Supporting Statement A for:

Genetic Testing Registry

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Table of Contents

A. Justification

The National Institutes of Health (NIH) is creating the 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 genetic tests, including newer types of tests such as pharmacogenomic tests.

The GTR project is overseen by the NIH Office of the Director. The National Center for Biotechnology Information (NCBI), part of the National Library of Medicine at NIH, is responsible for developing and maintaining the Registry, which is expected to be operational by the end of 2011. NCBI is considered a suitable developer of the GTR because of its experience in building databases of genetic and medical information and the ability to integrate the information with other data, greatly enhancing its utility for medical professionals and researchers,. The GTR will be integrated with other relevant NIH databases to assist these user groups. NIH is 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 would be 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—particularly in the last decade—have expanded our understanding of the genomic and genetic factors involved in health and disease. This increased knowledge has been accompanied by a rapid rise in the number and complexity of genetic tests. Laboratory tests for more than 2,000 genetic conditions are now available, but there is no comprehensive public resource that provides detailed information 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, and the Genetic Alliance, a health advocacy organization.

To address the information gap about genetic tests, the NIH initiated the development of the GTR, a publicly accessible online resource that will provide a centralized location for test developers to submit information voluntarily about genetic tests, including newer types of tests such as 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, and regulators.

A.2 Purpose and Use of the Information Collection

Information will be submitted electronically at the website http://www.ncbi.nlm.nih.gov/gtr. 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 genetic and genomic data sharing for research and new scientific discoveries.

The GTR will be developed in phases, and Phase I focuses on tests for heritable mutations, including pharmacogenomic tests and tests using complex arrays and multiplex panels. Future phases will incorporate other types of tests such as tests for somatic mutations and assays that use whole exome or whole genome sequencing.

The GTR will provide information about the test provider such as contact information and credentials of the laboratory (e.g., certification and licensure) and about the genetic test. Test information will include the purpose of the test and its limitations, whether it is a clinical or research test, the test methodology and analytes that are measured, 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 will be of immediate value to clinicians by providing information about the availability, accuracy, validity, and usefulness of genetic tests. Furthermore, the GTR will highlight 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 may also be of value to public and private payers. In addition, the GTR may facilitate collaborations such as laboratory participation in quality assurance exchanges. Also, given that the adequacy of genetic testing oversight has been an issue for more than two decades, the GTR's ability to enhance the transparency of this field will be of value to public policy makers.

The table below (Table 2-1) summarizes the information that will be collected in the GTR. Participation in GTR is voluntary, but if a laboratory chooses to participate it must submit a certain set of data fields (called the "minimal fields"). The minimal fields are designated with an asterisk. For more information, see screen shots of the information collection.

Table 2-1 Information collected for the Genetic Testing Registry

Laboratory Information
Laboratory Name*
Name of Institution
Name of Department
Facility Street Address
Facility Address – State/Province, Zip Code, Country*
Facility Phone Number*
Facility Fax Number
Facility Email Address*
Laboratory Main Website URL
Laboratory Types of Service
Laboratory Services Order Code
Laboratory Affiliations

Laboratory Participation in External Programs (Standardization and Data Exchange Programs)

Personnel Information
Person Name*
Primary Laboratory Contact*
Laboratory Director*
Display Person on GTR Website*
Person Title
Person Academic Degree(s)
Person Genetic Certifications
Person Other Certifications
Publically Displayed Credentials Autopopulate Based on Certification and Degree
Person Database Permissions*
Person Public Phone Number (* if test-specific contact)
Person Private Phone Number (* for at least one person)
Person Public Fax Number
Person Private Fax Number
Person Public Email Address (* if test-specific contact)
Person Private Email Address (* for at least one person)
Person Contact Public Comment

Licensure and Accreditation – Laboratory
CLIA Certification Number (* for U.S. labs providing clinical Tests)
CLIA Expiration Date (mm/dd/yyyy) (* for U.S. labs providing clinical tests)
State License
State License #
State License Expiration Date (mm/dd/yyyy)
Other Certifications/Licenses
Other Certification/License #
Other Certification Expiration Date (mm/dd/yyyy)

