Children's Health Exposure Analysis Resource (CHEAR)
Application - EXAMPLE

Application Template: This document is provided for informational purposes only. All CHEAR Applications must be submitted on-line at: mychear.chearprogram.org
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Step 1 of 5: Instructions and Applicant Information

The information provided in this Application will allow CHEAR to assess the merit of your project with respect to accessing CHEAR laboratory and data services.

Several items in the application have been prefilled with information previously provided in your Request CHEAR Services form and the outcome of your consultation with a CHEAR Lab Hub (the table of feasible analyses for your CHEAR project). As you complete the application, **please review this prefilled information and make updates as needed.**

If you need to exit the form before it is complete, select the green "**Save Draft**" button at the end of the page. When you are finished with the application and ready to submit, select the blue "**Save Changes and Submit**" button. Your application will then be in the queue for review by the CHEAR Data Center for a data feasibility assessment.

Additional information about the application review process can be found at https://chearprogram.org/access/application-and-review-process. If you have any questions, please contact CHEARHelp@westat.com.

Project #: _____

Principal Investigator: _____

Institution: _____

Address: _____

Street

_____

City State ZIP

Phone: _____

Email: _____

Project contact person (if different from PI)

Contact person first name: _____

Contact person last name: _____

Institution: _____

Address: _____

Street

_____

City State ZIP

Phone: _____

Email: _____

Co-Investigators

Co-Investigator 1

Co-I first name: _____

Co-I last name: _____

Co-I Institution: _____

Co-Investigator 2

Co-I first name: _____

Co-I last name: _____

Co-I Institution: _____

Biosketches

Upload a biosketch for the Principal Investigator and other significant contributors (up to 3).

Add a new file:

PI Eligibility

Are you eligible at your home institution to apply for an NIH grant as a principal investigator?

☐ Yes ☐ No

Do you agree to share experimental design details and supporting data, including phenotypic data at the individual level, needed to facilitate the analysis to be conducted by the CHEAR consortium?

☐ Yes ☐ No

Step 2 of 5: Original Study Information

Provide the following information about the original funded study.

Original project title: _____

Original specific aims: *Provide the specific aims for the original study in one or two paragraphs. You may copy the project description from the NIH RePORTER entry (https://projectreporter.nih.gov/)*

Original study design: *Provide a description of the original study design.*

Health outcomes: *Describe the specific children's health outcomes of the original study.*

Environmental exposure measures: *Describe environmental exposures assessments, if any, that have already been completed. This can include for example, previous analysis of biospecimens for chemical or stress biomarkers; metabolomics and/or gene expression profiles; collection of air, soil or water samples; and/or administration of questionnaires relating to stress, dietary or environmental exposures of interest.*

Summary of findings from original study: *Provide a brief summary of the key findings from your original funded study. If you wish to provide key figures, graphs or tables, do not attempt to "cut and paste" them into the text box. Rather, use the blue "Upload" button to provide pertinent figures, graphs or tables as a separate document.*

Add a new file

Human subjects' approval: *Record the institution providing IRB approval and the IRB approval number for your original study.*

***Approving institution:** _____

***Approval number:** _____

Funding: *Describe how the original study was funded including grant numbers. If the study was funded by NIH and non-NIH sources, describe the relative contribution of the sources:*

Key publications: *Provide the DOIs for publications that describe the original study:*

Data dictionary, codebook and questionnaires: *Use the CHEAR Data Dictionary Template and Instructions to provide the required variables in the designated format. Make sure to indicate those variables that will be used in the CHEAR analyses (see instructions). The CHEAR Data Dictionary Template and Instructions along with and example are available under Support Documents at mychear.chearprogram.org, or linked directly here:*

CHEAR Data Dictionary Template and Instructions

CHEAR Data Dictionary example

Upload the data dictionary, codebook (if not part of the data dictionary), and questionnaires below.

A data dictionary describes the data elements in a database. A data element is a logical unit of data that has a name, precise definition, and clear enumerated values (codes) if applicable. In epidemiologic data dictionaries, the data elements are variables representing information that is collected (e.g., completion of a questionnaire), measured (e.g., weight, biomarker), or derived (e.g., body mass index (BMI), pack years of smoking). If study data is collected from multiple family members (e.g., child and mother), a clear description of how the data is arranged to reflect these relationships (e.g., family ID) should be provided.

Add a new file

Comments (optional): *If you have any comments on the data dictionary, codebook and questionnaires you are submitting with this application, please provide them below:*

Step 3 of 5: Proposed CHEAR Project

Provide the following information for the proposed project.

Project title: _____

Specific aims: *List the specific aims for the proposed project.*

Significance: *Explain the importance of the problem that the proposed project addresses. Explain how the project will improve scientific knowledge in children's health and environmental health science. In addition, describe how the requested CHEAR analyses will uniquely enhance the findings from your original study.*

Is the cohort proposed here in your CHEAR project also part of an ECHO pediatric cohort?

