CHIA.

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and analysis

Application for Massachusetts All-Payer Claims Data (Non-Government) [Exhibit A – Data Application]

I.   INSTRUCTIONS

This form is required for all Applicants, Agencies, or Organizations, hereinafter referred to as "Organization", except Government Agencies as defined in 957 CMR 5.02, requesting protected health information. All Organizations must also complete the Data Management Plan, and attach it to this Application. The Application and the Data Management Plan must be signed by an authorized signatory. This Application and the Data Management Plan will be used by CHIA to determine whether the request meets the criteria for data release, pursuant to 957 CMR 5.00. Please complete the Application documents fully and accurately. Prior to receiving CHIA Data, the Organization must execute CHIA's Data Use Agreement. Organiations may wish to review that document prior to submitting this Application.

Before completing this Application, please review the data request information on CHIA's website:
- Data Availability
- Fee Schedule
- Data Request Process

After reviewing the information on the website and this Application, please contact CHIA at apcd.data@state.ma.us if you have additional questions about how to complete this form.

The Appliciaton and all attachments must be uploaded to IRBNet. All Application documents can be found on the CHIA website.

Information submitted as part of the Application may be subject to verification during the review process or during any audit review conducted at CHIA's discretion.

==Applications will not be reviewed until the Application and all supporting documents are complete and the required application fee is received.==

*A **Fee Remittance Form** with instructions for submitting the application fee is available on the CHIA website. If you are requesting a fee waiver, a copy of the Fee Remittance Form and any supporting documentation must be uploaded to IRBNet. Please be aware that if your research is funded and under that funding you are required to release raw data to the funding source, you may not receive CHIA Data.*

II.   FEE INFORMATION

1. Consult the most current Fee Schedule for All-Payer Claims Database data.

2. After reviewing the Fee Schedule, if you have any questions about the application or data fees, contact apcd.data@state.ma.us.

3. If you believe that you qualify for a fee waiver, complete and submit the Fee Remittance Form and attach it and all required supporting documentation with your application. Refer to the Fee Schedule (effective Feb 1, 2017) for fee waiver criteria.

4. Applications will not be reviewed until the application fee is received.

5. Data for approved Applications will not be released until the payment for the Data is received.

III.   ORGANIZATION & INVESTIGATOR INFORMATION

Project Title:	Health Care Transitions and the Health of Adolescents and Young Adults with Intellectual or Developmental Disabilities
IRBNet Number:	1776124
Organization Requesting Data (Recipient):	Boston Children's Hospital
Organization Website:	childrenshospital.org
Authorized Signatory for Organization:	**August P. Cervini, MBA**
Title:	Vice President of Research Administration Research Integrity Officer IACUC & IRB Institutional Official
E-Mail Address:	August.Cervini@childrens.harvard.edu
Telephone Number:	617-919-2272
Address, City/Town, State, Zip Code:	300 Longwood Avenue, Boston, MA 02115
Data Custodian: **(individual responsible for organizing, storing, and archiving Data)**	**Alyna T. Chien, MD, MS**
Title:	Assistant Professor, Department of General Pediatrics, Harvard Medical School Research Director, Division of General Pediatrics, Boston Children's Hospital
E-Mail Address:	alyna.chien@childrens.harvard.edu
Telephone Number:	857-218-4074
Address, City/Town, State, Zip Code:	300 Longwood Avenue, Boston, MA 02115
Primary Investigator (Applicant): **(individual responsible for the research team using the Data)**	**Alyna T. Chien, MD, MS**
Title:	Assistant Professor, Department of General Pediatrics, Harvard Medical School Research Director, Division of General Pediatrics, Boston Children's Hospital
E-Mail Address:	alyna.chien@childrens.harvard.edu
Telephone Number:	857-218-4074
Address, City/Town, State, Zip Code:	300 Longwood Avenue, Boston, MA 02115
Names of Co-Investigators:	Mary Beth Landrum, PhD; Ellen Meara, PhD; Megumi Okumura, MD, MAS; Mihail Samnaliev, PhD; Sara Toomey, MD, MPhil, MPH, MSc
E-Mail Addresses of Co-Investigators:	landrum@hcp.med.harvard.edu, emeara@hsph.harvard.edu, OkumuraM@peds.ucsf.edu, Mihail.Samnaliev@childrens.harvard.edu, Sara.Toomey@childrens.harvard.edu

