Notes

The CHEAR Human Material Collaboration Agreement (MCA) memorializes the agreement among CHEAR Laboratory Hubs (HUBS) regarding handling of CHEAR Investigator human materials. The CHEAR MCA is in-place for samples which are sent from a Recipient Hub to another Hub, e.g., if the Recipient Hub aliquots samples and sends aliquots to another Hub for laboratory analysis, or if samples are sent from one Hub to another Hub as part of quality control or other analysis activities.

This MCA will be completed before any CHEAR Research Project which involves human material transfer and laboratory analysis is approved.

The CHEAR Human Material Transfer Agreement (MTA) is used for transfer of human biological materials, such as blood, urine, saliva specimens, and so forth, with or without accompanying data (Human Material), between an academic or research institution (Provider) and the CHEAR Laboratory Hub (Recipient HUB) which directly receives Human Material from the Provider. The Recipient Hub is defined as CHEAR Laboratory Hub which receives Human Material directly from the Provider. For avoidance of doubt, the Recipient Hub shall include all cores and resources at the Recipient institution, collaborators and service providers working with or on behalf of the Recipient Hub for performance of the Research Project Plan.

Ownership, transfer and use of “Research Data” resulting from the Recipient Hub’s or other CHEAR Hub’s laboratory analysis of transferred Human Material will be addressed in the CHEAR Data Repository Data Submission Agreement and Data Sharing Plan for the CHEAR Data Repository.
Children’s Health Exposure Analysis Resource (CHEAR)  
CHEAR Human Material Collaboration Agreement

This Agreement is made by and between the National Exposure Assessment Laboratory at Emory, M-CHEAR: Michigan Children’s Health Exposure Analysis Resource Laboratory Hub, Minnesota CHEAR Exposure Assessment Hub, Mount Sinai CHEAR Exposure Assessment Hub, RTI CHEAR Exposure Assessment Hub, and Wadsworth Center’s Children’s Health Exposure Assessment Resource (hereinafter referred to as HUBS). Collectively or individually, the HUBS shall also be referred to as Parties or Party.

WHEREAS, each Party received a grant from the National Institute of Environmental Health Sciences (NIEHS) under the Children’s Health Exposure Analysis Resource (CHEAR) program to provide laboratory analytical or data support services for CHEAR, and

WHEREAS the Parties will receive de-identified human biological materials with or without accompanying data (Human Material) from investigators participating in the CHEAR (herein referred to as Provider), and Parties may be interested in transferring Human Material among the Parties;

NOW, THEREFORE, the Parties agree as follows:

1. To the extent described in each CHEAR Research Project Plan, each Party may transfer Human Material to one or more of the other Parties. To the extent the Parties decide to exchange Human Material not already in the Research Project Plan, each such transfer must be agreed upon by Provider and each Party in writing prior to the transfer.

2. Parties agree to abide by the terms of the CHEAR Human Material Transfer Agreement (MTA) between the Recipient Hub receiving the Human Material and the CHEAR Provider. The MTA is attached as Exhibit A and hereby incorporated and made part of this agreement.

3. The receiving Party therefore agrees to retain control over the Human Material and further agrees not to transfer the Human Material to other entities that are not members of the receiving Party without advance written approval of Provider, except when the transfer is between HUBS for analysis purposes.

4. Parties agree that the data (“Research Data”) obtained from the HUBS analysis of Human Material will be submitted to both the Provider and the CHEAR Data Center. The use and transfer of Research Data will be governed by a CHEAR Data Repository
Data Submission Agreement (DSA) and the Data Sharing Plan for the CHEAR Data Repository (DSP), which all users of the Research Data will be required to sign. The DSA and DSP are attached as Exhibits B and C.

5. When the research is completed, any unused Human Material or derivatives will either be destroyed in compliance with all applicable statutes and regulations or will be returned to the Provider, in accordance with the Research Project Plan and MTA.

I. General Terms

1. This Agreement shall remain in force for three (3) years or until the research has been completed, whichever occurs first. The term may be extended and the provisions of this Agreement may be modified only by amendment signed by the duly authorized signatory for each Party. The Agreement may be terminated by any Party for any reason by providing at least thirty (30) days written notice prior to the desired termination date.