☐ **Yes**

☐ **No**

Feasible Analyses Table: The table below provides information about the analyses for your project that were determined to be feasible in consultation with a CHEAR Lab Hub. Please review the information in this table**.**

Feasible analyses	**Analyte codes***	**Partici-pant type**	**Age at time of collection/ developmental stage**	**Sample matrix**	**# partici-pants with samples**	**Total volume/ quantity per participant** *(with units)*	**Collection method** *(e.g. cord blood drip)*	**Storage temp** *(with units)*	**# of freeze-thaws**	**Sample pre-test?**

*****Confirm the information in the above table is correct and that these are the analyses you propose to include in your CHEAR project**.**

☐ Yes ☐ No, modifications needed

If modifications are needed, please update the table and describe the updates below.

Biological sample shipment: When will samples be available for shipment**?** _____/_____/_____
mm / dd / yyyy

Step 4 of 5: Proposed Data Analysis Approach

Appropriate analysis of environmental health data depends on varying features including the scientific hypotheses (e.g., association, mediation, moderation), study design (e.g., case-control, cohort), type of dependent variable (e.g., continuous scale, binary, time-to-event with censoring), and appropriate covariates/confounders. Complete to the best of your ability – consultation with the Data Center is available. Please contact CHEARHelp@westat.com if consultation is needed at this point.

Study design: *Describe the proposed study design.*

Statement of analysis objectives: *Include hypotheses to be investigated.*

Health outcome variables: *Provide a description of the specific outcome variables that will be provided to CHEAR for data analysis. Provide details on outcome assessment.*

Covariates: *Provide a list of available covariates and the rationale for adjusting for covariates.*

Description of a modeling strategy: *What will be used to fit the available data (e.g., nonlinear or linear regression, logistic regression)? Discuss how you will evaluate goodness of fit of the data with the estimated model and select statistic(s) for testing for association, mediation or moderation (e.g., likelihood ratio test, Wald test).*

Power and/or sample size considerations:

Provide power calculations (e.g. measureable effect size, sample size calculations) or explain the rationale for anticipated sample size.

Study subject numbers:

Indicate the total number of study subjects for whom biological samples will be provided: _____

If your proposed project is approved for CHEAR services, you will be asked to submit your original project's epidemiologic data. Indicate the number of subjects included in your epidemiologic dataset to help us determine how many CHEAR Participant IDs would be required for linking and de-identifying your data. (For example, if you have 100 urine samples for pregnant mothers, but your project dataset includes data on 100 mothers plus data on their 100 children, you would require 200 total CHEAR Participant IDs.) : _____

Data format: What is the format of the study data?

☐ xls, xlxs ☐ csv ☐ SAS

☐ Other: _____

Data center services: *Indicate the services that you expect to request to execute this project.*

Statistical consulting	☐
Statistical analysis	☐
None	☐

Step 5 of 5: Agreements and Assurances

Data Submission Agreement and Data Sharing Plan: Have you reviewed and are you willing to sign the *CHEAR Data Repository Data Submission Agreement* and the *CHEAR Data Sharing Plan for the CHEAR Repository* should your project be accepted? These agreements are available at the following links:

CHEAR Data Repository Data Submission Agreement

Data Sharing Plan for the CHEAR Repository

☐ Yes ☐ No

If no, please provide an explanation:

Human subjects' approval: Does the CHEAR project you propose have human subjects' approval consistent with CHEAR's use of the samples and data?

☐ Yes

Approving institution: _____

Approval number: _____

☐ No, will apply for human subjects' approval consistent with CHEAR's use of the samples and data once CHEAR approval is received

Estimated length of time to obtain approval: _____

Important note about IRB attestation letter*: If your Application is approved by the CHEAR Access Committee, you will be asked to submit a letter from your/Principal Investigator's IRB attesting that the original study consent permits the use of samples and data for your CHEAR project. 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. An example of an IRB attestation letter is located under the myCHEAR Support Documents tab (https://mychear.chearprogram.org/workflow_docs).*

Material Transfer Agreement: Do you agree to utilize the CHEAR standard Material Transfer Agreement to govern the transfer of human biological materials and accompanying data from your institution to a CHEAR Lab Hub? *The CHEAR standard Material Transfer Agreement is available at the following link: The CHEAR Human Material Transfer Agreement (MTA).*

☐ Yes ☐ No

If no, please provide an explanation:

CHEAR ontology: To the extent possible, all Study data will be mapped to the CHEAR ontology. Do you agree to work with the CHEAR Data Center to map study data to the CHEAR ontology (common vocabulary)? *After project initiation, Study PI's will work with the CHEAR Data Center to map the variables from their data to corresponding terms contained in the CHEAR ontology.*

☐ Yes ☐ No

If no, please provide an explanation:

CHEAR Publication Policy: Have you reviewed and are you willing to agree to the CHEAR Publication Policy? *This policy document is available at the following link: CHEAR Publication Policy.*

☐ Yes ☐ No

If no, please provide an explanation:
