CHIA
center for health information 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. Organizations 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 Application 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:	Characterization of patient care pathways for complex pediatric conditions
IRBNet Number:	1991892-1
Organization Requesting Data (Recipient):	The Children's Hospital Corporation d/b/a Boston Children's Hospital
Organization Website:	https://www.childrenshospital.org/
Authorized Signatory for Organization:	Theresa Applegate
Title:	Senior Director, Office of Sponsored Programs
E-Mail Address:	osp@childrens.harvard.edu or Theresa.applegate@childrens.harvard.edu
Telephone Number:	617-919-2735 (direct) or 617-919-2729 (main)
Address, City/Town, State, Zip Code:	300 Longwood Avenue, BCH3158, Boston, MA 02115
Data Custodian: (individual responsible for organizing, storing, and archiving Data)	Piotr Sliz
Title:	Chief Research Information Office
E-Mail Address:	Piotr.Sliz@childrens.harvard.edu
Telephone Number:	617-919-1422
Address, City/Town, State, Zip Code:	300 Longwood, mailstop BCH3396, Boston, MA 02115
Primary Investigator (Applicant): (individual responsible for the research team using the Data)	Kenneth D. Mandl
Title:	Director, Computational Health Information Program
E-Mail Address:	Kenneth.Mandl@childrens.harvard.edu
Telephone Number:	617-355-4145
Address, City/Town, State, Zip Code:	300 Longwood, mailstop BCH3187, Boston, MA 02115
Names of Co-Investigators:	Rena Xu, Karen Olson
E-Mail Addresses of Co-Investigators:	Rena.Xu@childrens.harvard.edu Karen.Olson@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 **or** written request to CHIA, with approval being subject to CHIA's regulatory restrictions and approval process. Unauthorized use is a material violation of your Organization'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.

Significance: Diagnostic and treatment delays are associated with worse health outcomes and unnecessary health care costs. These delays are particularly prevalent for complex medical problems, such as mental health disorders, that lack standardized management algorithms and gold standard diagnostic tests. A novel approach to identify drivers of delays is to characterize ***care pathways***, defined as the sequence of encounters, tests, and interventions between first detection of symptoms and ultimate diagnosis and treatment. We hypothesize that 1) there is a **wide range in duration, composition, and cost** of care pathways from symptom to diagnosis and treatment for many common complex medical problems; 2) certain populations may be **exposed to increased risk** for prolonged care pathways; and 3) **optimal care pathways** can be identified and standardized to improve outcomes and reduce costs.

Specific aims: This study will use the APCD to characterize care pathways for common medical problems with varying degrees of diagnostic complexity and the availability of management algorithms. The aims of this study are: 1) to **quantify the range in care pathways** for different medical problems; 2) to **identify populations at greatest risk** for prolonged care pathways; and 3) to **define optimal care pathways** that minimize time to diagnosis and treatment and reduce unnecessary costs.

Need for APCD data: The APCD will be critical for mapping encounters at the individual patient level across care settings, providers, and payors and in chronological sequence. This is essential for accurately characterizing pathways, identifying areas of potential inefficiency, and developing predictors of risk.

Medical conditions to study

1. *Complex* medical conditions. Examples include:
   a. **Mental health disorders** (including depression, anxiety, disruptive mood dysregulation disorder, attention deficit hyperactivity disorder). These are the leading cause of disability and poor life outcomes among youth in the U.S and cost an estimated $247 billion per year. Such disorders affect one in five children ages three to 17 years and are growing in prevalence: in 2019, one in three high school students reported persistent feelings of sadness or depression, an increase of 40% from 2009. Moreover, mental health problems are vastly underdiagnosed and undertreated: seventy percent of children and adolescents in need of mental health treatment do not receive services, and on average, children wait eight to 10 years from the onset of symptoms to treatment.[1]