2. This Agreement, the CHEAR Data Repository Data Submission Agreement, and the Data Sharing Plan for the CHEAR Data Repository constitute the entire understanding between the Parties concerning the subject matter of this collaboration and supersedes any prior understanding or written or oral agreement regarding the subject matter hereof. The illegality or invalidity of any provision of this Agreement shall not impair, affect or invalidate the other provisions of this Agreement. The relationship of the Parties is that of independent contractors and not agents of each other or joint venturers or partners. Each Party shall maintain sole and exclusive control over its personnel and operations.

3. Each Party expressly certifies and affirms that the contents of any statements made herein are truthful and accurate to the best of knowledge and belief, and each official signing this Agreement on behalf of a Party further certifies and affirms that the official has the authority to do so.

4. This Agreement may be executed in counterparts, each of which shall be deemed an original but both of which together shall constitute one and the same instrument. This Agreement will be considered signed when the signature of a party is delivered by electronic digital transmission. The digital copy signature will be treated in all respects as having the same effect as an original signature.
SIGNATURES APPEAR ON THE FOLLOWING PAGE
Children's Health Exposure Analysis Resource (CHEAR)
CHEAR Human Material Collaboration Agreement

ACCEPTED AND AGREED

For EACH of the Lab Hubs

Authorized Signatory for Party
Name: Clifford Michaels, PhD RTTP
Title: Assistant Director, Licensing
Email for documents: ott-mta@emory.edu

Signature of Party's Investigator
Name: Gary Miller, Associate Dean, Research
Email: gwmille@emory.edu

Date 10/31/2016
Date 7/21/15

Effective Date: 09/14/2016
Children's Health Exposure Analysis Resource (CHEAR)
CHEAR Human Material Collaboration Agreement

ACCEPTED AND AGREED

For EACH of the Lab Hubs

[Signature]

Authorized Signatory for Party

Name: ___________________________

Title: ___________________________

Email for documents: _____________

[Signature]

Signature of Party's Investigator

Name: Lisa Peterson

Email: peter421@umn.edu

Effective Date: 09/14/2016
Children's Health Exposure Analysis Resource (CHEAR)
CHEAR Human Material Collaboration Agreement

ACCEPTED AND AGREED

For EACH of the Lab Hubs

[Signature]
(Signed by: ____________________________)
(Authorized signatory for Party) ____________ Date

Name: __________________________________
Title: __________________________________
Email for documents: __________________________

[Signature]
(Signed by: ____________________________)
(Signature of Party’s Investigator) ____________ Date

Name: __________________________________
Email: __________________________________

CHEAR Human Material Collaboration Agreement
V2.5
Effective Date: 09/14/2016
Children's Health Exposure Analysis Resource (CHEAR)
CHEAR Human Material Collaboration Agreement

ACCEPTED AND AGREED

For EACH of the Lab Hubs

Katherine M. Mangum
2017.02.16 16:25:59 -05'00'

(Authorized Signatory for Party)

Name: Katherine M. Mangum
Title: Senior Contracting Officer
Email for documents: km@rti.org

Timothy R. Fennell
02-17-2017

(Signature of Party's Investigator)

Name: Timothy R. Fennell
Email: FENNELL@RTI.ORG

Effective Date: 09/14/2016
Children's Health Exposure Analysis Resource (CHEAR)
CHEAR Human Material Collaboration Agreement

ACCEPTED AND AGREED

For EACH of the Lab Hubs

[Signature]
12/20/16
(Authorized Signatory for Party) Date

Name: Erasmus Schneider, Ph.D.
Title: Associate Director, Research & Technology
Email for documents: erasmus.schneider@health.ny.gov

[Signature]
12/20/16
(Signature of Party's Investigator) Date

Name: K.M. Aldous
Email: kenneth.aldous@health.ny.gov
Children’s Health Exposure Analysis Resource (CHEAR)
CHEAR Human Material Collaboration Agreement

ACCEPTED AND AGREED

For EACH of the Lab Hubs

(Authorized Signatory for Party)

