection is $2,138,647, which is comprised of program personnel costs and hardware/software/information technology (IT) costs associated with project's implementation and operation. The estimated personnel cost is $1,588,647, based on 7.4 employees (Federal and contractor staff) at an average annual rate of $211,450 and $218,924 respectively, (salary and benefits). The estimated cost of computer hardware, software and IT is $550,000.

Table 14-1 Annualized Cost to the Federal Government

Cost Descriptions	Grade/ Step	Salary	% of Effort FTE equiv	Fringe (if applicable)	Total Cost to Gov't

NIH Content Team Lead [Staff Scientist]	AD-00	$211,450	1.0		$211,450
NIH Content Specialist [Staff Scientist]	AD-00	$211,450	1.0		$211,450
NIH Data Specialist [Staff Scientist]	AD-00	$211,450	0.2		$42,290
NIH Software Developer [Staff Scientist]	AD-00	$211,450	2.0		$422,900
Contractor Technical Lead		$218,924	0.4		$87,570
Contractor Content Specialist		$218,924	1		$218,924
Contractor Software Developer		$218,924	1.2		$262,709
Contractor Project Manager		$218,924	0.3		$65,677
Contractor Product Manager		$218,924	0.3		$65,677
Travel					
Other Cost					
Computer Hardware and Software					$550,000
Total					$2,138,647

A.15 Explanation for Program Changes or Adjustments

NIH is requesting a reinstatement without change of the information collection approval. There are no program changes; burden estimates were adjusted based on actual GTR registration data over 12 years. Total annual burden hours have increased to 5,217 from 2,299 in 2021. This is largely due to the fact that we are now including calculations of the burden of performing the annual review which ensures that data in GTR is current and accurate. The increase is also due to an increase in new test submissions, update to existing test records, and the fact that the majority of current users are updating data manually. The estimated annualized cost to the Federal Government to support this information collection increased to $2,138,647 from $566,250 in 2021. This is because of the increase in percentage of effort for FTE equivalent in the collection.

A.16 Plans for Tabulation and Publication and Project Time Schedule

Information submitted to the GTR is made available to the public via a website operated and maintained by NIH at http://www.ncbi.nlm.nih.gov/gtr/. The only submitted information that will not be displayed on the website is a small number of fields for back-end database purposes (e.g., "person ID" and "laboratory unique code," which are both used for bulk data uploads) and private information for communication between the submitter and GTR staff (e.g., phone/fax numbers for internal communications). Submitters also have the option not to display credentials of personnel or the exact street address of the laboratory.

NIH publicly launched the GTR on February 29, 2012, following approval of its initial PRA submission (OMB No. 0925-0651). The GTR submission system is automated, and experience has shown that new submissions and updates are added to the public website quickly, generally within a day.

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate

No exemption is requested.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions are requested.