I. Introduction

The Human Health Exposure Analysis Resource (HHEAR) was established by the National Institute of Environmental Health Sciences (NIEHS) to provide analytical and laboratory services to support researchers who want to include environmental exposure assessment in their studies. The HHEAR Data Center ("Data Center") at the Icahn School of Medicine at Mount Sinai will provide a data repository for storing epidemiologic and biomarker data that was previously collected in an approved HHEAR research study and for all new biomarker data generated by the HHEAR National Exposure Assessment Laboratory Network ("Lab Hubs").

This agreement is for purposes of submitting data to the HHEAR Data Repository.

II. Definitions

The HHEAR data repository is designed to store the collection of data from participants in research studies related to children’s health. The HHEAR data repository will be housed at the Icahn School of Medicine at Mount Sinai. In order to take full advantage of such resources and maximize their research value, it is important that data be made available, on appropriate terms and conditions, to the largest possible number of qualified investigators in a timely manner.

All submitted data will be made available to researchers who have agreed to abide by the terms of the HHEAR Data Use Practices and HHEAR Publication Policy, after an embargo period, as publicly accessible de-identified datasets. The embargo period is intended to allow for sufficient time for submission of primary publications based on the Submitter’s (see below for definition) collected data. Investigators who collect the data have a legitimate interest in benefiting from their investment of time and effort.

For purposes of this agreement, "data" refers to the information which have been collected and recorded from participants in any study, regardless of the source of funding. For human subjects, data include, but are not limited to, all research and clinical assessments and information obtained via interviews, direct observations, biomarker data, records reviews, genetic and genomic data, psychophysiological assessments, data from physical examinations, etc. The following are not included as data: laboratory notebooks, preliminary analyses, drafts of scientific papers, plans for future research, peer review reports, communications with colleagues, or physical objects, such as gels or laboratory specimens.

A "Submitter" is defined as a researcher who has been approved by the Scientific Expert Panel (SEP) to submit data to the HHEAR Data Repository, according to the policies laid out in the HHEAR Data Repository Submission Agreement. The Submitter will always have access to all of their submitted study specific data.

III. Instructions

1. The Submitter must read the HHEAR Data Repository Data Submission Agreement (DSA) and complete and sign Section VII, Submitter Information and Certifications.

2. The signed DSA should be scanned and the electronic version should uploaded to the Submitter’s account on https://hhearprogram.org
IV. Terms and Conditions

I request approval to submit data to the HHEAR Data Repository to share data for research purposes. I agree to the following terms:

1. Research Project. These data will be submitted solely in connection with the "Research Project", specifically indicated and described in Section VII. Submitter Information and Certifications.

   This DSA covers only the Research Project as contemplated in Section VII. Submitter Information and Certifications and only for submission to the HHEAR Data Repository specified. Submitter will submit a completed DSA for each research project for which submission is requested.

2. Non-transferability of Agreement. This DSA is not transferable. Submitter agrees that substantive changes Submitter makes to the Research Project requires execution of a new DSA, in which the new Research Project is designated. If the Submitter changes institutions and wishes to retain submission privileges to the HHEAR Data Repository the Submitter must submit a new DSA in which the Submitter acknowledges and agrees to the provisions of the DSA.

3. Non-Identification of Subjects. Submitted data can be a limited data set (a limited data set may include city; state; ZIP Code; elements of date; and other numbers, characteristics, or codes not listed as direct identifiers but no other PHI) or a de-identified data set, so long as it is in accordance with the submitting institution’s policies and IRB. Submitter agrees not to disclose the identities of research participants to the HHEAR Data Repository.

4. Data Disclaimers. Submitter acknowledges that the HHEAR Data Center does not and cannot warrant the results that may be obtained by using any data included in the HHEAR Data Repository. The HHEAR Data Center disclaims all warranties as to the accuracy of the data in the HHEAR Data Repository or the performance or fitness of the data or data analysis tools for any particular purpose.

5. Supporting Materials. Submitter agrees to provide the HHEAR Data Repository with supporting information and documentation ("Supporting Materials") to enable efficient use of the submitted data by investigators unfamiliar with the data. These documents will be provided at the time of application process and by the time this data submission agreement is signed. Examples of supporting materials include:

   Data Dictionaries, codebooks
   Questionnaires
   Research protocols
   Study manuals

6. Data Accuracy. Submitter certifies to the best of his/her knowledge and belief that the data submitted to the HHEAR Data Repository are accurate. Submitter agrees to work with the Data Center Statistical core to ensure accuracy and quality of the data before biospecimen analyses commence. Submitter further agrees to notify the HHEAR Data Center as soon as
possible after submission if the Submitter discovers quality concerns in the data that are submitted.

