**Supporting Statement – Part A**
**Notice of Research Exception under the Genetic Information Nondiscrimination Act**
**(OMB Control No. 0938-1077)**

## A. Background

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 104 of Title I of GINA prevent employment-based group health plans, health insurance issuers in the group and individual markets, and issuers of Medicare supplemental (Medigap) policies from discriminating based on genetic information.

Under GINA, group health plans and health insurance issuers in the group, individual and Medigap markets (i.e., insurance companies or health maintenance organizations (HMOs)) cannot collect (defined in the regulations to mean "request, require, or purchase") genetic information for underwriting purposes or prior to or in connection with an individual's enrollment under the plan or coverage. With a few limited exceptions, plans and issuers are also prohibited from requesting or requiring an individual or family member to undergo a genetic test.

One of the exceptions to the prohibition from requesting or requiring an individual (or family member) to undergo a genetic test is the research exception. A plan or issuer may request (but not require) a genetic test in connection with certain research activities so long as such activities comply with specific requirements, including: (i) the research complies with 45 CFR part 46 or equivalent federal regulations and applicable State or local law or regulations for the protection of human subjects in research; (ii) the request for the participant or beneficiary (or in the case of a minor child, the legal guardian of such beneficiary) is made in writing and clearly indicates that compliance with the request is voluntary and that non-compliance will have no effect on eligibility for benefits or premium or contribution amounts; and (iii) no genetic information collected or acquired will be used for underwriting purposes.

The Secretary of Labor or the Secretary of Health and Human Services is required to be notified if a group health plan or health insurance issuer intends to claim the research exception permitted under Title I of GINA. Group health plans of private employers, issuers in group health insurance market, and issuers in the group as well as individual and/or Medigap markets will be required to notify the Department of Labor. Nonfederal governmental group health plans and issuers solely in the individual health insurance or Medigap market will be required to file with the Centers for Medicare & Medicaid Services (CMS).

The Notice of Research Exception under the Genetic Information Nondiscrimination Act (the Notice) is a model notice that can be completed by group health plans and health insurance issuers and filed with either the Department of Labor or CMS to comply with the notification requirement.

## B. Justification

1 . Need and Legal Basis

The Notice must be used by nonfederal governmental group health plans and by issuers solely in the individual health insurance market and/or Medigap market to file the required information with CMS as mandated by sections 2702(c)(4)(D) and 2753(d)(4)(D) of the Public Health Service Act. This information collection will permit CMS to track those health insurance issuers that are conducting genetic research and must comply with the genetic research requirements of GINA.

2. Information Users

The Notice must be submitted by mail to CMS by nonfederal group health plans and issuers solely in the individual health insurance market and /or Medigap market who are conducting genetic research and are requesting individual beneficiaries to participate in genetic testing.

3. Use of Information Technology

Information will not be collected electronically. The hard copy forms submitted by mail and are required to be signed.

4. Duplication of Efforts

There is no duplication of effort regarding the Notice. Staff from CMS has coordinated with staff from the Departments of the Treasury and Labor in developing the Notice. Group health plans of private employers, issuers in group health insurance market, and issuers in the group market as well as the individual and/or Medigap markets will be required to file the Notice with the Department of Labor. Nonfederal governmental group health plans and issuers solely in the individual health insurance market and/or Medigap market will be required to file with CMS.

5. Small Businesses

The information collection does not impose any burden on small businesses or entities.

6. Less Frequent Collection

This is a one-time collection. If the information collection is not conducted, CMS will not be notified as to which nonfederal governmental plans and issuers in the individual or Medigap market are conducting genetic research in a manner that is in compliance with GINA.

7. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

A Federal Register notice was published on May 3, 2013 (78 FR 26035), providing the public with a 60-day period to submit written comments on the information collection requirement (ICR). No comments were received.

9. Payments/Gifts to Respondents

No payments or gifts are associated with this ICR.

10. Confidentiality

No personal identifiable information is being collected. CMS will protect privacy of the information provided to the extent provided by law.

11. Sensitive Questions

This ICR involves no sensitive questions.

12. Burden Estimates (Hours & Wages)

The burden estimates have been updated based on recent data on labor and mailing costs. We generally used data from the Bureau of Labor Statistics to derive average labor costs (including fringe benefits) for estimating the burden associated with the ICR.

CMS estimates that up to two such 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.

CMS also estimates that completing and mailing the Notice will require 15 minutes of clerical time at an hourly rate of approximately $31 per hour. Therefore, the total hour burden associated with completing the Notice is estimated to be 0.5 hours of clerical time. The cost of materials (paper and ink) for each two page Notice is estimated to be $0.10 and mailing

cost is $0.46 for each Notice. The total cost burden including material and mailing costs is estimated to be approximately $16.

13. Capital Costs

    There is no capital cost associated with this collection.

14. Cost to Federal Government

    There is no cost to the federal government.

15. Changes to Burden

    There are no changes to burden.

16. Publication/Tabulation Dates

    There are no publication or tabulation dates associated with these ICRs

17. Expiration Date

    There is no expiration date for this collection requirement.

18. Certification Statement

    There are no exceptions to the certification.