Name: Anthony L. Nielsen, J.D.
Title: Interim Assistant Managing Project Representative
Email for documents: anielsen@umich.edu

(Date)

(Signature of Party’s Investigator)

Name: JOHN MEEKER
Email: meekerj@umich.edu

(Date)
Exhibit A:
CHEAR Human Material Transfer Agreement
NOTES

A Material Transfer Agreement (MTA) is a contract that governs the transfer of tangible research materials between two organizations, when the recipient intends to use it for his or her own research purposes. An MTA defines the rights of the provider and the recipient with respect to the materials and any derivatives.¹

The CHEAR Human Material Transfer Agreement (MTA) is used for transfer of human biological materials, such as blood, urine, saliva specimens, and so forth, with or without accompanying data (Human Material), between an academic or research institution (Provider) and the CHEAR Laboratory Hub (Recipient Hub) which directly receives human biological materials from the Provider. The Recipient Hub is defined as CHEAR Laboratory Hub which receives Human Material directly from the Provider. The name and address of the Recipient Hub is specified in Section II of this document. For avoidance of doubt, the Recipient Hub shall include all cores and resources at the Recipient institution, collaborators and service providers working with or on behalf of the Recipient Hub for performance of the Research Project Plan. A CHEAR MTA will be completed between Provider and the Recipient Hub prior to project initiation and transfer of any Human Material. A separate MTA will be completed between Provider and each Recipient Hub which directly receives Human Material from the Provider.

A CHEAR Human Material Collaboration Agreement is in place for samples which are sent from a Recipient Hub to another CHEAR Laboratory Hub, e.g., if the Recipient Hub aliquots samples and sends aliquots to another Hub for laboratory analysis, or if samples are sent from one Hub to another Hub as part of quality control or other analysis activities.

Ownership, transfer and use of “Research Data” resulting from the Recipient Hub’s or other CHEAR Hub's laboratory analysis of transferred Human Material will be addressed in the CHEAR Data Repository Data Submission Agreement.

¹ https://en.wikipedia.org/wiki/Material_transfer_agreement
Children’s Health Exposure Analysis Resource (CHEAR)
CHEAR Human Material Transfer Agreement

CHEAR Research Project ID: ______________

CHEAR Research Project Title: _____________________________________________

CHEAR MTA ID: ______________

I. Definitions

1. Provider: Institution providing Human Material. The name and address of the Provider for purposes of this MTA is specified in Section II of this document.

2. Provider Principal Investigator: The Provider Investigator from the Provider Institution authorized to provide Human Material. The name and address of the Provider Investigator for purposes of this MTA is specified in Section II of this document.

3. Recipient Hub: The Recipient Hub is defined as CHEAR Laboratory Hub which receives Human Material directly from the Provider. The name and address of the Recipient Hub is specified in Section II of this document. For avoidance of doubt, the Recipient Hub shall include all cores and resources at the Recipient institution, collaborators and service providers working with or on behalf of the Recipient Hub for performance of the Research Project Plan.

4. Recipient Hub Principal Investigator: The Investigator from the Recipient Hub authorized to receive the Human Material directly from the Provider. The name and address of the Recipient Hub Investigator for purposes of this MTA is specified in Section II of this document.

5. Human Material: Human biological materials, such as blood, urine, saliva specimens, and so forth, and accompanying phenotypic or other data for use solely as outlined in the Research Project Plan.

6. Research Project Plan: The CHEAR Application and Data Analysis Plan completed for the approved CHEAR research project.

7. Research Data: Data obtained from Recipient Hub’s or other CHEAR Lab Hub’s analysis of Human Material.
8. Personally Identifiable Information (PII): Information that can be used to distinguish or trace an individual’s identity, either alone or when combined with other personal or identifying information that is linked or linkable to a specific individual.

II. Terms and Conditions of this Agreement:

This Human Material Transfer Agreement (MTA) is between the (Provider) located at Fill in address of Provider institution and the Children’s Health Exposure Analysis Resource (CHEAR) Laboratory Hub, (Recipient Hub) Fill in name of Recipient Hub institution having an address at Fill in address of Recipient Hub institution for the transfer of Human Material for research purposes as further defined below. The Provider and Recipient Hub may each be referred to as Party or collectively as Parties. This MTA will become effective on the date of the last signature on the Signature Page.

