

DATA USE AGREEMENT

This data use agreement (“Agreement”) is effective upon execution, and is entered into by and between the National Institute for Occupational Safety and Health (NIOSH), an agency of the Centers for Disease Control and Prevention (“Data Recipient”) and **NAME OF DATA PROVIDER** (“Data Provider”).

Data Provider and Data Recipient mutually agree to enter into this Agreement to comply with any applicable requirements of the Amended Privacy Rule, 45 Code of Federal Regulations (“CFR”) § 164.514 (e), issued pursuant to the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”).

1. Provision of Limited Data Set.

a. Upon Data Recipient’s execution of this Agreement, the Data Provider will provide Data Recipient a “Limited Data Set” containing the certain necessary Protected Health Information (“PHI”) reasonably appropriate for the purposes for which Data Recipient is to receive the “Limited Data Set” as set out in Section 2 of this Agreement.

b. The “Limited Data Set” will contain all the past and current audiometric data from those workers who were tested one or more times by the Data Provider, **ending on December 31, 2012.**

c. A list of client companies will be sent to Data Recipient for industry coding. The list along with the industry codes will be sent back to Data Provider. The Data Provider will notify the Data Recipient when the industry codes have been successfully merged into the dataset. At this point, the Data Recipient will destroy all copies of the list of client companies unless otherwise required under Federal law. Furthermore, while in possession of the list of client companies, the Data Recipient will not disclose the list to anyone except with project staff who are involved with assigning industry codes, or as required by law. Then, Data Provider will merge the industry codes with the audiometric data.

d. All personal identifiers will be removed by the Data Provider from the “Limited Data Set”.

2. Data Recipient’s Permitted Uses and Disclosures.

a. The Data Recipient may use and disclose the “Limited Data Set” for the following purposes solely in connection with research or public health as described below:

(1) The “Limited Data Set” shall be used and disclosed solely in connection with a study entitled "National Surveillance of Occupational Hearing Loss"

which will estimate the incidence/prevalence rate of occupational hearing loss and the average change in hearing ability per year by industry and identify workplace characteristics associated with a high risk of occupational hearing loss (the “Study”).

(2) An intended product of this Agreement is to produce reports of prevalence/incidence of occupational hearing loss by industry sectors, presentations, and manuscripts for publication in the peer reviewed scientific literature.

(3) Analysis will be conducted by the Data Recipient pursuant to Section 4 below.

3. Data, Publications and Other Rights.

a. In recognition of the importance of disseminating information relating to important observations or results arising from the Study and understanding that such need shall be balanced with the Data Recipient’s obligations to the Data Provider to maintain control over Confidential Information received from the Data Provider, as well as to comply with any applicable HIPAA requirements, the Parties further agree as follows:

(1) All information included in the “Limited Data Set” provided by the Data Provider during the course of or as a result of the Agreement shall be the Property of the Data Provider. Such information shall be marked, or accompanied by a written designation, as “confidential,” “trade secret,” or “privileged,” as appropriate.

(2) Subject to the terms and conditions of this Agreement, the Parties shall have the right to publish or publicly present the results of the Study. Data Provider shall have the right to review and comment on Data Recipient’s proposed reports, presentations, and publications resulting from this study, including review for trade secret information, but in no case shall the Data Recipient abandon its right to publish information resulting from the expenditures of public funds or the use of public facilities.

b. All information submitted for publication or other public releases of information by Data Provider regarding this project shall carry the following disclaimer:

The views and conclusions contained in this document are those of the authors and should not be interpreted as representing the opinions or policies of the U.S. Government. Mention of trade names or commercial products does not constitute their endorsement by the U.S. Government.

c. Data Provider must obtain prior Government approval for any public information releases concerning the Agreement which refer to Data Recipient or one of its employees (by name or title). The specific text, layout photographs, etc. of the proposed release must be submitted with the request for approval. Governmental approval or disapproval of any request by the Data Provider shall not be unreasonably delayed.