IV.   PROJECT INFORMATION

IMPORTANT NOTE: Organization represents that the statements made below as well as in any study or research protocol or project plan, or other documents submitted to CHIA in support of the Data Application are complete and accurate and represent the total use of the CHIA Data requested. Any and all CHIA Data released to the Organization under an approved application may ONLY be used for the express purposes identified in this section by the Organization, and for no other purposes. Use of CHIA Data for other purposes requires a separate Data Application to CHIA written request to CHIA, with approval being subject to CHIA's regulatory

restrictions and approval process. Unauthorized use is a material violation of your institution's Data Use Agreement with CHIA.

1. What will be the use of the CHIA Data requested? [Check all that apply]

☒ Epidemiological	☐ Health planning/resource allocation	☒ Cost trends
☒ Longitudinal Research	☒ Quality of care assessment	☐ Rate setting
☐ Reference tool	☒ Research studies	☒ Severity index tool (or other derived input)
☐ Surveillance	☐ Student research	☐ Utilization review of resources
☐ Inclusion in a product	☐ Other (describe in box below)	

> Click here to enter text.

2. Provide an abstract or brief summary of the specific purpose and objectives of your Project. This description should include the research questions and/or hypotheses the project will attempt to address, or describe the intended product or report that will be derived from the requested data and how this product will be used. Include a brief summary of the pertinent literature with citations, if applicable.

> The main goal of this project is to improve our understanding of how health care is delivered to adolescents and young adults with intellectual or developmental disabilities and the roles that health insurance and health care providers may play in the experience of gaps or in care quality.
>
> The specific research questions that we are trying to answer with this data request are:
>
> **Question 1**: What characterizes health care transitions for adolescents and young adults with intellectual or developmental disabilities (e.g., which types of physicians are involved; at which ages do health care transfers appear to occur)?
>
> **Question 2**: What is the quality of the care being delivered during the time that adolescents and young adults with intellectual or developmental disabilities are making health care transitions?
>
> **Question 3**: Are there gaps in insurance coverage among those turning 19 years of age and how do the gaps associated with Medicaid insurance differ from those who are commercially insured?
>
> **Question 4**: What relationship exists between insurance gaps following Medicaid's eligibility redetermination at age 19 and service utilization indicating lower quality care?

3. Has an Institutional Review Board (IRB) reviewed your Project?

☒ Yes [*If yes, a copy of the approval letter and protocol must be included with the Application package on IRBNet.*]
☐ No, this Project is not human subject research and does not require IRB review.

4. **Research Methodology**: Applicantions must include either the IRB protocol or a written description of the Project methodology (typically 1-2 pages), which should state the Project objectives and/or identify relevant research questions. This document must be included with the Application package on IRBNet and must provide sufficient detail to allow CHIA to understand how the Data will be used to meet objectives or address research questions.

V.   PUBLIC INTEREST

1. Briefly explain why completing this Project is in the public interest. Use quantitative indicators of public health importance where possible, for example, numbers of deaths or incident cases; age-adjusted, age-specific, or crude rates; or years of potential life lost. *Uses that serve the public interest under CHIA regulations include, but are not limited to:*

health cost and utilization analysis to formulate public policy; studies that promote improvement in population health, health care quality or access; and health planning tied to evaluation or improvement of Massachusetts state government initiatives.

This project will benefit Massachusetts residents in three main ways:

1.   It will identify how many insured adolescents and young adults with intellectual or developmental disabilities are living in MA. Childhood-onset intellectual or developmental disabilities is a life-long condition. Adolescent and young adults with intellectual or developmental disabilities are an understudied group of "high cost high need" patients—their spending levels can be highest among all sub-populations of children (Chien 2017), the quality of the care being delivered to this population can be sub-optimal (Chien 2015, Chien 2017), and this population likely relies on additional disabilities-related state services. Knowing the size of this population will help state policymakers plan necessary resources and services as teenagers with intellectual or developmental disabilities grow into adults.

2.   It will help state officials, health plans, health care providers, and patient stakeholder groups understand what health care transitions look like for MA teenagers with intellectual or developmental disabilities, how such transitions may vary in terms of timing or provider.