Test Information
Laboratory Test Name*
Test Development
Test-Specific Laboratory Services
How to Order
Specimen Source (can be entered as default)[1]
Test-Specific Contact Person
Test-Specific Contact Policy (can be entered as default)[1]
Informed Consent Required
Genetic Counseling Required (Pre-test and/or Post-test)
Testing Strategy/Sequence
Laboratory Test Order Code
Test Codes URL
URL for the Test
Availability
Test Performed In House*
I Am Authorized to Enter Details of Test (* if test or part(s) of test performed externally)
This Entry Has Been Reviewed by the External Collaborator(s) for Accuracy (* if test or part(s) of test performed externally)
Accessibility
Test Orderable By
Reporting of Test Results
Sample Negative Report Upload Document (can be entered as default)[1]
Sample Positive Report Upload Document (can be entered as default)[1]
What is the Protocol for Interpreting a Variation as a Variant of Unknown Significance (VUS)? (can be entered as default) [1]
What Software is Used to Interpret Novel Variations? (can be entered as default)[1]
What Is the Laboratory's Policy on Reporting Novel Variations? (can be entered as default)[1]
Are Family Members Who Have Defined Clinical Status Recruited to Assess Significance of VUS Without Charge? (can be entered as default)[1]

[1] "Can be entered as default" means that the submitter can enter the information into the data field once and designate the entry as the default for that field. The system will automatically populate that field when the laboratory submits subsequent test records. Thus, entering the information once is equivalent to entering it for every test.

Sample VUS Report Upload Document (can be entered as default)[1]

Will the Laboratory Re-contact the Ordering Physician if Variant Interpretation Changes?

Is Research Performed After Clinical Testing is Complete?

Indications for Use

Purpose of the Test*

Clinical or Research Test or Both*

Condition(s) for Which Test is Offered*

Lab-displayed Disease Name

Disease Identifier(s) - Automatically Provided by NCBI[2]

Disease Synonym(s) - Automatically Provided by NCBI[2]

Lab-displayed Disease Synonym

Disease Preferred Acronym - Automatically Provided by NCBI[2]

Disease Acronym(s) - Automatically Provided by NCBI[2]

Lab-displayed Disease Acronym

Disease Type - Automatically Provided by NCBI[2]

Disease Clinical Summary - Automatically Provided by NCBI[2]

Disease Clinical Feature(s) - Automatically Provided by NCBI[2]

Drug Information - Automatically Provided by NCBI[2]

Mode of Inheritance - Automatically Provided by NCBI[2]

Disease Mechanism - Automatically Provided by NCBI[2]

Similar Disorders - Automatically Provided by NCBI[2]

Prevalence - Automatically Provided by NCBI[2]

Description of the target population

Test Methodology

Method Category*

Primary Test Methodology*

Platforms

Instrument(s) Used during Testing

[2] Fields that are automatically provided by NCBI's resources require no input from the submitter. However, some of the NCBI-provided fields allow the submitter to provide comments/suggestions.

Description of Test Procedure/Protocol

Confirmation of Test Results

Analytes

What the Test Measures*

Gene(s) Being Tested*

Gene Symbol - Automatically Provided by NCBI[2]

Gene Synonym(s) - Automatically Provided by NCBI[2]

Gene Location - Automatically Provided by NCBI[2]

Gene Family - Automatically Provided by NCBI[2]

OMIM Gene # - Automatically Provided by NCBI[2]

Chromosomal Location Being Tested - Automatically Provided by NCBI if gene name or analyte provided[2]

Exon(s) Being Tested

Mutation(s) / Analyte(s) Tested*

Variant Identifier (rs#/nsv#) – Automatically Provided by NCBI[2]

Sequence Location – Automatically Provided by NCBI[2]

Sequence(s) Being Tested

Probe(s) Being Tested

Protein(s) Name - Automatically Provided by NCBI if gene name or analyte provided[2]

