SUPPORTING STATEMENT FOR PAPERWORK REDUCTION ACT OF 1995: NOTICE OF RESEARCH EXCEPTION UNDER THE GENETIC INFORMATION NONDISCRIMINATION ACT

This ICR seeks approval for an extension of an existing control number.

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 (the 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 2590.702-1, 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, it does establish rules that generally prohibit a group health plan and a health insurance issuer in the group market from:

- adjusting group premium or contribution amounts based on genetic information;
- requesting or requiring a covered individual, an individual seeking coverage, or a family member of those individuals 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 2590.702-1(c)(5)) provide an exception to the limitations on requesting or requiring genetic testing that allows 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, 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 specified address. The Notice and the address are available on the Department of Labor's website (https://www.dol.gov/agencies/ebsa/employers-and-advisers/plan-administration-and-compliance/health-plans/notice-of-research-exception-under-gina).

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 in the Participant Disclosure will be used to inform prospective research participants of their rights under GINA. The information provided in the Notice will be used to notify EBSA of the group health plans or issuers that are taking advantage of GINA's research exception 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. For this information collection, the Department assumes that plans or issuers will distribute disclosures by mail, as reflected in Question 13.

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 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.**

There are no special circumstances that require the collection to be conducted in a manner inconsistent with the guidelines in 5 CFR 1320.5.

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 July 9, 2024, the Department published in the *Federal Register* (89 FR 56416) the notice announcing its intention to request extension of OMB's approval of this information collection. The notice solicited public comment on the extension and provided 60 days for such purpose, as required by 5 CFR 1320.8(d). No comments were received.

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

No payments or gifts are provided to respondents.

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

There is no assurance of confidentiality provided to respondents.

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.

There are no questions of a sensitive nature.

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.**
- **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.**

Based on the number of submissions made to the Department over the last three years, the Department estimates that, on average, 35 entities will take advantage of the research exception annually, and that all of the entities will comply with the requirements of 45 CFR Part 46, including providing the participant disclosure. The entities must complete a copy of the Notice and provide it to the specified address. The Notice and the address are available on the Department of Labor's website:

(https://www.dol.gov/agencies/ebsa/employers-and-advisers/plan-administration-and-compliance/health-plans/notice-of-research-exception-under-gina).

The Department assumes that preparing and mailing the Notice will require 15 minutes of clerical time. at an hourly rate of $69.41 per hour.[1] See Table 1 for calculations and burden totals.

The burdens associated with complying with the participant disclosure requirement are accounted for in the information collection request for the informed consent requirements contained in 45 CFR Part 46 approved under the Department of Health and Human Services' OMB Control Number (0990–0260).

Table 1. Estimated Annualized Respondent Cost and Hour Burden

Activity	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden (Hours)	Total Burden (Hours)	Hourly Wage Rate	Equivalent Cost of Hour Burden
Clerical staff preparing and mailing disclosure	35	1	35	15/60	9	$69.41	$607
Unduplicated Totals	**35**	**1**	**35**	**-**	**9**	**--**	**$607**

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 or 14).

- **The cost estimate should be split into 2 components: (a) a total capital and start up cost component (annualized over its expected useful life); and (b) a total operation and maintenance and purchase of service component. The estimates should take into account costs associated with generating, maintaining, and disclosing or providing the information. Include descriptions of methods used to estimate major cost factors including system and technology acquisition, expected useful life of capital equipment, the discount rate(s), and the time period over which costs will be incurred. Capital and start-up costs include, among other items, preparations for collecting information such as purchasing computers and**

1 Internal DOL calculation based on 2024 labor cost data. For a description of the DOL's methodology for calculating wage rates, see https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/rules-and-regulations/technical-appendices/labor-cost-inputs-used-in-ebsa-opr-ria-and-pra-burden-calculations-june-2019.pdf.

software; monitoring, sampling, drilling and testing equipment; and record storage facilities.

- **If cost estimates are expected to vary widely, agencies should present ranges of cost burdens and explain the reasons for the variance. The cost of purchasing or contracting out information collection services should be a part of this cost burden estimate. In developing cost burden estimates, agencies may consult with a sample of respondents (fewer than 10), utilize the 60-day pre-OMB submission public comment process and use existing economic or regulatory impact analysis associated with the rulemaking containing the information collection, as appropriate.**
- **Generally, estimates should not include purchases of equipment or services, or portions thereof, made: (1) prior to October 1, 1995, (2) to achieve regulatory compliance with requirements not associated with the information collection, (3) for reasons other than to provide information or keep records for the government, or (4) as part of customary and usual business or private practices.**

The Department assumes a distribution cost of on average $5.68 per notice ($4.85 + $0.73 + $0.05 x 2 pages). This includes the actual cost of distribution, which is $4.85 for certified mail, $0.73 for postage, and any overhead costs associated with printing the documentation.[2] The Department assumes material and printing cost is $0.05 and that the notice is approximately two pages. See Table 2 for calculations and burden totals.

Table 2. Cost Burden: Materials and Mailing Cost

	Number of Notices Sent by Mail	Paper and Printing Costs	Certified Mail	Postage	Cost Burden
	(A)	(B)	(C)	(A x B x C)	(A x (B + C + D))
Mail distribution of disclosures	35	$0.10	$4.85	$0.73	$199
Total	**35**	-	-	-	**$199**

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

2 The cost of certified mail is $4.85 and the cost for a first-class postage stamp is $0.73. For more information on mailing rates, see at https://www.simplecertifiedmail.com/usps-postal-rates/#:~:text=New%20USPS%20prices%20will%20start,$0.69%20when%20using%20SimpleCertifiedMail.com

collection of information. Agencies also may aggregate cost estimates from Items 12, 13, and 14 in a single table.

There are no costs to the Federal government.

15. Explain the reasons for any program changes or adjustments reporting in Items 13 or 14.

There have been no program changes since the last submission. The average annual number of companies requesting genetic research disclosure has decreased by 13 responses. The labor rates and postage costs have also been adjusted. As a result, the hour burden has decreased by three hours and cost burden has decreased by $14.

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.

There are no exceptions to the certification statement identified in Item 19.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

There are no statistical methods used in this information collection.