Supporting Statement A for:

National Institutes of Health Information Collection Forms to Support Genomic Data Sharing for Research Purposes

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A. Justification

The mission of the National Institutes of Health (NIH) is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability. The sharing of research data supports this mission and is essential to facilitate the translation of research results into knowledge, products, practices, and procedures that improve human health. By enabling secondary research questions to be addressed, data sharing also maximizes research investments. In 2008, NIH implemented the *Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS)*[1] to enable the full value of GWAS data to be realized.

The GWAS policy addresses data submission, data maintenance, and data access. It provides two levels of data access: (1) open access for the release of non-sensitive data and (2) controlled access that provides oversight and accountability for sensitive datasets. A wide array of data types are maintained, including survey or questionnaire instruments; tables detailing the measured variables; summary-level phenotype or clinical measures; high-level summary genotype data; annotated and coded phenotype measures; and sequence, genotype, microarray, pedigree data, as well as aggregated versions of those data. GWAS data are maintained in a central data repository, the database of Genotypes and Phenotypes (dbGaP), which is administered by the National Center for Biotechnology Information (NCBI), part of the National Library of Medicine at NIH.

The nature of the genomic, phenotypic, and other associated data generated through large-scale human genomic studies requires responsible stewardship throughout research and data sharing activities. Since the data being collected and shared are from human research participants, the protection of participant interests is paramount. To minimize privacy risks to study participants, data submitted to dbGaP are de-identified according to the HIPAA Privacy Rule (45 CFR 46.102(f);[2] 45 CFR 164.514(b)(2)).[3] In addition, principal investigators (PIs) submitting controlled-access data to dbGaP must provide data use limitations, which describe appropriate research uses for the data as defined in the informed consent provided by the participants from whom the data were originally collected. A senior official from the institution submitting data to dbGaP, designated as an Institutional Signing Official, approves an institutional certification that confirms that data submission is consistent with applicable laws, regulations, and institutional policies.

PIs and institutions requesting data from dbGaP are expected to meet data security measures (e.g., physical security, information technology security, and user training). To obtain controlled-access data, PIs and institutions must submit a Data Access Request (DAR) that includes a description of the proposed research use of the requested dataset(s). In addition, the PI and an Institutional Signing Official agree to the Data Use Certification,[4] which specifies the terms and conditions for use of the data and certifies they will adhere to the terms of the GWAS policy. NIH Data Access Committees (DACs) refer to data use limitations to determine whether the PIs' proposed research use for secondary studies is consistent with participants' informed consent. PIs whose proposed

[1] NIH Guide Notice. Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS). See: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html.
[2] Code of Federal Regulations. 45 CFR 46.102(f). See http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html/#46.102.
[3] Code of Federal Regulations. 45 CFR 164.514(b)(2). See http://www.gpo.gov/fdsys/pkg/CFR-2011-title45-vol1/pdf/CFR-2011-title45-vol1-sec164-514.pdf.
[4] Model Data Use Certification Agreement. See http://gwas.nih.gov/pdf/docs/ModelDUC.docx.

research is approved by a DAC are granted access to millions of dollars of genomic research data free of charge.

A.1 Circumstances Making the Collection of Information Necessary

The collection of information activities set forth herein would be conducted under the authorities granted in Section 301 of the Public Health Service Act, 42 USC 241 and in accordance with the policies and procedures set forth in the NIH GWAS policy.

As stipulated in the NIH GWAS policy, all PIs who receive NIH funding to conduct genomic research are expected to register studies with genomic data in dbGaP. As part of the registration process, PIs must provide basic study information such as the type of data that will be submitted to dbGaP (*e.g.*, individual-level genotype data, aggregate-level association data), a description of the study, and any data use limitations on the secondary use of the data (*e.g.*, data cannot be shared with for-profit companies, data can be used only for research of particular diseases).

Although NIH encourages data sharing through this policy, circumstances beyond the control of PIs may preclude submission of data to dbGaP (*e.g.*, country or state laws that prohibit data deposition in a U.S. database). In such cases, an exception to deposit data in a NIH-designated data repository may be granted.

PIs interested in using controlled-access data for secondary research must apply through dbGaP and be granted permission from the relevant NIH DACs. As part of the application process, PIs must provide information such as a description of the proposed research and use of controlled-access datasets that conforms to the data use limitations, a data security plan, and a Data Use Certification agreement.