3.   It will provide MA residents with better understanding of how frequently insurance gaps occur at age 19 (in conjunction with changes in Medicaid eligibility) and potentially affect health care access, quality, or spending.

VI.   DATASETS REQUESTED

The Massachusetts All-Payer Claims Database is comprised of medical, pharmacy, and dental claims and information from the member eligibility, provider, and product files that are collected from health insurance payers licensed to operate in the Commonwealth of Massachusetts. This information encompasses public and private payers as well as data from insured and self-insured plans. APCD data are refreshed and updated annually and made available to approved data users in Release Versions that contain five calendar years of data and three months of run-out. For more information about APCD Release Versions, including available years of data and a full list of elements in the release please refer to release layouts, data dictionaries and similar documentation included on CHIA's website.

Data requests are typically fulfilled on a one time basis, however; certain Projects may require future years of data that will become available in a subsequent release. Projects that anticipate a need for future years of data may request to be considered for a subscription. Approved subscriptions will receive, upon request, the same data files and data elements included in the initial Release annually or as available. Please note that approved subscription requests are subject to the Data Use Agreement, will require payment of fees for additional Data for Non-Government Entities, and subject to the limitation that the Data can be used only in support of the approved Project.

1. Please indicate below whether this is a one-time request, or if the described Project will require a subscription.
    ☒ One-Time Request   **OR**   ☐ Subscription

2. Select Release Version and years of data requested (Release Versions and years not listed are not available).

☒ **Release Version 8.0**	☐ **Release Version 10.0**
☒ 2014	☐ 2015
☒ 2015	☐ 2016
☒ 2016	☐ 2017
☒ 2017	☐ 2018
☒ 2018	☐ 2019
	☐ 2020

3. Specify below the data files requested for this Project, and provide your justification for requesting *each* file.

☒ Medical Claims

Describe how your research objectives require Medical Claims data:

Longitudinal medical claims data are needed to compute measures of spending, utilization, and quality at the patient level in order to generate a broad range of provider-specific cost and quality metrics. We will relate these metrics to provider characteristics to examine which characteristics are associated with high quality and/or low cost, as well as to help identify people with intellectual or developmental disabilities and people with health care transitions.

☒ Pharmacy Claims

Describe how your research objectives require Pharmacy Claims data:

Since pharmacy claims constitute a significant spending component and are often used to construct quality measures, these claims are needed to measure spending, utilization, and quality. We will use pharmacy claims to generate some key measures of clinical quality, such as the appropriate use of antibiotics, as well as to help identify people with intellectual or developmental disabilities and people with health care transitions.

☒ Dental Claims

Describe how your research objectives require Dental Claims data:

Dental care is an often understudied dimension of overall health. Many health systems now include dental practices. Dental claims data will allow us to assess the extent that dental care is integrated to the rest of the health care system and the relationship between such integration and quality outcomes, as well as to help identify people with intellectual or developmental disabilities and people with health care transitions.

☒ Member Eligibility

Describe how your research objectives require Member Eligibility data:

Member eligibility data will be crucial in identifying participation in the Medicaid program, tracking Medicaid patients as they move in and out of Medicaid, and in identifying comparison groups. Demographic and residential location data will be important in controlling for patient characteristics and access to providers. This information will be used to study how providers and health systems vary by the patient population they serve. By accurately identifying patients on Medicaid and comparison groups, we will be able to compare outcomes for Medicaid and commercially insured patients within the state, and to examine how delivery system differences affect one of the populations most at risk of losing access to care, as well as to help identify people with intellectual or developmental disabilities and people with health care transitions.

☒ Provider

Describe how your research objectives require Provider data:

We will use data on providers to study how differences in provider characteristics and delivery system impact the cost and quality of care. We have identified health systems across the nation using a large number of proprietary and government datasets.
These health systems will be matched on provider identification codes (e.g., NPIs and TINs) to providers in the Massachusetts APCD, as well as to help identify people with intellectual or developmental disabilities and people with health care transitions.

☒ **Product**
Describe how your research objectives require Product data:
Spending (decomposed into utilization and prices) is a central outcome measure in this project. The computation of spending measures requires both insurer and patient payment information so that we can control for any differences in benefit design on utilization. We do not need to know the name of the insurer but would like access to a de-identified insurer codes and plan codes. These codes will help us to infer the networks that patients can access through their plan and to control for variation in benefit generosity in our regression analyses, as well as to help identify people with intellectual or developmental disabilities and people with health care transitions.

