SUPPORTING STATEMENT FOR PAPERWORK REDUCTION ACT 1995 SUBMISSIONS

A. Justification

1. *Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.*

The Genetic Information Nondiscrimination Act of 2008 (GINA), Public Law 110-233, was enacted on May 21, 2008. Title I of GINA amended the Employee Retirement Income Security Act of 1974 (ERISA), the Public Health Service Act (PHS Act), the Internal Revenue Code of 1986 (Code), and the Social Security Act (SSA) to prohibit discrimination in health coverage based on genetic information. Sections 101 through 103 of Title I of GINA prevent employment-based group health plans and health insurance issuers in the group and individual markets from discriminating based on genetic information, and from collecting such information. The interim final regulations, which are codified at 29 CFR 2590.702A, only interpret Sections 101 through 103 of Title I of GINA

While GINA does not mandate any specific benefits for health care services related to genetic tests, diseases, conditions, or genetic services, GINA establishes rules that generally prohibit a group health plan and a health insurance issuer in the group market from:

- increasing the group premium or contribution amounts based on genetic information;
- requesting or requiring an individual or family member to undergo a genetic test; and
- requesting, requiring or purchasing genetic information prior to or in connection with enrollment, or at any time for underwriting purposes.

GINA and the interim final regulations (29 CFR 2590.702A(c)(5)) provide an exception to the limitations on requesting or requiring genetic testing that allow a group health plan or group health insurance issuer to request, but not require, a participant or beneficiary to undergo a genetic test if all of the following conditions of the research exception are satisfied:

- The request must be made pursuant to research that complies with 45 CFR Part 46 (or equivalent Federal regulations) and any applicable State or local law or regulations for the protection of human subjects in research. To comply with the informed consent requirements of 45 CFR 46.116(a)(8), a participant must receive a disclosure that participation in the research is voluntary, refusal to participate cannot involve any penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at anytime without penalty or loss of benefits to which the participant is entitled (the Participant Disclosure). The interim final regulations provide that when the

Participant Disclosure is received by participants when their informed consent is sought, no additional disclosures are required for purposes of the GINA research exception.

- The plan or issuer must make the request in writing and must clearly indicate to each participant or beneficiary (or in the case of a minor child, to the legal guardian of such beneficiary) to whom the request is made that compliance with the request is voluntary and noncompliance will have no effect on eligibility for benefits or premium or contribution amounts.

- None of the genetic information collected or acquired as a result of the research may be used for underwriting purposes.

- The plan or issuer must complete a copy of the "*Notice of Research Exception under the Genetic Information Nondiscrimination Act*" (the Notice) and provide it to the address specified in its instructions. The Notice and instructions are available on the Department of Labor's website (**http://www.dol.gov/ebsa**).

The Participant Disclosure and the Notice are the information collection requests (ICRs) contained in the interim final rules.

2. *Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.*

The information provided on the Notice will be used to notify EBSA of the group health plans or issuers that are taking advantage of GINA's research exemption and to provide EBSA with information about the research program.

3. *Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration for using information technology to reduce burden.*

The Notice will be available on the Department's website, and the Department will provide the capability for applicants to file their Notices electronically.

4. *Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above.*

There is no duplication of information. The Department consulted with the Secretary of Health and Human Services (HHS), who is responsible for receiving Notices from issuers in the

individual health insurance market, in designing the Notice, and HHS will be using a similar Notice.

5. *If the collection of information impacts small businesses or other small entities (Item 5 of OMB Form 83-I), describe any methods used to minimize burden.*

The information collection does not impact small businesses or entities.

6. *Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.*

If the information collection is not conducted, the Department will not have sufficient information to determine whether group health plans or issuers in the group health insurance market are in compliance with the requirements of GINA's research exception.

7. *Explain any special circumstances that would cause an information collection to be conducted in a manner:*

- *requiring respondents to report information to the agency more often than quarterly;*
- *requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;*
- *requiring respondents to submit more than an original and two copies of any document;*
- *requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;*
- *in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;*
- *requiring the use of a statistical data classification that has not been reviewed and approved by OMB;*
- *that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or*
- *requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.*

None.

8. *If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the agency in response to these comments. Specifically address comments received on cost and hour burden.*

Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.

Consultation with representatives of those from whom information is to be obtained or those who must compile records should occur at least once every 3 years -- even if the collection of information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.

On October 10, 2008, the Departments published in the Federal Register (73 FR 60208) a request for information (RFI) soliciting comments on the requirements of sections 101 through 104 of GINA. In addition, the Departments consulted with and obtained technical guidance from the scientific community, including the National Human Genome Research Institute within the National Institutes of Health (NIH) and the Office for Human Research Protections, both within HHS. The Departments also coordinated with the Equal Employment Opportunity Commission, which has responsibility for Title II of GINA, and the Office for Civil Rights within HHS, which has responsibility for Section 105 of GINA.

9. *Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.*

None.

10. *Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.*

Not applicable

11. *Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.*

Not applicable.

12. *Provide estimates of the hour burden of the collection of information. The statement should indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. Unless directed to do so, agencies should not conduct special surveys to obtain information on which to base hour burden estimates. Consultation with a sample (fewer than 10) of potential respondents is desirable. If the hour burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated hour burden, and explain the reasons for the variance. Generally, estimates should not include burden hours for customary and usual business practices.*

- *If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens in Item 13 of OMB Form 83-I.*
- *Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories. The cost of contracting out or paying outside*

parties for information collection activities should not be included here. Instead, this cost should be included in Item 14.

- *The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included in Item 14.*

The Department estimates that up to three entities will take advantage of the research exception, and that all of the entities will comply with the requirements of 45 CFR Part 46, including providing the participant disclosure.[1] The Department is not soliciting comments concerning an ICR pertaining to the participant disclosure, because the interim final regulations provide that group health plans and group health insurance issuers meeting the informed consent requirements of 45 CFR Part 46, which are discussed under Item 1, above, are not required to provide additional disclosures, and the Department has assumed that all entities using the research exemption will meet these requirements. The costs and burdens associated with complying with the participant disclosure requirement already are accounted for under the Department of Health and Human Service's OMB Control Number (0990-0260) for the informed consent requirements under 45 CFR Part 46.

The Department estimates that completing and mailing the Notice will require15 minutes of clerical time at an hourly rate of $26 per hour. Therefore, the total hour burden associated with completing the Notice is estimated to be .75 hours of clerical time with an equivalent cost of $20.

13. *Provide an estimate of the total annual cost burden to respondents or record-keepers resulting from the collection of information. (Do not include the cost of any hour burden shown in Items 12.)*

The cost burden associated with this ICR consists of material and mailing cost to mail three two-page Notices and is estimated to total $10.

14. *Provide estimates of annualized cost to the Federal government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information. Agencies also may aggregate cost estimates from Items 12, 13, and 14 in a single table.*

Not applicable.

15. *Explain the reasons for any program changes or adjustments reporting in Items 13 or 14 of the OMB Form 83-I.*

Not Applicable.

1 **Comments to the RFI indicated that at least one issuer is engaging in a long-term research study involving genetic testing. The Department's estimated takes into account that others may be planning similar research.**

16. *For collections of information whose results will be published, outline plans for tabulation, and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.*

There are no plans to publish the results of this collection of information.

17. *If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.*

The OMB expiration date will be published in the Federal Register following OMB approval.

18. *Explain each exception to the certification statement identified in Item 19, "Certification for Paperwork Reduction Act Submission," of OMB 83-I.*

None.

B. Collections of Information Employing Statistical Methods

Not applicable.