Currently, the processes to register studies and access data in dbGaP involve paper applications that are burdensome to complete. For example, the OMB-approved SF424 Research and Related (R&R) form is used to apply for controlled-access data. However, because the SF424 R&R form is not tailored to this information collection, it can be confusing and take more time to complete. NIH has developed online forms, which will be available through dbGaP, in an effort to reduce the burden for PIs and their institutional officials to complete the study registration, data submission, and data access processes.

A.2 Purpose and Use of the Information Collection

The information collection is necessary to support NIH's data sharing goals for genomic data. The online forms are expected to reduce burden for PIs who submit data to dbGaP and for requesters who wish to access the data for secondary research.

Study Registration and Data Submission

The required elements for study registration in dbGaP include basic study information and an institutional certification approved by the Institutional Signing Official. Basic study information includes the name of the PIs, funding information, a description of the study data, a statement that secondary researchers can use to acknowledgement the original data collection, and a summary of the study. The institutional certification confirms that study registration and data submission are consistent with all applicable laws, regulations, and institutional policies; outlines data use limitations; certifies that the identities of research participants will not be disclosed to dbGaP; and documents that an Institutional Review Board (IRB) and/or Privacy Board reviewed and

approved the plan to submit the data to dbGaP. Data files are submitted at the time of registration and on an ongoing basis. Attachments 1 and 2 illustrate the information that will be collected for dbGaP study registration and data submission.

Data Access

The application to request controlled-access dbGaP data includes information about the credentials of the PIs requesting data access; the proposed use of the data; an agreement to comply with NIH policies and the NIH Genomic Data User Code of Conduct;[5] and certification by an Institutional Signing Official at the PI's institution that data will not be sold, distributed, re-identified, or used by unauthorized users and collaborators not named in the DAR. Requests to renew data access and reports to close out data use are similar to the initial DAR but also ask for information about publications, presentations, or intellectual property based on the research conducted with the accessed data as well as any data security issues or other data management incidents.

As a prerequisite to applying for controlled-access data, the PI and Institutional Signing Official must be registered in the electronic Research Administration (eRA) Commons.[6] Most PIs seeking access to dbGaP data have already registered with eRA Commons in applying for NIH funding. For PIs not previously registered in eRA Commons, this step is not expected to add significantly to the burden. Several of the mandatory fields in the DAR form will be automatically filled based on eRA registration information, and most fields in the renewal and close-out request will be automatically filled from the initial DAR form. Attachment 3 illustrates the information that will be collected for data access.

A.3 Use of Improved Information Technology and Burden Reduction

In lieu of using the time-consuming paperwork traditionally completed by PIs and submitted to NIH program staff, NCBI has created an online system to register studies, submit data, and request access to data. The online system will allow PIs to submit their information directly to dbGaP, thereby minimizing burden not only for PIs but also for NIH program staff. The online system uses time-saving features, such as the use of pull-down and scrolling menus to fill data fields, "find as you type" (or "type ahead") functionality, and text fields that allow PIs to cut and paste information from other sources. Where possible, data fields are automatically filled with information from other data sources, such as eRA Commons, which provides the PI's name, institution, and Institutional Signing Official. Also, information from one online form can be used to pre-fill data fields on subsequent forms. For example, information from a DAR will be used to pre-fill many of the data fields on the renewal and close-out forms. In addition, the data entry system has been designed to allow PIs to submit their data in any format.

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

Currently, no comparable genomic data repository exists. dbGaP is unique in that it provides a single site for all NIH-funded genomic research studies, in addition to some non-NIH-funded genomic research studies.

A.5 Impact on Small Businesses or Other Small Entities

[5] NIH Genomic Data User Code of Conduct. See https://dbgap.ncbi.nlm.nih.gov/aa/GWAS_Code_of_Conduct.html.
[6] eRA Commons. See https://commons.era.nih.gov/commons/.

The information collection does not have a differential effect on small businesses.

A.6 Consequences of Collecting the Information Less Frequently

Delaying submission of the information to dbGaP would impede secondary studies of data in dbGaP and lessen the value of NIH's investment.

