



Instructions to the Notice of Research Exception under the Genetic Information Nondiscrimination Act

I. Introduction.

This notice is required to be provided if a group health plan or health insurance issuer intends to claim the research exception permitted under Title I of the Genetic Information Nondiscrimination Act of 2008 (GINA). Under GINA, a plan or issuer generally may not request or require an individual or family member to undergo a genetic test. However, 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.

If there is no group health plan or health insurance issuer involved in the research, this form is not required to be filed.

II. Definitions

“Church Plan”

In general, a church plan is a plan established or maintained for its employees or their beneficiaries by a church or by a convention or association of churches that is exempt from tax under section 501 of the Internal Revenue Code (Code).

“Employer Identification Number” or “EIN”

An EIN is a nine-digit employer identification number (for example, 00-1234567) that has been assigned by the Internal Revenue Service (IRS). Entities that do not have an EIN should apply for one on Form SS-4, Application for Employer Identification Number as soon as possible. You can obtain Form SS-4 by calling 1-800-829-4933 or at the IRS Web site at www.irs.gov.

“Group Health Insurance Coverage”

Group health insurance coverage means health insurance coverage offered in connection with a group health plan.

“Group Health Plan”

In general, a group health plan means an employee welfare benefit plan to the extent that the plan provides benefits for medical care to employees (including both current and former employees) or their dependents (as defined under the terms of the plan) directly or through insurance, reimbursement, or otherwise. See section 733(a) of the Employee Retirement Income Security Act (ERISA) and 29 CFR 2590.732(a). See also section 5000(b)(1) of the Code.

“Health Insurance Coverage”

Health insurance coverage means benefits consisting of medical care (provided directly, through insurance or reimbursement, or otherwise) under any hospital or medical service policy or certificate, hospital or medical service plan contract, or HMO contract offered by a health insurance issuer. Health insurance coverage includes group health insurance coverage and individual health insurance coverage.

“Health Insurance Issuer” or “Issuer”

The term “health insurance issuer” or “issuer” is defined, in pertinent part, in 29 CFR 2590.701-2 as “an insurance company, insurance service, or insurance organization (including an HMO) that is required to be licensed to engage in the business of insurance in a State and that is subject to State law which regulates insurance....Such term does not include a group health plan.”

“Individual Health Insurance Coverage”

Individual health insurance coverage means health insurance coverage offered to individuals in the individual market, but does not include short-term, limited duration insurance. Individual health insurance coverage can include dependent coverage.

“Nonfederal Governmental Plan”

Nonfederal governmental plan means a governmental plan that is not a Federal governmental plan.

“Medigap Coverage”

Medigap coverage means Medicare supplemental insurance coverage offered to individuals enrolled in Original Medicare.

“Plan Number” or “PN”

A PN is a three-digit number assigned to a plan or other entity by an employer or plan administrator. For plans or other entities providing welfare benefits, the first plan number should be number 501 and additional plans should be numbered consecutively.

“Underwriting Purposes”

Underwriting purposes, with respect to any group health plan, or health insurance coverage offered in connection with a group health plan—

- Rules for, or determination of eligibility (including enrollment and continued eligibility) for benefits under the plan or coverage;
- The computation of premium or contribution amounts under the plan or coverage;
- The application of any preexisting condition exclusion under the plan or coverage; and
- Other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.

III. Where to File.

- A. Church Plans. A church plan (as defined in section 414(e) of the Code) claiming the research exception must provide this notice to the IRS at:

Internal Revenue Service
Cincinnati Compliance Services (CEO)
Attn: MS 8100G
201 West Rivercenter Blvd
Covington, KY 41011

- B. Group Health Plans and Issuers Subject to ERISA. A group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, subject to Part 7 of Subtitle B of Title I of ERISA claiming the research exception for any genetic testing request must provide notice to the Department of Labor at:

Public Disclosure Office, EBSA
Room N-1513, U.S. Department of Labor
200 Constitution Avenue, N.W.
Washington, DC 20210

- C. Nonfederal Governmental Plans. A group health plan that is a nonfederal governmental plan claiming the research exception, or a health insurance issuer claiming this exception in connection with the provision of group health insurance coverage provided only to nonfederal governmental plans, must provide notice to the Department of Health and Human Services at:

Centers for Medicare & Medicaid Services
Center for Consumer Information & Insurance Oversight
Room 739H
200 Independence Avenue, SW
Washington, DC 20201

- D. Health Insurance Issuers Claiming the Exception Only for Individual Insurance Coverage or Only for Medigap coverage or for Both Individual Insurance Coverage and Medigap Coverage. A health insurance issuer claiming the research exception in connection with the provision of health insurance coverage provided only in the individual insurance market or the Medigap market or both, must provide notice to the Department of Health and Human Services at:

Centers for Medicare & Medicaid Services
Center for Consumer Information & Insurance Oversight
Room 739H
200 Independence Avenue, SW
Washington, DC 20201

- E. Health Insurance Issuers Claiming the Exception for Only Group Insurance Coverage or for Group and Individual Insurance Coverage and/or Medigap Coverage. A health insurance issuer claiming the research exception in connection with the provision of health insurance coverage provided only in the group market, or health insurance

coverage provided in the group as well as individual and/or Medigap markets, must provide notice to the Department of Labor at:

Public Disclosure Office, EBSA
Room N-1513, U.S. Department of Labor
200 Constitution Avenue, N.W.
Washington, DC 20210

IV. When to File.

A plan or issuer claiming the research exception must file at least 60 days prior to the date the first request is made to a participant or beneficiary to undergo a genetic test.