VII.   DATA ENHANCEMENTS REQUESTED

State and federal privacy laws limit the release and use of CHIA Data to the minimum amount of data needed to accomplish a specific Project objective.

All-Payer Claims Database data is released in Limited Data Sets (LDS). All Organizations receive the "Core" LDS, but may also request the data enhancements listed below for inclusion in their analyses. Requests for enhancements will be reviewed by CHIA to determine whether each represents the minimum data necessary to complete the specific Project objective.

For a full list of elements in the release (i.e., the core elements and additional elements), please refer to release layouts, data dictionaries and similar documentation included on CHIA's website.

1. Specify below which enhancements you are requesting in addition to the "Core" LDS, provide your justification for requesting each enhancement.

a. Geographic Subdivisions

The geographic subdivisions listed below are available for Massachusetts residents and providers only. Select one of the following options.

☐ 3-Digit Zip Codes (standard)	☒ 5-Digit Zip Codes***
***If requested, provide justification for requesting 5-Digit Zip Code. Refer to specifics in your methodology: We need 5-digit zip code to impute socio-demographic characteristics (using census data), to assign beneficiaries to health care markets, and to measure distances travelled to access care.	

b. Date Resolution

Select one option from the following options.

☐ Year (YYYY) (Standard)	☐ Month (YYYYMM) ***	☒ Day (YYYYMMDD) *** [for selected data elements only]
*** If requested, provide justification for requesting Month or Day. Refer to specifics in your methodology: Month and year of birth will be necessary to compute certain quality measures (e.g. pediatric care) and to compute age for risk adjustment. Month and day on claims will be required to link claims for a single episode (e.g. patients seen in a doctor's office and an emergency department on the same day), to analyze the sequence of providers seen by patients, and to analyze quality measures in health care service delivery such as follow-up after discharge and the timeliness and appropriate setting of care.		

c. National Provider Identifier (NPI)

Select *one* of the following options.

☐ Encrypted National Provider Identifiers (standard)	☒ Decrypted National Provider Identifiers***
*** If requested, provide justification for requesting decrypted National Provider Identifier(s). Refer to specifics in your methodology: We need decrypted National Provider Identifiers in order to link to external data sources with information on provider characteristics (e.g. physician specialty, license (e.g. nurse practitioner, MD, MSW), years in practice).	

VIII.   MEDICAID (MASSHEALTH) DATA

1. Please indicate whether you are seeking Medicaid Data:

☒ Yes
☐ No

2. Federal law (42 USC 1396a(a)7) restricts the use of individually identifiable data of Medicaid recipients to uses that are ***directly connected to the administration of the Medicaid program***. If you are requesting MassHealth Data, please describe, in the space below, why your use of the Data meets this requirement. *Your description should focus on how the results of your project could be used by the Executive Office of Health and Human Services in connection with the administering the MassHealth program*. Requests for MassHealth Data will be forwarded to MassHealth for a determination as to whether the proposed use of the Data is directly connected to the administration of the MassHealth program. CHIA cannot release MassHealth Data without approval from MassHealth. This may introduce significant delays in the receipt of MassHealth Data.

The goal of this project is to examine how characteristics of health care organizations and systems relates to health care quality and cost. Medicaid data are essential for comparing outcomes for Medicaid and commercially insured patients within the state and for examining how delivery system differences affect one of the populations most at risk of losing access to care. Specifically, we are trying to characterize which types of health care providers and systems provide high quality care to Medicaid beneficiaries. Findings from these analyses will inform plan design and regulation in the MassHealth program, such as regulations related to network design.

3. Organizations approved to receive Medicaid Data will be required to execute a Medicaid Aknowlegment of Conditions MassHealth may impose additional requirements on applicants for Medicaid Data as necessary to ensure compliance with federal laws and regulations regarding Medicaid.

IX.   DATA LINKAGE

Data linkage involves combining CHIA Data with other data to create a more extensive database for analysis. Data linkage is typically used to link multiple events or characteristics within one database that refer to a single person within CHIA Data.