Protein Synonym(s) - Automatically Provided by NCBI[2]

Protein Acronym(s) Automatically Provided by NCBI[2]

Protein Type(s) - Automatically Provided by NCBI[2]

Clinical Significance

Test Comment

Performance Characteristics

Analytical Validity*

Assay Limitations

Quality Control and Quality Assurance

Proficiency Testing Performed on this Test

Method used for Proficiency Testing

PT Provider

CAP Test List

Description of Proficiency Testing Method

Internal Test Validation Method Description

Clinical Validity

Clinical Utility

Clinical Utility

Regulations – Test

FDA Category Designation

FDA Review of

FDA Regulatory Status

FDA Application #

FDA Approval Documents

Test Specific Certifications/Licenses

Test Specific Certifications/Licenses Approval #

Test Specific Certifications/Licenses Expiration Date (mm/dd/yyyy)

A.3 Use of Improved Information Technology and Burden Reduction

The GTR utilizes the latest software and Internet technologies for registration and searching capabilities and provides a range of tools to simplify and speed the process of registering tests. For example, test providers who already have tests listed in the laboratory directory of GeneTests (http://www.ncbi.nlm.nih.gov/sites/GeneTests/lab?db=GeneTests) can have their information automatically imported from GeneTests into the GTR once they review and approve the information to be transferred. Of the 31 minimal fields necessary to submit a genetic test to the GTR, only 5 fields would remain incomplete after the transfer of a test from GeneTests.

The GTR data entry system has been designed to minimize burden to registrants with 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 will be 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 will 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 or conditions. The GTR also has a mechanism for bulk submission of data, which will significantly reduce the burden for laboratories who want to provide information on multiple

genetic tests. The GTR will support submission as an XML file or uploading subsets of information from spreadsheets.

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

Currently, there is no centralized database with detailed information about the availability and the scientific basis of genetic tests. Two existing resources provide limited information for a subset of genetic tests. When fully operational, the GTR will be unique because it will include a broad range of tests for inherited and somatic mutations, and test providers will be able to submit detailed information about genetic tests.

One of the existing genetic test resources is the GeneTests laboratory directory (http://www.ncbi.nlm.nih.gov/sites/GeneTests/lab?db=GeneTests), which provides basic information about tests for chromosomal and single-gene disorders and laboratories performing those tests. This directory provides the name of the laboratory director and laboratory contact information, Clinical Laboratory Improvement Amendments (CLIA) certification status and/or other types of certification, and the test method. It does not include detailed information such as the gene(s), variation(s), or analyte(s) that are evaluated by each genetic test. Additionally, GeneTests does not include tests for somatic mutations or pharmacogenomic tests. GeneTests is produced by the University of Washington and funded by NIH. NIH considered the option of expanding GeneTests to accommodate comprehensive information on genetic tests but found it was not technically feasible or financially sensible, as GeneTests was not designed or built to support the range of test technologies and the detailed test data that are planned for the GTR. To meet the needs of increasingly complex testing technologies, a completely new database structure —based on the test, not the genetic disease—is required. The GTR is designed to meet this need. The GeneTests laboratory directory eventually will be phased out after the GTR is publically available.

The other genetic test resource is the Association for Molecular Pathology test directory (http://www.amptestdirectory.org/index.cfm), which provides information about tests for infectious disease, solid tumors, and hematopathology. Its information is also limited and includes test methodology and laboratory location.

Some data elements proposed for the GTR are required by the Centers for Medicare & Medicaid Services (CMS) for CLIA certification and by FDA for the premarket review of manufactured test kits. NIH is in consultation with those agencies 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 certification 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 and copy functions (further explained in Section A.12) will also reduce the burden.

The GTR has 31 minimal data fields (which must be completed to register a test in GTR) and 85 optional fields (available for completion at the submitter's discretion). Sixteen of the minimal fields, which consist of contact information for the submitting laboratory and associated staff, are

submitted only once. Furthermore, data from tests that are in GeneTests can be automatically transferred to the GTR, which will complete 26 of the 31 GTR minimal fields and leave only 5 fields that require data entry. For research tests, the minimal dataset for registration will be smaller than that for clinically available tests.