      In addition to using APCD data to characterize pediatric mental health problem prevalence and pathway duration and composition, we will also use ongoing APCD data to characterize how these elements have changed and continue to evolve following the COVID-19 pandemic. We hypothesize that there is an increase in the prevalence of pediatric mental health conditions as well as ED encounters and hospitalizations from 2021 onward as compared to 2019 and before, with longer

pathway duration from symptom to diagnosis and shorter duration from diagnosis to ED encounters or hospitalizations for mental health conditions.

b. **Autism spectrum disorder.** This affects one in 44 children, and prompt diagnosis is critical because early intervention can improve outcomes.[2] Yet many presenting signs and symptoms, including delayed speech and behavioral disturbances, are nonspecific; they can indicate a range of psychological, neurological, and ontological issues.[3] Currently, autism is diagnosed by many different types of providers using a wide range of tests, without a clear consensus on the optimal pathway. The result is inefficient use of limited resources, which exacerbates wait times to see specialty providers and potentially creates even longer delays in diagnosis and treatment.

c. **Long COVID.** Increasing evidence suggests rates of post-COVID-19 condition, or Long COVID, are substantial.[4] Incomplete understanding of the disease process and a lack of consensus on diagnostic criteria have contributed to delays in diagnosis. Disparities in the effects of COVID-19 on different populations suggest potential disparities in the diagnosis and management of Long COVID.

d. **Inflammatory bowel disease.** Lifelong management is required for this chronic condition, yet no consensus exists on the optimal sequence of biologic agents for treatment. Many therapies have limited effectiveness and high rates of adverse effects, some of which can be life-threatening. Furthermore, it is unclear where many of the newer agents ideally should fit in the treatment pathway. Lastly, data are lacking on the appropriate timing of therapy de-escalation and exit strategies.[5, 6]

2. *Reference* conditions. These are more straightforward to diagnose because standardized algorithms and gold standard diagnostic tests are available. Examples include:
   a. **Vesicoureteral reflux f**ollowing febrile urinary tract infection.
   b. **Leukemia** following fatigue.

References:

1. Cullins LM, Gabriel M, Solages M, et al. Pediatric Community Mental Health. Curr Probl Pediatr Adolesc Health Care 2016;46(11):354-388; doi:10.1016/j.cppeds.2016.09.001.
2. Hus Y, Segal O. Challenges Surrounding the Diagnosis of Autism in Children. Neuropsychiatr Dis Treat 2021;17:3509-3529; doi:10.2147/ndt.S282569.
3. Wooles N, Swann J, Hoskison E. Speech and language delay in children: a case to learn from. Br J Gen Pract 2018;68(666):47-48; doi:10.3399/bjgp17X694373.
4. Chen C, Haupert SR, Zimmermann L, et al. Global Prevalence of Post COVID-19 Condition or Long COVID: A Meta-Analysis and Systematic Review. J Infect Dis 2022;doi:10.1093/infdis/jiac136.
5. Baumgart DC, Le Berre C. Newer Biologic and Small-Molecule Therapies for Inflammatory Bowel Disease. N Engl J Med 2021;385(14):1302-1315; doi:10.1056/NEJMra1907607.
6. Cheifetz AS, Abreu MT, Afif W, et al. A Comprehensive Literature Review and Expert Consensus Statement on Therapeutic Drug Monitoring of Biologics in Inflammatory Bowel Disease. Am J Gastroenterol 2021;116(10):2014-2025; doi:10.14309/ajg.0000000000001396.

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**: Applications 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.*

The public interest is served in several important ways. First, this study has the potential to **improve population health** by expediting diagnosis and treatment, thereby improving outcomes for complex medical issues. This can reduce rates of death, morbidity, and lost productivity for some of the most burdensome conditions in the U.S. Second, it has the potential to **reduce unnecessary health care costs** by identifying areas of inefficiency in care pathways and predicting which patients are most vulnerable to prolonged care pathways. This will enable more effective triaging of patients and more efficient resource use.

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 fully-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 may not be available).