Following the initial request and approval to use controlled-access data, requesters must provide annual updates on their research progress and renew access to the dataset(s) for another year or close-out access to the dataset(s). The consequence of not submitting the required information annually is reduced NIH oversight of dbGaP data and reduced knowledge of how the data are being used, possibly leading to an increased rate of adverse data management incidents.

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

In accordance with 5 CFR 1320.8(d), the proposed information collection was published in the *Federal Register* (FR) on October 5, 2012, (77 FR 61008) and allowed 60 days for public comment. No public comments were received.

In addition to the Paperwork Reduction Act requirements for public consultation, NIH engaged with stakeholders in 2006 during the development of the GWAS policy through requests for public comment in the *Federal Register*[7] and the *NIH Guide for Grants and Contracts*[8] and through a Town Hall meeting. NIH received 196 written comments from professional societies, scientists, ethicists, IRB administrators, privacy advocates, patient advocacy groups, and members of the general public. The comments, which reflected a variety of interests and perspectives, were considered in the development of the final policy and in the governance and oversight procedures established to carry out the policy.

There are ongoing opportunities for data submitters and data requesters to provide feedback to NIH about how the system works and how the registration, submission, and access processes could be improved. This input helped NIH recognize the need for automating the process, and it helped shape the design of the online system for study registration and data submission and access.

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

[7] Request for Information (RFI): Proposed policy for sharing of data obtained in NIH supported or conducted genome-wide association studies (GWAS). *Federal Register*. 71(168): 51629-51631. See http://edocket.access.gpo.gov/2006/E6-14416.htm.

[8] Request for Information (RFI): Proposed policy for sharing of data obtained in NIH supported or conducted genome-wide association studies (GWAS). NIH Guide. NOT-OD-094. August 30, 2006. See http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-094.html.

Respondents (both data submitters and data requesters) are not afforded an assurance of confidentiality because their names and institutional affiliations will be posted on the dbGaP website. However, it is important to emphasize that no private information is requested from PIs submitting or accessing data beyond their name and institutional affiliation. Submitters of data to dbGaP are largely NIH-funded PIs whose names and institutional affiliations are already a matter of public record (see http://projectreporter.nih.gov/reporter.cfm). Approved users of the data are both publicly and privately funded PIs. Making the names of submitters and users of the data publicly available is an important ethical underpinning of the NIH GWAS policy as it allows research participants, the scientific community, and the general public to know how genomic data are being shared, with whom, and for what research purpose.

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

The burden associated with this information collection is calculated in two parts: the burden associated with registering genomic studies and submitting data to dbGaP; and the burden associated with applying for controlled-access data in dbGaP. Respondents are (1) PIs submitting data to dbGaP; (2) Institutional Signing Officials who certify that data submission is consistent with all applicable laws, regulations, and institutional policies; (3) PIs who request and receive data; and (4) Institutional Signing Officials who certify that they will abide by the GWAS policy.

Study Registration and Data Submission

The burden associated with registering genomic studies and submitting data to dbGaP involves the time and effort necessary for the PI to complete the online form and upload the data to dbGaP. The burden for the Institutional Signing Official includes the time and effort to review and approve the registration and data submission. Because NIH will now be making it possible to submit the information through tailored, user-friendly online forms, the time and effort should be considerably reduced. Moreover, some of the information PIs will need to complete the forms will be automatically provided from eRA Commons and other information can be retrieved from the PI's NIH grant award.

To estimate the annual number of registrants, NIH averaged the number of study registrations and data submissions received by NCBI in 2011 and the number of registrations anticipated for 2012, based on NIH funding allocated for genomic data research grants that will fall under the GWAS policy. Based on this calculation, NIH estimates 100 respondents per year (50 PIs and 50 Institutional Signing Officials). NIH does not expect the number of registrations to increase significantly in the next three years. Based on prior experience, most PIs do not make changes to their initial registration information but may add additional datasets. Since dbGaP accepts various data formats, additional datasets submitted after the initial registration do not require any reformatting and thus does not add additional burden to the registration process. Therefore, the average frequency of response per PI is estimated to be once.