1. Do you intend to link or merge CHIA Data to other data?
    ☒ Yes
    ☐ No linkage or merger with any other data will occur

2. If yes, please indicate below the types of data to which CHIA Data will be linked. [Check all that apply]

☐ Individual Patient Level Data (e.g. disease registries, death data)

☒ Individual Provider Level Data (e.g., American Medical Association Physician Masterfile)

☒ Individual Facility Level Data (e.g., American Hospital Association data)

☐ Aggregate Data (e.g., Census data)

☐ Other (please describe):

3. If yes, describe the dataset(s) to which the CHIA Data will be linked, indicate which CHIA Data elements will be linked and the purpose for each linkage.

We will conduct this study in full concordance with the Health Insurance Portability and Accountability Act (HIPAA). All of the basic processing of the raw data and all data linkages required for individual research projects are conducted centrally through Boston Children's Hospital's full-time data management personnel, subject to our highest data security standards.

We will be merging and linking APCD data with one dataset as described below for the purpose of analyses. However, we will not be stacking CHIA APCD data with databases from other states, and we will not be adding CHIA APCD data into our health systems and providers database (HSPD) itself. The MA APCD will remain a discrete database to which we can make linkages for the purposes of our analyses, but which will be destroyed at the conclusion of the project.

Claim line-level data, including zip code, will not be linked to individual patient-level data.

Provider level linkage: We will merge information at the provider level from the health systems and providers databse (HSPD) we have built as part of this project. The HSPD integrates data from a number of sources, including: Medicare Fee-for-Service Claims, Medicare Provider Enrollment, Chain, and Ownership System (PECOS), Medicare Data on Provider Practice & Specialty (MD-PPAS), Medicare Provider of Services (POS), Hospital Compare, Physician Compare, National Plan & Provider Enumeration System (NPPES) NPI Registry, commercial claims, IRS 990, IRS Business Master, SEC 10K filings, SK&A, Irving Levin Health Care Acquisition Reports, S&P Capital IQ M&A Transactions, and the AHA Annual survey. The linking variables we will use include provider IDs (e.g. NPIs, hospital CCNs); tax IDs (TINs and/or EINs); and zip codes.

We will also merge information at the provider level from CMS Open Payment. Linking variables may include hospital/system name, CMS provider number, names, tax ID, or other available identifiers.

Zip code level linkage: We will link patient zip codes to U.S. Census data to obtain aggregated socio-economic characteristics of individuals living in the zip code and to classify regions as urban/surburban/rural.

4. If yes, for each proposed linkage above, please describe your method or selected algorithm (e.g., deterministic or probabilistic) for linking each dataset. If you intend to develop a unique algorithm, please describe how it will link each dataset.

> We will first attempt to link providers and facilities using government IDs (deterministic). We will map zip codes directly to Census data (deterministic).

5. If yes, attach or provide below a complete listing of the variables from all sources to be included in the final linked analytic file.

> We wish to have the following variables included for **Providers:**
> specialty, years in practice, medical school, affiliation with academic medical center, practice address, practice characteristics (size, specialty composition, owner, hospital outpatient dept. status, # of practice sites, health system). Hospitals and other facilities: beds by type, services available, satellite facilities, health system membership, affiliation with health systems or other facilities, provision of specific services by staff or contract, staffing, finances; tax status, address of main campus and all satellite facilities, GME and DSH payments.
>
> We wish to have the following variables included for **Zip code:**
> % residents with incomes below federal poverty level, racial composition, urban/suburban/rural classification, education attainment, insurance coverage, age distribution, employment status.

Data Set	Level of Observation	Linkage Variable
Health Systems and Providers Database	Provider (hospital or physician)	National Provider ID or Tax ID
CMS Open Payment data	Individual physician	NPI (or other available identifiers if NPI is not available)
CMS Open Payment data	Individual hospital (teaching hospitals only)	CMS provider number, names, tax ID, or other available identifiers
Census data	Zipcode	Zipcode
CMS Provider Utilization and Payment Data	Individual physician	NPI
Publically available information (from new reports, etc.) on local providers	Hospital, physician groups, or health systems	Hospital name, CMS provider number, names, tax ID, or other available
National Survey of Healthcare Organizations and Systems (NSHOS)	Hospital, physician groups, or health systems	Hospital/system name, CMS provider number, names, tax ID, or other available identifiers

6. If yes, please identify the specific steps you will take to prevent the identification of individual patients in the linked dataset.