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 plans to request that submitters update their test information at least once every 12 months. 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.

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

This collection fully complies with 5 CFR 1320.5.

A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

This proposed information collection was previously published in the *Federal Register* (FR) on July 27, 2011, (76 FR 44937) and allowed 60 days for public comment and on November 23, 2011, (76 FR 72424) and allowed 30 days for public comment. Twelve public comments were received in the 60-day comment period,[3] and four comments were received in the 30-day comment period. The majority of commenters indicated that the time and cost estimates to submit information to the GTR were underestimated. Several commenters also mentioned the need for more information regarding the ability to submit tests in bulk. Some commenters made suggestions for help documents that explain how to submit tests to the GTR. A few comments noted the need to safeguard against false and inaccurate data and the impression that NIH endorses tests and laboratories listed in the GTR. Other comments were about issues outside the scope of the Federal Register notice, and these issues are addressed on the GTR's FAQ page, found at http://oba.od.nih.gov/gtr/gtr_faqs.html.

NIH re-evaluated the estimated time and cost burdens to submit genetic test information to the GTR and decided that the estimated time burden remains valid. In response to the comments on the estimated time burden, an explanation of GTR time-saving features—such as a copy function, data migration from other databases, and the bulk upload option (further detailed in section A.12)—was added to the discussion in the 30-day FR notice. The cost estimate was recalculated using a mean hourly wage that is more appropriate for the experienced laboratory personnel who are likely to submit test information to the GTR (e.g., a genetic counselor). In response to requests for additional guidance in making submissions to the GTR, NCBI will offer 'in-line' help tips on the submission and public websites as well as a user manual with definitions and references for the data fields.

NIH has taken the following steps to safeguard against false and inaccurate data and the impression that NIH endorses tests and laboratories listed in the GTR:

[3] Public comments in response to the FR notice are available at http://oba.od.nih.gov/GTR/gtr_request_comments.html.

- NCBI will incorporate basic checks for mistakes made by the submitter during the submission process.
- Submitters must agree to abide by the following terms of a code of conduct: (1) to uphold the integrity of the GTR through the submission of information that is accurate and not misleading; (2) to assure the accuracy of the data at the time of submission and to review and, if necessary, update the submitted information at least once a year; and (3) to make no explicit or implicit claims that the National Institutes of Health, the Department of Health and Human Services, or the U.S. Government approves or endorses tests listed in, or any other information submitted to, the GTR.
- FAQs explaining actions that NIH may take if submitters violate these terms were added to the GTR website at http://oba.od.nih.gov/gtr/gtr_faqs.html.
- A prominent note on the GTR homepage clearly states that "NIH does not independently verify information submitted to the GTR; it relies on submitters to provide information that is accurate and not misleading." The note also appears at the bottom of all other GTR webpages.
- A question mark icon appears next to several terms used in the GTR. When the user scrolls over the icon, an explanation of the term is provided and notes that the information is provided by the laboratory.
- NCBI will assign a unique accession number to each test record, allowing uniform reference to tests in scientific publications. This feature will facilitate third-party evaluations of GTR content, and NCBI will link published reviews to tests referenced in the publication.
- GTR users will be encouraged to contact NCBI staff (at http://www.ncbi.nlm.nih.gov/projects/gtr_feedback/feedback.cgi) if they wish to report information that appears to be inaccurate or misleading, inappropriate endorsement claims, or any other breaches of this Code of Conduct.

In addition to the PRA requirements for public consultation, NIH has been engaged with numerous stakeholders for the past year. Stakeholders—such as genetic test developers, test kit manufacturers, health care providers, researchers, patients, and relevant federal agencies—have been instrumental in the development of the GTR. NIH has used several mechanisms to solicit their insights on critical data elements and the best way to display information in the GTR.