Table 12-1 provides the estimated burden hours for registration and data submission of NIH-funded genomic studies. Based on a simulation of the registration and submission processes using the new forms, NIH estimates that it will take a PI, on average, 0.75 hours to enter the study information and upload the study data, and that it will take an Institutional Signing Official, on

average, 0.50 hours to certify the information. Multiplying the frequency of response (1) by the total number of PIs (50) by the time it takes a PI to register a study and submit data (0.75 hour), yields a total annual hour burden for submitting PIs of 38 hours. The same formula was used to derive the total annual burden for Institutional Signing Officials (i.e., the frequency was multiplied by the number of Institutional Signing Officials by the time it takes an Institutional Signing Official to carry out the certification process). The total annual hour burden for Institutional Signing Officials is 25 hours. The total annual burden for both groups is 63 hours.

Table 12-1 Estimates of Hour Burden for Study Registration and Data Submission

Type of Respondent	Number of Respondents	Frequency of Response	Average Time per Response	Annual Hour Burden
PI Submitting Data	50	1	45/60 hour	38
Institutional Signing Official	50	1	30/60 hour	25
Total	100	n/a	n/a	63

Table 12-2 provides the estimated annualized cost to register a study and submit data in dbGaP. To estimate the annual cost to respondents, NIH used figures from the U.S. Bureau of Labor and Statistics 2011 National Occupational Employment and Wage Estimates.[9] The mean hourly wage of $35.68 for Life Scientists was used for PIs, and the mean hourly wage of $46.72 for Education Administrators, Postsecondary, was used for Institutional Signing Officials. The estimated annual cost of $1,338 for PIs to register studies and submit data was calculated by multiplying the number of PIs (50) by frequency of response (1) by the average time per response (0.75 hour) by the hourly wage rate for PIs ($35.68). The estimated annual cost of $1,168 for Institutional Signing Officials to certify study registration and data submission was similarly calculated (i.e., multiplying the number of Institutional Signing Officials by the frequency of response by the average time per response by the hourly wage rate). The total annual cost of study registration and data submission is $2,506.

Table 12-2 Annualized Cost to Respondents for Study Registration and Data Submission

Type of Respondent	Number of Respondents	Frequency of Response	Average Time per Response	Hourly Wage Rate	Respondent Cost
PI Submitting Data	50	1	45/60 hour	$35.68	$1,338.00
Institutional Signing Official	50	1	30/60 hour	$46.72	$1,168.00
Total	100	n/a	n/a	n/a	$2,506.00

Data Access

[9] U.S. Bureau of Labor and Statistics. May 2011. National Occupational Employment and Wage Estimates. See http://www.bls.gov/oes/current/oes_nat.htm#19-0000 and http://www.bls.gov/oes/current/oes_nat.htm#11-0000.

On an annual basis, the PI completes only one of the three forms for a given project (i.e., initial or renewal data request or a close-out report). The first step a PI must take to request data from dbGaP is to complete a DAR form. This step also requires the Institutional Signing Official to review the DAR, and both the PI and Signing Official must certify that they agree to the terms and conditions for use of the data and will adhere to the GWAS policy.

Upon approval of their request, PIs are granted access to the data for one year. At the end of the year, PIs who wish to continue to use the data must complete a renewal form to extend the access period for another year. Information from the original DAR is automatically incorporated into the PI's renewal form, and the PI provides additional information such as a description of publications, presentations, and intellectual property that are based on the secondary use of dbGaP data.

PIs who do not wish to renew their access request are expected to complete a project close-out form. Information from the original DAR or renewal form is automatically incorporated into the PI's close-out form, and the PI provides additional information such as a description of publications, presentations, and intellectual property that are based on the secondary use of dbGaP data. The information in the close-out form is needed because it provides NIH with information on final project outcomes and provides the oversight mechanism by which the Institutional Signing Official confirms that the project has been discontinued and the dbGaP data were deleted from the institution's computers.

The annual time burden estimates are calculated separately for the initial DAR and renewal/project close-out forms. To estimate the number of data requesters (respondents) and the number of requests made per year, NIH totaled the number of requesters and DARs that were submitted over a two-year period and divided by two, for an average of 633 respondents and 933 DARs per year.

To calculate the number of annual requests per respondent, NIH divided the number of DARs per year by the number of respondents, and estimated two DARs per year, per respondent. Since each DAR is either renewed or closed out at the end of the one-year access period, the renewal/close-out process also involves 633 respondents submitting two reports per year.