Provider Principal Investigator (PI): Fill in Provider PI name

Recipient Hub Principal Investigator: Fill in Recipient Hub PI name

Recipient Hub and Provider agree as follows:

1. Provider will transfer to Recipient Hub the following biospecimens and data:

   List biospecimens to be transferred ________________________________

   List data to be transferred ________________________________

   Further details on biospecimens, data and transfer conditions are provided in the Research Project Plan for Fill in Project ID and Project Title for approved CHEAR Research Project

2. Provider represents that it has obtained Institutional Review Board approval, as appropriate, for obtaining and for proposed laboratory analysis of the Human Material (human biological material and any associated phenotypic data provided to Recipient Hub pursuant to the Research Project Plan, and its transfer under this MTA is authorized by donors under informed consent in accordance with federal, state and local laws and regulations which address protection of human subjects in research, including 45 CFR part 46.
3. Provider will not provide Recipient Hub with personally identifiable information (PII) or the code to PII with the Human Material. A Recipient Hub may request phenotypic or other data from the Provider for interpretation of laboratory analysis results, but the data provided will not include PII. If PII is submitted to Recipient Hub, it will be returned to the Provider Investigator for de-identification and resubmission.

4. Provider will not provide Confidential Information to Recipient Hub.

5. Recipient Hub will perform the analysis and/or, as required, coordinate any transfer of the Human Material to one or more of the designated CHEAR Laboratory Hubs for analyses per the Research Project Plan. All CHEAR Laboratory Hubs have agreed to abide by the terms of this MTA via the CHEAR Human Material Collaboration Agreement located at www.chearpprogram.org under Support Documents.

6. Recipient Hub agrees to use the Human Material solely as outlined in the Research Project Plan, and will not use the Human Material for any commercial purposes, including selling, commercial screening, or transferring Human Material to a third party for commercial or other purposes.

7. Recipient Hub agrees that this Human Material shall not be used in humans or for any diagnostic, prognostic, or treatment procedures.

8. Recipient Hub will allow the use of Human Materials only by Recipient Hub Investigator and other employees of the Recipient Hub, collaborators, and service providers working with or on behalf of the Recipient Hub for the performance of the Research Project Plan (or other CHEAR Laboratory Hub, if Human Materials are distributed to other Laboratory Hubs pursuant to Paragraph 5 of this Section II) only after they have been informed of and agreed to the provisions and restrictions stated herein. Any transfer of Human Material outside of the Recipient Hub or other CHEAR Laboratory Hub requires the advanced written approval of Provider.

9. Recipient Hub will not contact or make any effort to identify individuals who are or may be the sources of Human Material, without specific written approval from Provider.

10. Recipient Hub represents that its intended use of Human Material for Research Project Plan has been approved or exempted by the relevant Institutional Review Board. Recipient Hub will comply with all laws, rules and regulations applicable to the handling and use of the Human Material, including but not limited to 45 CFR part 46 and the Health Insurance Portability and Accountability Act of 1996 as amended, and all similar applicable state laws and regulations (collectively, “HIPAA”).

11. Provider and Recipient Hub agree that the data (“Research Data”) obtained from the Recipient Hub’s analysis of Human Materials will be submitted to both the Provider and
the CHEAR Data Center. The use and transfer of Research Data will be governed by a CHEAR Data Repository Data Submission Agreement which all users of the Research Data will be required to sign.

12. When the Research Project is completed or this MTA is terminated, whichever comes first, any unused Human Material or derivatives will either be destroyed in compliance with all applicable statutes and regulations or will be returned to the Provider, as requested by the Provider.

13. In all oral presentations or written publications concerning the use of Human Material, Recipient Hub will acknowledge Provider’s contribution of Human Material unless requested otherwise by Provider.