As a first step in stakeholder engagement, NIH issued a Request for Information (RFI) that was published June 11, 2010 (FR volume 75, number 112, pages 33317-33319). It sought input on data elements that should be included in the GTR and processes that would ease the data submission process. In response to this RFI, NIH received 68 comments from a broad range of stakeholders.[4] Overall, the comments were supportive of the GTR concept and generally agreed with the most of the proposed data elements. However, some commenters pointed out that certain data elements (e.g., clinical utility) will be difficult to provide, particularly for rare diseases, and that it could be challenging to keep information up to date.

The RFI public comments assisted in the development of an initial GTR prototype and informed the focus questions for a November 2, 2010, public meeting. The FR notice (volume 75, number 195, pages 62406-62407) announcing the meeting solicited responses to five questions about the availability of particular data elements and how the misuse or misinterpretation of GTR content

[4] Public comments in response to the RFI are available at http://oba.od.nih.gov/GTR/gtr_rfi_comments.html.

could be mitigated. The 17 comments that NIH received in response to this FR notice[5] and a panel discussion during the meeting provided additional insights that were used for the further refinement and development of the GTR.

Other mechanisms for stakeholder input include an e-mail comment box on the GTR website (http://oba.od.nih.gov/gtr/gtr.html) and meetings with interested parties to discuss conceptual issues and technical specifications for GTR data elements. In addition, two clinical advisory groups are consulted on an ongoing basis about the design and structure of the Registry. (For rosters of these advisory groups, please see http://oba-test.od.nih.gov/oba/gtr/Roster_NIH_Clinical_Advisors_to_GTR_1-5-12.pdf and http://oba-test.od.nih.gov/oba/gtr/Roster_NCBI_BSC_Medical_Genetics_Working_Group_1-5-12.pdf.)

Stakeholder comments have led to revisions in the GTR prototype. For example, some data elements, such as patent information and test turn-around time, will be excluded from the Registry, at least in its initial version. In addition, some data fields were reformatted to ease the submission process (e.g., use of pull-down menus instead of open-text fields), and NIH will link to existing resources to satisfy some data elements (e.g., practice guidelines for clinical utility).

The GTR development also benefits from coordination with HHS agencies. NIH has met with FDA and CMS to evaluate how the agencies' related activities could be harmonized to minimize reporting burden and maximize GTR utility for data submitters, users, and agency mission.

NIH will continue its engagement with interested stakeholder groups and HHS agencies as GTR development advances. It will revise and adjust the GTR data elements and display of information based on feedback from these interactions.

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 Assurance of Confidentiality Provided to Respondents

No personally identifiable information is to be sent to the databank, other than contact information for designated points-of-contact. Respondents can choose whether their contact information is made accessible to the public or not.

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, in order to participate, the submitter must provide information for a certain subset of data fields, identified as the "minimal fields." The GTR includes 31 minimal fields and 85 optional fields. Table 12-1 provides estimated burden hours to submit information for the minimal fields, optional fields, and all fields. The calculations include the time and effort necessary for the respondent to gather information for the data fields and to enter the information in the GTR online submission form.

[5] Public comments in response to the FR notice are available at http://oba.od.nih.gov/GTR/gtr_nov_comments.html.

To estimate the number of submitters, NIH examined the number of laboratories that participate in the GeneTests Laboratory Directory, which is currently the most comprehensive listing available for laboratories that provide genetic tests. GeneTests includes information from 593 laboratories. Approximately half of the laboratories in GeneTests (291, or 49 percent) list 12 or fewer tests, while approximately 40 percent (239) list between 13 and 100 tests, and the remaining 10 percent (63) list 100 or more tests. To account for genetic test providers that are not listed in GeneTests, a multiplier of 1.2 was used, bringing the estimated number of potential participants in the GTR to 770.