Identification of individual patients may occur during the following:

1.   Linked data in combination with additional data available on the web, especially for those with very sparsely populated zip codes. Investigators have been trained and certified in human subjects research and ethics and understand this is a violation of patient's privacy.

2.   The presentation and publication of research results. All research results will be aggregated to a level that would make it impossible to identify individual patients.

X.   PUBLICATION / DISSEMINATION / RE-RELEASE

1. Do you anticipate that the results of your analysis will be published or made publically available? If so, how do you intend to disseminate the results of the study (e.g.; publication in professional journal, poster presentation, newsletter, web page, seminar, conference, statistical tabulation)? Any and all publication of CHIA Data must comply with CHIA's cell size suppression policy, as set forth in the Data Use Agreement. Please explain how you will ensure that any publications *will not disclose a cell less than 11*, and percentages or other mathematical formulas that result in the display of a cell less than 11.

We anticipate publishing the results of our analyses in peer-reviewed journals and working paper series. We will submit to clinical, health policy, disability, and economics outlets such as the New England Journal of Medicine, Journal of the American Medical Association, and Health Affairs. We will also disseminate our findings with policy leaders, payers, provider networks, and academic leaders within Massachusetts and at professional meetings such as AcademyHealth. All tables and figures will be reviewed by investigators and research compliance officers in our department to ensure that no results with a cell size less than 11 are divulged.

2. Describe your plans to use or otherwise disclose CHIA Data, or any Data derived or extracted from such Data, in any paper, report, website, statistical tabulation, seminar, or other setting that is not disseminated to the public.

We have no plans to publish or otherwise disclose CHIA data directly. We will disseminate our findings with policy leaders, payers, provider networks, and academic leaders within Massachusetts and at professional meetings such as AcademyHealth.

3. What will be the lowest geographical level of analysis of data you expect to present for publication or presentation (e.g., state level, city/town level, zip code level, etc.)? Will maps be presented? If so, what methods will be used to ensure that individuals cannot be identified?

The lowest geographical level of data analysis we expect to present is the county. There are sufficiently large populations in Massachusetts counties that it will not be possible to identify individuals from the results.

4. Will you be using CHIA Data for consulting purposes?

☐ Yes
☒ No

5. Will you be selling standard report products using CHIA Data?
   ☐ Yes
   ☒ No

6. Will you be selling a software product using CHIA Data?
   ☐ Yes
   ☒ No

7. Will you be using CHIA Data as in input to develop a product (i.e., severity index took, risk adjustment tool, reference tool, etc.)
   ☐ Yes
   ☒ No

8. Will you be reselling CHIA Data in any format not noted above?
   ☐ Yes
   ☒ No

If yes, in what format will you be reselling CHIA Data?

Click here to enter text.

9. If you have answered "yes" to questions 5, 6, 7 or 8, please provide the name and a description of the products, software, services, or tools.

Click here to enter text.

10. If you have answered "yes" to questions 5, 6, 7 or 8, what is the fee you will charge for such products, software, services or tools?

Click here to enter text.

XI.   APPLICANT QUALIFICATIONS

1. Describe your previous experience using claims data. This question should be answered by the primary investigator and any co-investigators who will be using the Data.

PI Chien is a physician researcher who is expert on the effect of incentives on care access and quality for medically and socially vulnerable populations. **PI Chien** along with several members of the current study team developed the Children with Disabilities Algorithm so that it could be used to assess the health of populations of persons with disabilities within the proliferating number of large administrative databases as the current study proposes.

Econometrically-trained analyst **Co-I Dr. Samnaliev** is a PhD economist whose career has focused on implementing comparative effectiveness analyses in large databases. He has the track record needed to implement the descriptive longitudinal analyses.

2. **Resumes/CVs**: When submitting your Application package on IRBNet, include résumés or curricula vitae of the principal investigator and co-investigators. (These attachments will not be posted on the internet.)

XII.   USE OF AGENTS AND/OR CONTRACTORS

By signing this Application, the Organization assumes all responsibility for the use, security and maintenance of the CHIA Data by its agents, including but not limited to contractors. The Organization must have a written agreement with the agent of contractor limiting the use of CHIA Data to the use approved under this Application as well as the privacy and security standards set forth in the Data Use Agreement. CHIA Data may not be shared with any third party without prior written consent from CHIA, or an amendment to this Application. CHIA may audit any entity with access to CHIA Data.