The burden associated with an initial DAR includes the time and effort necessary for PIs to (1) identify the studies and datasets in dbGaP of interest, (2) prepare information for their proposed research use statement, and (3) complete the DAR form. The burden also involves the Institutional Signing Official's review and certification of the DAR.

Table 12-3 provides the estimated burden hours for completing a DAR. Based on simulations, NIH estimates that it will take a requester an average of 0.75 hours to complete the DAR and 0.50 hours for the Institutional Signing Official to review and certify the DAR. To derive the annual hour burden for PIs, NIH multiplied the number of DARs submitted per year (2) by the number of PIs (633) by the time it takes a PI to complete a DAR (0.75 hour), for a total of 950 hours. The same formula was used to derive the total annual burden for Signing Officials (i.e., the frequency was multiplied by the number of Institutional Signing Officials by the time it takes an Institutional Signing Official to complete the certification process). The total annual hour burden for Institutional Signing Officials is thereby 633 hours, with a total annual burden of 1,583 hours for all respondents.

Table 12-3 Estimates of Hour Burden for Data Access Request Form				
Type of	**Number of**	**Frequency of**	**Average Time per**	**Annual Hour**

Respondent	Respondents	Response	Response	Burden
PI Requesting Data	633	2	45/60 hour	950
Institutional Signing Official	633	2	30/60 hour	633
Total	1,266	n/a	n/a	1,583

The burden associated with renewal and project close-out involves the time and effort necessary for requesters to (1) prepare information on their research use of NIH datasets, (2) complete the renewal or close-out form, and (3) have the Institutional Signing Official review and approve the form. Importantly, when PIs stop using dbGaP data, NIH expects them to delete the datasets from the institution's computer systems and mobile devices, and Institutional Signing Officials are expected to verify that the data were deleted. PIs who are registered in eRA Commons, or those who have made previous data requests or submitted data to dbGaP, will have information from those systems automatically transferred to the renewal/close-out forms, significantly reducing data entry time.

Table 12-4 shows the estimated burden hours for renewal/project close-out forms. Based on simulations, NIH estimated that it will take an average of 0.25 hours for the PI to provide the required information and 0.30 hours for the Institutional Signing Official to review and approve the form and to confirm that data were deleted from the institution's computer system for projects that are closed-out. To derive the annual hour burden for PIs, NIH multiplied the frequency of response (2) by the number of PIs (633) by the time it takes a PI to complete a renewal or close-out form (0.25 hour), for a total of 317 hours. The same formula was used to derive the total annual burden for Institutional Signing Officials (i.e., the frequency was multiplied by the number of Institutional Signing Officials by the time it takes an Institutional Signing Official to complete the certification process). The total annual hour burden for Institutional Signing Officials is 380 hours, with a total annual burden of 697 hours for all respondents.

Table 12-4 Estimates of Hour Burden for Renewal/Close-Out Forms

Type of Respondent	Number of Respondents	Frequency of Response	Average Time per Response	Annual Hour Burden
PI Requesting Data	633	2	15/60 hour	317
Institutional Signing Official	633	2	18/60 hour	380
Total	1,266	n/a	n/a	697

To estimate the annual cost to respondents, NIH used statistics from the U.S. Bureau of Labor and Statistics 2011 National Occupational Employment and Wage Estimates.[10] The mean hourly wage of $35.68 for Life Scientists was used for PIs, and the mean hourly wage of $46.72 for Education Administrators, Postsecondary, was used for Institutional Signing Officials. The annual cost burden estimates are calculated separately for the initial DAR and renewal/project close-out forms.

[10] U.S. Bureau of Labor and Statistics. May 2011. National Occupational Employment and Wage Estimates. See http://www.bls.gov/oes/current/oes_nat.htm#19-0000 and http://www.bls.gov/oes/current/oes_nat.htm#11-0000.

Table 12-5 provides the estimated annual cost for respondents to complete an initial DAR form. The estimated annual cost of $33,878 for PIs to complete an initial DAR was calculated by multiplying the number of PIs (633) by frequency of response (2) by the average time per response (0.75 hour) by the hourly wage rate for PIs ($35.68). The estimated annual cost of $29,574 for Institutional Signing Officials to certify the DAR was similarly calculated (i.e., multiplying the number of Institutional Signing Officials by the frequency of response by the average time per response by the hourly wage rate). The total annual cost of study registration and data submission is $63,452.