GeneTests also was used to estimate the number of genetic tests for which information might be submitted to the GTR. Analysis of the database showed that there are approximately 7,800 genetic tests listed in GeneTests. A multiplier of 1.2 was used to account for tests that are not in GeneTests but that might be submitted to the GTR, including test categories not covered by GeneTests (e.g., pharmacogenomic tests), as well as tests that meet the criteria for GeneTests but that have not been submitted to the database. Applying the 1.2 multiplier yields an estimated 9,360 tests for which information could be submitted to the GTR.

Based on simulated trials of entering test information in the GTR, NIH projects that it will take submitters an average of 0.5 hours to provide test information for the minimal fields. Sixteen of the 31 minimal fields request laboratory data and contact information, which the submitter completes only once. These data will autopopulate new test records, leaving 15 minimal fields that require completion. Furthermore, test providers whose tests are already listed in GeneTests can have that data automatically transferred to the GTR, saving them data entry time. Transferred data will fill 26 of the 31 minimal fields, leaving only 5 fields for the submitter to complete.

The 2.5 hour estimate to provide information for the optional fields reflects 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 will provide some time-saving features. For example, a copy (clone) function will be available to expedite entry for tests that differ by just a few data fields (e.g., test order code, test name). Submitters will be able to modify any of the copied data. The copy function is especially helpful for entering tests based on a similar platform. The GTR also will have a mechanism for the bulk submission of data, which will significantly reduce the burden for laboratories that want to provide information on multiple genetic tests. The GTR will support bulk submission as an XML file or uploading subsets of information from spreadsheets. The expectation is that large laboratories will have their tests already stored electronically and will have the computational support to convert their test information to XML for submission to the GTR.

Table 12-1 Estimates of Hour Burden

Type of Respondent	Number of Respondents	Frequency of Response	Average Time per Response	Annual Hour Burden
Laboratory Personnel	770	12	Minimal Fields: 0.5 hr	Minimal Fields: 4,620
			Optional Fields: 2.5 hr	Optional Fields: 23,100
Total			3.0 hr	27,720

To estimate the annualized cost to respondents, NIH used the mean hourly wage of a genetic counselor from the National Society of Genetic Counselor's 2010 Professional Status Survey: Executive Summary.[6] Table 12-2 provides the estimated annualized cost for respondents. Based an average of 12 submissions per respondent and a mean hourly wage of $30.63, the estimated annualized cost per respondent is $183.78 to complete minimal data fields and $1,102.68 to complete all data fields. Laboratories can reduce cost by using time-saving features such as the copy function and bulk upload feature.

Table 12-2 Annualized Cost to Respondents

Type of Respondent	Number of Respondents	Frequency of Response	Average Time per Respondent	Hourly Wage Rate	Respondent Cost
Laboratory Personnel	770	12	Minimal Fields: 0.5 hrs	$30.63	$183.78
			Optional Fields: 2.5 hrs	$30.63	$918.90
Total	770		3.0 hrs		$1,102.68

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

There are no capital costs associated with this collection.

A.14 Annualized Cost to the Federal Government

The estimated annualized cost to the Federal Government is $2.9 million comprised of personnel and IT costs associated with project implementation and operation. This cost is based on 15 staff (contractor and federal) at an average rate of $164,000 (salaries and benefits) and $504,000 for hardware and software.

A.15 Explanation for Program Changes or Adjustments

The GTR is a new collection of information.

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

Information submitted to the GTR will be 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 are 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 the GTR (e.g., phone/fax numbers for internal communications). Submitters also have the option to specify that credentials of personnel or the exact street address of the laboratory not be displayed.

NIH expects to launch the GTR in late 2011, following approval of its PRA submission. The majority of GTR's initial content will come from laboratories that already list their tests in GeneTests. The GTR will provide for automatic transfer of data from GeneTests and will facilitate laboratory updates of this information to include the broader range of fields provided for

[6] National Society of Genetic Counselors. 2010 Professional Status Survey: Executive Summary. See www.nsgc.org/Portals/o/Publications/PSS 2010 Executive Summary FINAL.pdf. Accessed October 15, 2011.

in the GTR. The GTR submission system is automated, and it is expected that new submissions and updates will be 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.