Provide the following information for **all** agents and contractors who will have access to the CHIA Data. [*Add agents or contractors as needed.*]

AGENT/CONTRACTOR #1 INFORMATION	
Company Name:	Click here to enter text.
Company Website	Click here to enter text.
Contact Person:	Click here to enter text.
Title:	Click here to enter text.
E-mail Address:	Click here to enter text.
Address, City/Town, State, Zip Code:	Click here to enter text.
Telephone Number:	Click here to enter text.
Term of Contract:	Click here to enter text.

1. Describe the tasks and products assigned to the agent or contractor for this Project and their qualifications for completing the tasks.

Click here to enter text.

2. Describe the Organization's oversight and monitoring of the activities and actions of the agent or contractor for this Project, including how the Organization will ensure the security of the CHIA Data to which the agent or contractor has access.

Click here to enter text.

3. Will the agent or contractor have access to and store the CHIA Data at a location other than the Organization's location, off-site server and/or database?

☐ Yes
☐ No

4. If yes, a separate Data Management Plan **must** be completed by the agent or contractor.

AGENT/CONTRACTOR #1 INFORMATION	
Company Name:	Click here to enter text.
Company Website	Click here to enter text.
Contact Person:	Click here to enter text.
Title:	Click here to enter text.
E-mail Address:	Click here to enter text.
Address, City/Town, State, Zip Code:	Click here to enter text.
Telephone Number:	Click here to enter text.
Term of Contract:	Click here to enter text.

1. Describe the tasks and products assigned to the agent or contractor for this Project and their qualifications for completing the tasks.

Click here to enter text.

2. Describe the Organization's oversight and monitoring of the activities and actions of the agent or contractor for this Project, including how the Organization will ensure the security of the CHIA Data to which the agent or contractor has access.

Click here to enter text.

3. Will the agent or contractor have access to or store the CHIA Data at a location other than the Organization's location, off-site server and/or database?

☐ Yes
☐ No

4. If yes, a separate Data Management Plan **must** be completed by the agent or contractor.

[INSERT A NEW SECTION FOR ADDITIONAL AGENTS/CONTRACTORS AS NEEDED]

XIII. ATTESTATION

By submitting this Application, the Organization attests that it is aware of its data use, privacy and security obligations imposed by state and federal law *and* confirms that it is compliant with such use, privacy and security standards. The Organization further agrees and understands that it is solely responsible for any breaches or unauthorized access, disclosure or use of CHIA Data, including, but not limited to, any breach or unauthorized access, disclosure or use by any third party to which it grants access.

Organizations approved to receive CHIA Data will be provided with Data following the payment of applicable fees and upon the execution of a Data Use Agreement requiring the Organization to adhere to processes and procedures designed to prevent unauthorized access, disclosure or use of data.

By my signature below, I attest: (1) to the accuracy of the information provided herein; (2) this research is not funded by a source requiring the release of raw data to that source; (3) that the requested Data is the minimum necessary to accomplish the purposes described herein; (4) that the Organization will meet the data privacy and security requirements described in this Application and supporting documents, and will ensure that any third party with access to the Data meets the data use, privacy and security requirements; and (5) to my authority to bind the Organization.

Signature: (Authorized Signatory for Organization)	*august Cervini* Drag signature image here or delete and physically sign
Printed Name:	August Cervini ~~Click here to enter text.~~
Title:	SVP Research Administration ~~Click here to enter text.~~
Date:	10/11/2021 ~~Click here to enter text.~~

Attachments:
A completed Application must have the following documents attached to the Application or uploaded separately to IRBNet:
☒ 1. IRB approval letter and protocol (if applicable), or research methodology (if protocol is not attached)
☒ 2. Data Management Plan (including one for each agent or contractor that will have access to or store the CHIA Data at a location other than the Organization's location, off-site server and/or database);
☒ 3. CVs of Investigators (upload to IRBNet)

==**APPLICATIONS WILL NOT BE REVIEWED UNTIL THEY ARE COMPLETE, INCLUDING ALL ATTACHMENTS.**==