Table 12-5 Annualized Cost to Respondents for Initial Data Access Request

Type of Respondent	Number of Respondents	Frequency of Response	Average Time per Response	Hourly Wage Rate	Respondent Cost
PI Requesting Data	633	2	45/60 hour	$35.68	$33,878
Institutional Signing Official	633	2	30/60 hour	$46.72	$29,574
Total	1,266	n/a	n/a	n/a	$63,452

Table 12-6 provides the estimated annualized cost for respondents to complete a renewal or close-out report. The estimated annual cost of $11,293 for PIs to complete a renewal or close-out report was calculated by multiplying the number of PIs (633) by frequency of response (2) by the average time per response (0.25 hour) by the hourly wage rate for PIs ($35.68). The estimated annual cost of $17,744 for Institutional Signing Officials to certify the report was similarly calculated (i.e., multiplying the number of Institutional Signing Officials by the frequency of response by the average time per response by the hourly wage rate). The total annual cost of study registration and data submission is $29,037.

Table 12-6 Annualized Cost to Respondents for Renewal/Close-outs

Type of Respondent	Number of Respondents	Frequency of Response	Average Time per Response	Hourly Wage Rate	Respondent Cost
PI Requesting Data	633	2	15/60 hour	$35.68	$11,293
Institutional Signing Official	633	2	18/60 hour	$46.72	$17,744
Total	1,266	n/a	n/a	n/a	$29,037

Table 12-7 summarizes the total annualized hour burden for this information collection. The estimated annual number of respondents involved in submitting data to dbGaP is 100 (50 PIs plus 50 Institutional Signing Officials). The estimated annual number of respondents involved in requesting data from dbGaP is 1,266. NIH estimated that 633 PIs annually request, renew, or close-out access to dbGaP data (i.e., on an annual basis, a PI completes only one of three forms for a given project—an initial request, a renewal request, or a close-out report). Similarly, the estimated annual number of Institutional Signing Officials for PIs requesting data is 633. The total estimated number of annual respondents involved in the submission and access of dbGaP data is 1,366 (100 plus 1,266). The values for the frequency of response, average time per response, and hourly wage rate are the same values used in the tables above. For this information collection, the total estimated annual hour burden for all respondents is 1,646 (63 plus 1,583) hours and the total estimated cost burden for all respondents is $65,958.

Table 12-7 Total Annualized Hour Burden for the Information Collection				
Type of Respondent	**Number of Respondents**	**Frequency of Response**	**Average Time per Response**	**Annual Hour Burden**
Study Registration and Data Submission				
PI Submitting Data	50	1	45/60 hour	38
Submitter's Institutional Signing Official	50	1	30/60 hour	25
Total	100			63
Data Access Request				
PI Requesting Data	633	2	45/60 hour	950
Requester's Institutional Signing Official	633	2	30/60 hour	633
Total	1,266	n/a	n/a	1,583

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 to support this information collection is $9.25 million, which is comprised of program personnel costs and computer hardware/software costs associated with the project's implementation and operation. The estimated personnel cost is $6.75 million, based on 45 programmers (contractors and federal) at an average annual rate of $150,000 (salary and benefits). The estimated cost of computer hardware and software is $2.5 million.

A.15 Explanation for Program Changes or Adjustments

NIH has been collecting study information and data from submitters and processing data access requests since 2008 under the OMB-approved SF424 R&R form (OMB Number 4040-0001, expiration date February 28, 2013). NIH is seeking approval to modify the manner of collecting the study registration information, study data, and access information in order to ease the burden for submitters and requesters.

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

Information submitted to dbGaP to register studies or access genomic data will be made available to the public via the dbGaP website. The only submitted information that will not be publicly displayed on the website is contact information of the submitting PIs and requesters (i.e., the PI's email addresses and phone and fax numbers).

NIH will periodically publish an analysis of dbGaP usage that would include summary statistics such as the number of registered studies, the number of submitted/approved DARs, trends in

usage, and number of publications. Additionally, these summary statistics may be posted on the dbGaP website.

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.