Notice of Research Exception
Under
The Genetic Information Nondiscrimination Act

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; or

(C) □ Both group and individual health insurance 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:

_____
_____
_____
_____
_____

Paperwork Reduction Act Statement

According to the Paperwork Reduction Act of 1995 (Pub. L. 104-13) (PRA), no persons are required to respond to a collection of information unless such collection displays a valid Office of Management and Budget (OMB) control number. The Department notes that a Federal agency cannot conduct or sponsor a collection of information unless it is approved by OMB under the PRA, and displays a currently valid OMB control number, and the public is not required to respond to a collection of information unless it displays a currently valid OMB control number. See 44 U.S.C. 3507. Also, notwithstanding any other provisions of law, no person shall be subject to penalty for failing to comply with a collection of information if the collection of information does not display a currently valid OMB control number. See 44 U.S.C. 3512.

The public reporting burden for this collection of information is estimated to average approximately 15 minutes per respondent. Interested parties are encouraged to 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 Labor, Office of the Chief Information Officer, Attention: Departmental Clearance Officer, 200 Constitution Avenue, N.W., Room N-1301, Washington, DC 20210 or email DOL_PRA_PUBLIC@dol.gov and reference the OMB Control Number 1210-0136.

OMB Control Number 1210-0136 (expires 07/31/2028)