14. Any Human Material delivered pursuant to this MTA is understood to be experimental in nature and may have hazardous properties. Provider Investigator agrees and represents that universal precautions are sufficient for the handling of the Human Materials, or, alternatively, the following additional precautions are required:

Fill in additional precautions required for handling Human Material

15. Provider makes no representations other than as set forth in Paragraph 2 and Paragraph 14 of this Section II and extends no warranties of any kind, either expressed or implied. There are no express or implied warranties of merchantability or fitness for a particular purpose, or that the use of human material will not infringe any patent, copyright, trademark, or other proprietary rights.

16. No indemnification for any loss, claim, damage, or liability is intended or provided by any Party under this MTA. To the extent permitted by law, each shall be liable for its own loss, claim, damage, or liability that said Party incurs as a result of its activities under this MTA. If the provider is an agency of the U.S. it assumes liability only to the extent provided under the Federal Tort Claims Act, 28 USC § 2671 et seq.

17. Either Party may terminate this MTA with sixty (60) days written notice to the other Party.

18. This MTA may be executed in any of two counterparts, each of which, when executed, shall be deemed an original and both of which together shall constitute one and the same document. This Agreement may be executed by facsimile or PDF signatures, which shall have the same force and effect as original signatures.

SIGNATURES FOLLOW ON NEXT PAGE
SIGNATURE PAGE

For Provider:

Provider’s Investigator: I have read and understood the terms and conditions of this MTA.

Name of Provider Principal Investigator: ____________________________________________________________

Signature of Provider Principal Investigator: _____________________________ Date: __________

Agreed:

Name and Title of Authorized Official for Provider: ________________________________________________

Signature of Authorized Official for Provider: _____________________________ Date: __________

Email address for documents: ________________________________________________________________

For Recipient Hub:

Recipient Hub’s Investigator: I have read and understood the terms and conditions of this MTA and I agree to abide by them.

Name of Recipient Hub Investigator: ______________________________________________________________

Signature of Recipient Hub’s Investigator: _____________________________ Date: __________

Agreed:

Name and Title of Authorized Official for Recipient Hub: ________________________________________________

Signature of Authorized Official for Recipient Hub: _____________________________ Date: __________

Email address for documents: ________________________________________________________________
Exhibit B:

CHEAR Data Repository Data Submission Agreement
I. Introduction

The Children’s Health Exposure Analysis Resource (CHEAR) 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 Center for Data Science (“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 CHEAR research study and for all new biomarker data generated by the CHEAR National Exposure Assessment Laboratory Network (“Lab Hubs”).

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

II. Definitions

The CHEAR data repository is designed to store the collection of data from participants in research studies related to children’s health. The CHEAR 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 for public use access, after an embargo period, as publically 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. Data will be shared no later than the acceptance for first publication of the findings from the data set.

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 CHEAR Access Committee to submit data to the CHEAR Data Repository, according to the policies laid out in the CHEAR 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 CHEAR Data Repository Data Submission Agreement (SA) and complete and sign Section VII, Submitter Information and Certifications.
2. The signed SA should be scanned and the electronic version should uploaded to the Submitter’s account on https://chearprogram.org

IV. Terms and Conditions

I request approval to submit data to the CHEAR 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 SA covers only the Research Project as contemplated in Section VII. Submitter Information and Certifications and only for submission to the CHEAR Data Repository specified. Submitter will submit a completed SA for each research project for which submission is requested.

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

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 CHEAR Data Repository.

4. **Data Disclaimers.** Submitter acknowledges that the CHEAR Data Center does not and cannot warrant the results that may be obtained by using any data included in the CHEAR Data Repository. The CHEAR Data Center disclaims all warranties as to the accuracy of the data in the CHEAR 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 CHEAR 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 CHEAR 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 CHEAR Data Center as soon as possible after submission if the Submitter discovers quality concerns in the data that are submitted.

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

8. **Data Access for Research and Non-Research activities.** Submitter agrees that data and Supporting Materials submitted to the CHEAR Data Repository can be accessed and used broadly. The submitter will review and sign the Data Sharing Plan for the CHEAR Data Repository.
Non-sensitive data such as summary information on the CHEAR 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 CHEAR 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 for public use access. 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 publically available de-identified datasets will register by completing a data user registration form on the website https://chearprogram.org.

