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, INC.** ("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, 2019, with the potential for future data updates.

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 project entitled "Occupational Hearing Loss Surveillance" (formerly

study entitled "National Surveillance of Occupational Hearing Loss") which will estimate the incidence/prevalence rate of occupational hearing loss, identify workplace characteristics associated with a high risk of occupational hearing loss, and perform other occupational hearing loss surveillance (the "Project").

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

(3) Another intended product of this Agreement is to post limited, aggregated data from the "Limited Data Set" to the Data Recipient's Internet page so that the data can be analyzed by other researchers. This limited, aggregated data will only include the following 21 data fields:

	Field	Description
1	NIOSH ID	Arbitrary unique number created by the Data Recipient and assigned to each worker
2	Age group	A field created by the Data Recipient, e.g., 18-25, 26-35, 36-45, 46-55, 56-65, 66-75
3	Gender	M, F
4	Geographical Region	A field created by the Data Recipient, e.g., Mid-Atlantic, Midwest, New England, South, Southwest, West
5	Test Date	DD/MM/YYYY
6	NAICS Code	North American Industry Classification System Code - 6-digit number indicating industry of the worker
7	NAICS Code Description	Industry title associated with the NAICS Code
8-14	Threshold Values - Right Ear	R 500, R 1,000, R 2,000, R 3,000, R 4,000, R 6,000, R 8,000
15-21	Threshold Values - Left Ear	L 500, L 1,000, L 2,000, L 3,000, L 4,000, L 6,000, L 8,000

No other data fields will be posted to the Data Recipient's Internet page without the Data Provider's prior written consent.

(4) 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 Project 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 Project. Data Provider shall have the right to review and comment on Data Recipient's proposed reports, presentations, and publications resulting from this Project, 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 Project 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 Health Informatics Branch of the Division of Field Studies and Engineering 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 take effect upon signature and will remain in effect unless cancelled by the Data Provider or the Data Recipient providing 30 days written notice. The provisions of Sections 3, 4 and 9 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 permitted under this Agreement and that make return or destruction of the "Limited Data Set" infeasible.

10. General Provisions.

a. Definitions. The capitalized terms "Protected Health Information," "Research," and "Required by Law" have the meanings set out in 45 CFR §164.501. The capitalized term "Limited Data Set" means PHI from which the identifiers specified in 45 CFR §164.514(e)(2) have been removed.

b. Amendment to Agreement. Upon the compliance date of any final regulation or amendment to a final regulation promulgated by the U.S. Department of Health and Human Services pursuant to the Administrative Simplification provisions of Title II, Subtitle F of the Health Insurance Portability and Accountability Act of 1996, with respect to a Limited Data Set this Agreement will automatically amend such that the obligations imposed on Data Recipient remain in compliance with the final regulation.

11. Conflicts. The terms and conditions of this Agreement shall override and control any conflicting term or condition of any agreement between the parties.

IN WITNESS WHEREOF, Data Provider and Data Recipient execute this Agreement in multiple originals to be effective on the last date written below.

DATA RECIPIENT

By: _____
Terri Schnorr, PhD Date
Director, Division of Field Studies and Engineering
National Institute for Occupational Safety and Health
Centers for Disease Control and Prevention

DATA PROVIDER

By: _____
President Name Date
President
DATA PROVIDER COMPANY NAME

I have read and agree to this data use agreement.
I will not divulge the data to persons not authorized to work on this project.
I will destroy all copies of the data in my possession according to the agreement.
I will follow NIOSH Sensitive Data Security Program guidelines regarding the safeguarding of electronic data and records.

_____
Marie Haring Sweeney Date
Chief, Health Informatics Branch

_____
Elizabeth A. Masterson Date
Project Officer