7. Notification to HHEAR of Publication. Submitter agrees to promptly notify the HHEAR Coordinating Center via email at https://hhearprogram.org as to when and where a publication (or other public disclosure) from the Research Project will appear.

8. Data Access for research activities. Submitter agrees that data and Supporting Materials submitted to the HHEAR Data Repository can be accessed and used broadly for research purposes. The submitter will review and sign the Data Sharing Plan for the HHEAR Data Repository.

Non-sensitive data such as summary information on the HHEAR study, data aggregates, and description of measured variables, and experimental method are always available to the public. At any time after data submission, an approved HHEAR study PI (data contributor) can access their own study-specific data, including results from the Lab Hub. Similarly, at any time after data submission, the members of the Data Center team can access all submitted data. Study participant individual level data will not be made available to the public within the agreed upon embargo period. Embargoed data will be available only to the study PI (data contributor) and members of the Data Center within the embargo period.

The Submitter agrees that after an embargo period, all submitted data will be de-identified according to the following criterion: the identities of subjects cannot be readily ascertained or otherwise associated with the data by the repository staff or secondary data users (45 C.F.R.46.102(f)) and the de-identified data sets will be made available to researchers who have agreed to abide by the terms of the HHEAR Data Use Practices and Publication Policy. Data will be shared no later than the acceptance for first publication of the findings from the data set. Anyone who would like access to the publicly available de-identified datasets will register by completing a data user registration form on the website https://hheardatacenter.mssm.edu/.

9. Acknowledgments. In any and all oral and written presentations, disclosures, and publications (including abstracts, as space allows) based upon dataset(s) submitted to the HHEAR Data Repository, Submitter agrees to cite the HHEAR Network. Note that this is in addition to the acknowledgement of NIH support (http://grants.nih.gov/grants/acknow.htm) Sample acknowledgement text is provided:

Data used in the preparation of this article/presentation/etc. reside in the NIH-supported HHEAR Data Repository

10. Non-Endorsement; Liability. Submitter agrees not to claim, infer, or imply endorsement by the United States Government, the Department of Health & Human Services, the National Institutes of Health, or the National Institute of Environmental Health Science of the Research Project, the entity, or personnel conducting the Research Project or any resulting commercial product(s). The United States Government assumes no liability except to the extent provided under the Federal Tort Claims Act (28 U.S.C. § 2671-2680).

11. Submitter's Compliance with Institutional Requirements. Submitter acknowledges that these data were collected in a manner consistent with all applicable laws and regulations, as well as institutional policies. Submitter further acknowledges that the data were collected pursuant to
an informed consent that is consistent with the data submission. The submitter will have provided evidence of approval by their institutional IRB to deposit their data into the HHEAR Data Center repository. This approval will indicate that data submission and subsequent data sharing for research purposes are consistent with the informed consent of study participants from whom the data were obtained.

12. **Submitter’s Permission to Post Information Publicly.** Submitter agrees to permit the HHEAR Network to summarize and release for public use on the appropriate HHEAR Web site the Supporting Materials along with the Submitter’s name and organizations/institutional affiliation.

13. **Privacy Act Notification.** Submitter agrees that information collected from the Submitter, as part of the DSA, may be made public in part or in whole for tracking and reporting purposes. This Privacy Act Notification is provided pursuant to Public Law 93-579, Privacy Act of 1974, 5 U.S.C. Section 552a. Authority for the collection of the information requested below from the Submitter comes from the authorities regarding the establishment of the National Institutes of Health, its general authority to conduct and fund research and to provide training assistance, and its general authority to maintain records in connection with these and its other functions (42 U.S.C. 203, 241, 289I-1 and 44 U.S.C.3101), and Section 301 and 493 of the Public Health Service Act. These records will be maintained in accordance with the Privacy Act System of Record Notice 09-25-0156 covering “Records of Participants in Programs and Respondents in Surveys Used to Evaluate Programs of the Public Health Service, HHS/PHS/NIH/OD.” The primary uses of this information are to document, track, and monitor and evaluate the submission of data from clinical, basic, and population-based research activities and to notify Submitters in the event a potential error in the dataset is identified or in the event of updates or other changes to the database.