V. Attaching Additional Pages

For paper filings, if more space is needed to complete any item on the Notice of Research Exception, additional pages may be attached. Additional pages must be the same size as this form (8 ½" x 11") and should include the name of the entity claiming exception, the title of the research project, the item number, and the word "Attachment" in the upper right corner. In addition, the attachment for any item should be in a format similar to that item on the form.

If filing online, these additional pages may be uploaded online at the Web filing site.

VI. Line-by-Line Instructions

Part I: Entity Classification and Identification

Item 1: Enter the date this filing is being submitted.

Item 2: Check either box 2(A) or box 2(B).

Box 2(A): Check this box if the entity claiming the research exception is a group health plan. (See Section II for the definition of a group health plan.)

Box 2(B): Check this box if the entity claiming the research exception is a health insurance issuer. (See Section II for the definition of a health insurance issuer.)

If you checked box 2(A), complete item 3 and skip item 4. If you checked box 2(B), skip item 3 and complete item 4.

Item 3: If you checked box 2(A), check one of the following: box 3(A), box 3(B), or box 3(C).

Box 3(A): Check this box if the entity is a group health plan subject to Part 7 of Title I of ERISA. (See Section II for a discussion of plans subject to Part 7 of Title I of ERISA.)

Box 3(B): Check this box if the entity is a group health plan that is a church plan (See Section II for the definition of a church plan.)

Box 3(C): Check this box if the entity is a group health plan that is a nonfederal governmental plan. (See Section II for the definition of a nonfederal governmental plan.)

Item 4: If you checked box 2(B), check one of the following: box 4(A), box 4(B), or box 4(C).

Box 4(A): Check this box if the entity is a health insurance issuer claiming the exception in connection with the provision of group health insurance coverage only.

Box 4(B): Check this box if the entity is a health insurance issuer claiming the exception in connection with the provision of individual health insurance coverage only.

Box 4(C): Check this box if the entity is a health insurance issuer claiming the exception in connection with the provision of Medigap coverage only.

Box 4(D): Check this box if the entity is a health insurance issuer claiming the exception in connection with the provision of both individual health insurance and Medigap coverages.

Box 4(E): Check this box if the entity is a health insurance issuer claiming the exception in connection with group as well as individual health insurance coverage and/or Medigap coverage.

Items 5a through 5d: Enter the name, address, and telephone number of the entity claiming the research exception, and any EIN or PN used by the entity in reporting to the Department of Labor or the Internal Revenue Service. If the entity does not have any EINs associated with it, leave item 5c blank. If the entity does not have any PNs associated with it, leave item 5d blank. For more information on EINs or PBs, see Section II on Definitions.

Part II: Research Project Information

Item 6: Provide the title of the research project.

Item 7: Provide the name of the principal investigator for the research project.

Item 8: Provide the research project number, if available.

Part III: Attestation of Compliance with the Requirements of the Research Exception

Sign the attestation, certifying compliance with the requirements of the research exception and declaring the contents of the filing true and correct. Type or print the relevant contact information.

Paperwork Reduction Act Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless such collection displays a valid OMB control number. The valid OMB control number for this information collection is **0938-1077**. The time required to complete this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, gathering the data needed, and completing and reviewing the collection of information. The obligation to respond to this collection is required to obtain or retain a benefit (*see* sections 102(a)(2) and (b)(1)(B) of the Genetic Information Nondiscrimination Act, P.L. 110-233). Please send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850 and reference the OMB Control Number. **Note:** Please do not return the completed application to this address.



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PART I: Entity Classification and Identification

1. Date of submission: _____

2. Specify whether the entity claiming the research exception is:
 - (A) A group health plan (plan); or
 - (B) A health insurance issuer (issuer).

3. If the entity is a plan (as designated in Box 2A), is the plan:
 - (A) A plan subject to Part 7 of Title I of ERISA;
 - (B) A church plan; or
 - (C) A nonfederal governmental plan.

4. If the entity is an issuer (as designated in Box 2B), is the issuer claiming the exception in connection with the provision of:
 - (A) Group health insurance coverage only;
 - (B) Individual health insurance coverage only;
 - (C) Medigap coverage only;
 - (D) Both individual health insurance coverage and Medigap coverage; or
 - (E) Group as well as individual health insurance coverage and/or Medigap coverage.

5a. Name and address of the entity claiming the exception:

5b. Telephone number of the entity claiming the exception:

5c. Employer Identification Number (EIN) of the entity claiming the exception:

5d. If the entity is a plan (as designated in Box 2A), specify plan number:

PART II: Research Project Information

6. Title of the research project:

7. Name of the principal investigator:

8. Research project number (if available):

Part III: Attestation of Compliance with the Requirements of the Research Exception

With respect to the research project described in Part II, I attest that the following is true:

- (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) each request of a participant or beneficiary (or in the case of a minor child, the legal guardian of such beneficiary) to undergo genetic testing as part of the research will be made in writing and clearly indicate 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 through this research will be used for underwriting purposes.*

Under penalty of perjury, I declare that I have examined this notice, including any accompanying attachments, and to the best of my knowledge and belief, it is true and correct. Under penalty of perjury, I also declare that this notice is complete.

Signature: _____ Date: _____

Type or print name, address, and telephone number:

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