4. Prohibition on Unauthorized Use or Disclosure.

a. Data Recipient shall not use or disclose the “Limited Data Set” for any purpose other than as permitted by Section 2 of this Agreement unless otherwise permitted in writing by the Data Provider or as otherwise required by law.

b. Data Recipient is not authorized to use or disclose the “Limited Data Set” in a manner that would violate the Amended Privacy Rule, 45 CFR Part 164, Subpart E, if done by Data Provider.

c. Data Recipient shall not attempt to identify the individuals whose PHI is contained in the “Limited Data Set” or contact any individual who may be subject of information contained in the “Limited Data Set”.

d. Data Recipient agrees that it will not use or disclose the identity of Data Provider or any of its employees (by name or title) in any publication, presentation or release of information to the public relating to this Agreement or the Study without Data Provider’s prior written consent, unless otherwise required to by law.

e. Data Recipient agrees that it will treat the information specifically described in Section 4, subsections a. through d. of this Agreement as covered by one or more of the exemptions at 45 CFR §5, Subpart F, except that Data Recipient will disclose such information if required by law. No disclosures under the Freedom of Information Act will be made without a careful and exacting evaluation by Data Recipient giving due regard to the need for safeguarding material considered by Data Provider to be privileged or confidential. Pursuant to 45 CFR §5.65, Data Recipient will provide advance notice of a decision to disclose information designated as privileged or confidential, so that Data Provider will have an opportunity to object to such disclosure.

5. Permitted Recipients. Researchers within the Surveillance Branch of the Division of Surveillance, Hazard Evaluations, and Field Studies at NIOSH and other investigators and analysts employed by the Data Recipient are permitted to receive and use the “Limited Data Set” provided that they agree to the same restrictions and conditions that apply to the Data Recipient’s use and disclosure of the “Limited Data Set” under this Agreement.

6. Information Safeguards. Data Recipient shall adopt and use appropriate administrative, physical and technical safeguards to preserve the integrity and confidentiality of the “Limited Data Set” and prevent its use or disclosure other than as permitted by Section 2 of this Agreement or as otherwise required by law.

7. Breach of Privacy Obligations.

a. Reporting. Data Recipient will report to Data Provider any use or disclosure of the “Limited Data Set” not permitted by this Agreement. Data Recipient will make the report to Data Provider within five (5) business days after the Data

Recipient learns of such non-permitted use or disclosure. Data Recipient's report shall at a minimum include the following:

- (1) Identify the nature of the non-permitted use or disclosure;
- (2) Identify the Limited Data Set content used or disclosed;
- (3) Identify who made the non-permitted use or disclosure and who received the non-permitted disclosure;
- (4) Identify what corrective action Data Recipient took or will take to prevent further non-permitted uses or disclosures;
- (5) Identify what Data Recipient did or will do to mitigate any deleterious effect of the non-permitted use or disclosure; and
- (6) Provide such information, including a written report, as Data Provider may reasonably request.

b. Termination. The Data Provider or the Data Recipient may terminate this Agreement at any time by providing written notice of termination. Any such termination will be effective at such date specified in the notice of termination. The provisions of Sections 3, 4 and 9 of this Agreement shall survive termination of this Agreement.

8. Expiration. This Agreement will expire on December 31, 2020. For a period of ten years after Data Recipient's receipt of information described in Sections 3, 4 and 9 (unless a longer period is required by law), those sections shall survive expiration of this Agreement.

9. Return of Limited Data Set.

a. Upon termination or expiration of this Agreement, Data Recipient shall, if feasible, return to Data Provider or destroy the "Limited Data Set," including all copies of the "Limited Data Set" and any derivative work from the "Limited Data Set" that may allow identification of any individual whose information is contained in the "Limited Data Set", in whatever form or medium (including in any electronic medium under Data Recipient's custody or control) in which Data Recipient has retained it.

b. The Data Recipient shall complete such return or destruction as promptly as possible, but not later than forty-five (45) days after the effective date of the termination or expiration of this Agreement, and will within these forty-five (45) days certify in writing to the Data Provider that such return or destruction has been completed.

c. If return or destruction is not feasible, the Data Recipient shall provide Data Provider with a written explanation as to why the return or destruction is not feasible, and shall certify in writing to Data Provider that the Data Recipient will neither use nor disclose the "Limited Data Set" for any purpose other than the purposes that are