The Federal Privacy Act protects the confidentiality of the Submitter’s NIH records. The NIH will use the information collected for the purposes described above. In addition, the Act allows the release of some information in the Submitter’s records without the Submitter’s permission; for example, if it is requested by members of Congress or other authorized individuals. The information requested in the DSA is voluntary, but necessary for submitting data to the HHEAR Data Repository.


15. **Amendments.** Amendments to this DSA must be made in writing and signed by authorized representative.

**V. Information Security Best Practices and Security Standards**

The purpose of these Security Best Practices and Security Standards, which are subject to applicable law, is to provide security standards and best practices for individuals who use the HHEAR Data Repository to submit, access, and analyze data.

The Data Center Portal system shall be the access route to the repository for approved HHEAR study data. This data will be uploaded through the Portal by the HHEAR study PI and by the Lab Hub
performing the sample analysis. The Portal system and all associated data are kept on encrypted
secure servers on the Mount Sinai Hospital network, which has a higher level of security than the
Medical School network. All data will be encrypted. The Hospital network is audited by the Sinai
Security Department and undergoes a full IRB review of its protocols every year. The Data Repository
conforms to HIPAA and NYS Privacy regulations. The Data Center implementation of these provisions
is reviewed and approved by the Mount Sinai HIPAA/Privacy Officer.

Before any data are accepted by the Data Center, the HHEAR study PIs will have provided
evidence of approval by their institutional IRB to deposit their data, including biomarker data, into
the HHEAR Data Center repository. This approval will indicate that data submission and
subsequent data sharing for research purposes are consistent with the informed consent of study
participants from whom the data were obtained.

Keeping HHEAR Data Repository information secure through these best practices is of the utmost
importance. By signing this agreement, submitters agree to abide by the following Security Best
Practices. Subject to applicable law, Submitters agree to immediately report breaches of data
confidentiality to the HHEAR Data Repository.

Security Best Practices

- Do not attempt to override technical or management controls to access data for which you have not
  been expressly authorized.
- Do not use your trusted position and access rights to exploit system controls or access data for any
  reason other than in the performance of the proposed research.
- Do not allow others to use your account, including the data that you have accessed from the HHEAR
  Repository. Each user must obtain and use their own account in order to access HHEAR data.
- Ensure that anyone directed to use the system has access to, and is aware of, HHEAR Data
  Repository Information Security Best Practices and Security Standards as well as all existing policies
  and procedures relevant to the use of the HHEAR Data Repository, including but not limited to 45
  CFR Part 46.
- Follow the HHEAR Data Repository password policy which includes:
  - Choose passwords of at least seven characters including at least three of the following types of
    characters: capital letters, lower case letters, numeric characters and other special characters.
  - Change your passwords every six months.
  - Protect your HHEAR Data Repository password from access by other individuals—for example,
    store it electronically in a secure location.
- Notify the HHEAR Data Repository staff at: hhearsupport@mssm.edu of security incidents, or any
  incidents of suspected fraud, waste or misuse of the HHEAR Data Repository or when access to
  HHEAR Data Repository is no longer required.

Security Standards

- Protect the data, providing access solely to authorized researchers permitted access to such data
  by your institution.
- Neither store nor transmit links between personally identifiable information and HHEAR
  Participant IDs (PIIDs).
- When you download HHEAR Data Repository data, download the data to a secured computer,
  with strong password protection, and encrypted storage.
For the computers hosting HHEAR Data Repository data, ensure that they have the latest security patches and are running virus protection software.

Make sure the data are protected from anonymous access from users both inside and outside of the organization.

If you leave your office, close out of data files or lock your computer. Consider the installation of a timed screen saver with password protection.

When finished using the data, destroy the data or otherwise dispose of it properly.

VII. Submitter Information and Certifications

1. Submitter Information:
   First Name: 
   Degree: 
   Academic Position (or Title): 
   Institution: 
   Department: 
   Street Address: 
   City: 
   State/Province: 
   Zip/Postal Code: 
   Country: 
   Phone: FAX: 
   Institutional E-mail Address: 
   Point of Contact (POC) Name (if different from the Submitter): 
   POC Phone: 
   POC E-mail Address: 

2. Signatures:

   By signing and dating this DSA as part of submitting data to the HHEAR Data Repository, and I certify that we will abide by the DSA for the use of the HHEAR Data Repository. I further acknowledge that I have shared this document with any research staff who will participate in the use of HHEAR Data Repository.

   HHEAR Project #: ________________________________

   Submitter Signature: ________________________________
   Date: ________________________________