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 CHEAR Data Repository, Submitter agrees to cite the CHEAR 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 CHEAR Data Repository

10. Non-Endorsment; 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 CHEAR 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 CHEAR Network to summarize and release for public use on the appropriate CHEAR 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 SA, 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, 2891-1 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 (http://oma.od.nih.gov/public/ms/privacy/pafiles/0156.htm) 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 SA is voluntary, but necessary for submitting data to the CHEAR Data Repository.


15. Amendments. Amendments to this SA 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 CHEAR Data Repository to submit, access, and analyze data.

The Data Center Portal system shall be the access route to the repository for approved CHEAR study data. This data will be uploaded through the Portal by the CHEAR 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 CHEAR study PIs will have provided evidence of approval by their institutional IRB to deposit their data, including biomarker data, into the CHEAR 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 CHEAR 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 CHEAR 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. Each user must obtain and use their own account.
- Ensure that anyone directed to use the system has access to, and is aware of, CHEAR Data Repository Information Security Best Practices and Security Standards as well as all existing policies and procedures relevant to the use of the CHEAR Data Repository, including but not limited to 45 CFR Part 46.
- Follow the CHEAR 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 CHEAR Data Repository password from access by other individuals—for example, store it electronically in a secure location.
- Notify the CHEAR Data Repository staff at https://chearprogram.org of security incidents, or any incidents of suspected fraud, waste or misuse of the CHEAR Data Repository or when access to CHEAR 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 CHEAR Participant IDs (PIDs).
- When you download CHEAR Data Repository data, download the data to a secured computer, with strong password protection, and encrypted storage.
- For the computers hosting CHEAR 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:
   Last Name:
   Degree:
   Academic Position (or Title):
   Institution:
   Department:
   Street Address:
2. Signatures:
By signing and dating this SA as part of submitting data to the CHEAR Data Repository, and I certify that we will abide by the SA for the use of the CHEAR Data Repository. I further acknowledge that I have shared this document with any research staff who will participate in the use of CHEAR Data Repository.

CHEAR Project #: ________________________________

Submitter Signature: ______________________________

Date: ________________________________
Exhibit C:
Data Sharing Plan for the CHEAR Data Repository
1. Data Type: The data being shared with the CHEAR Data Repository involves human data. These data will include individual-level data such as epidemiologic data, information which has been collected and recorded from study participants. These data include, but are not limited to, research and clinical assessments and information obtained via interviews, direct observations, biomarker data, records reviews, genomic data (e.g., sequence, transcriptomic, epigenomic, and/or gene expression data), psychophysiological assessments, data from physical examinations, etc. Additionally, information necessary to interpret the data (e.g., study protocols, data collection instruments, survey tools) will be shared.

2. Data Repository: The data will be submitted to the CHEAR Data Repository at the CHEAR Center for Data Science at Mount Sinai (CHEAR Data Center). Within the embargo period, the data will be available only to the CHEAR Data Center and the Study PI through controlled-access. After the embargo period, de-identified data will be available through unrestricted access. If appropriate, it is expected that the Study PI will have registered all studies in the database of Genotypes and Phenotypes (dbGaP) in addition to submitting the data to the relevant NIH-designated data repository (e.g., dbGaP, Gene Expression Omnibus (GEO), Sequence Read Archive (SRA), the Cancer Genomics Hub) after registration.

3. Data Submission and Release Timeline: De-identified data will be shared no later than the acceptance for first publication of the findings from the data set (embargo period).

4. IRB Assurance of the Data Sharing Plan: The Study PI's Institutional Review Board (IRB) or analogous review body has reviewed the data sharing aspects of the project. The Study PI will provide evidence of approval by their institutional IRB to deposit their data into the CHEAR 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. IRB Approval will be submitted prior to use of the data/data sharing.

5. Appropriate Uses of the Data: The Study PI agrees that data and supporting materials submitted to the CHEAR Data Repository may be accessed and used broadly.

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

CHEAR Project #: ________________________________

Submitter Signature: ________________________________

Date: ________________________________

The signed Data Sharing Plan should be scanned and the electronic version should uploaded to the Study PI's account on https://chearprogram.org