ANNUAL RELEASE 2020	ANNUAL RELEASE 2021
☐ 2016	☒ 2017
☐ 2017	☒ 2018
☐ 2018	☒ 2019
☐ 2019	☒ 2020
☐ 2020	☒ 2021

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:

Medical Claims are needed to characterize the medical care that patients receive in different care pathways. This is important for accurately capturing pathway duration, composition, and cost.

☒ Pharmacy Claims

Describe how your research objectives require Pharmacy Claims data:

Pharmacy Claims are needed to capture any medication-based treatments that patients receive in different care pathways. This is important for accurately characterizing pathway composition and cost differences in treatment across pathways.

☐ Dental Claims

Describe how your research objectives require Dental Claims data:

Click here to enter text.

☒ Member Eligibility

Describe how your research objectives require Member Eligibility data:

Member eligibility data are needed to characterize pathway duration, composition, and cost across populations with different demographic characteristics, and different eligibility and insurance coverage.

☒ Provider

Describe how your research objectives require Provider data:

Provider data are needed to characterize the number, specialty, and professional category of providers involved in different care pathways and to determine which pathway compositions are most efficient and effective. These data are also needed to determine the duration of and degree of turnover in patient-provider relationships. They may be important predictors of pathway efficiency and outcomes.

☐ Product

Describe how your research objectives require Product data:

Click here to enter text.

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

ZIP code and state geographic subdivisions are available for Massachusetts residents and providers only. Small population ZIP codes are combined with larger population ZIP codes. One ZIP Code per person (MEID) per year has been assigned based on the ZIP code/state reported in the member eligibility record's earliest submission year month. If the record does not have an MEID, assignment is based on distinct OrgID/Carrier Specific Unique Member ID.

Non-Massachusetts ZIP codes and sate codes except for CT, MA, ME, NH, NY, RI, and VT are suppressed.

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: Some of the socio-economic and demographic variables associated with US Census Dept. Zip Code Tabulation Areas (ZCTAs) will enhance related data in the Member Eligibility file. ZCTAs are created by combining census block areas based on the most frequently occurring zip codes for addresses within each block. Therefore, they correspond to US Postal Service 5-digit zip code areas. Summary statistics for populations within census blocks are reported for each ZCTA. Zip codes will also be used to add variables from the Child Opportunity Index (COI) which measures neighborhood resources and conditions that affect healthy child development. The diversitydatakids.org project built and maintains the COI, which is housed at the Heller School at Brandeis University. It is publicly available at their web site.	

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: Dates including month and day are needed to chronologically sequence encounters to accurately characterize the care pathways, which are sequential in nature.		

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:**

Decrypted NPIs will allow us to utilize additional provider information available in the National Plan and Provider Enumeration System (NPPES). This lets us assess potential differences in practice and care pathway patterns across geography, specialty, and other provider characteristics such as gender. Of particular importance is a complete provider taxonomy list. Besides the primary taxonomy code, up to 14 additional codes are allowed in the NPPES registry.

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.

Variables that affect health outcomes and costs are of direct relevance to the administration of the Medicaid program. Understanding the drivers of prolonged care pathways and inefficient resource use can lead to recommendations for care redesign, which is a major emphasis of the Affordable Care Act. For example, the study may identify an optimal pathway for diagnosing and managing depression that results in fewer ED visits for suicidal ideation. Such information will assist Medicaid in implementing policies and programs that steer more patients toward this optimal pathway, thereby helping to reduce unnecessary costs and improve health outcomes. Because Medicaid covers a distinct population, including these individuals in the study population contributes to the accuracy of the measures we construct and the reliability and validity of results we report. Of particular importance is the pediatric population. Children are often underrepresented in medical studies. Including those insured by Medicaid, as well as those with private insurance, makes any findings more generalizable and noteworthy.

3. Organizations approved to receive Medicaid Data will be required to execute a Medicaid Acknowledgement 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.

US Census ZCTA summary statistics (member zip code link) – to enhance socio-economic and demographic data available in the Member Eligibility file. National Plan and Provider Enumeration System (NPPES) Registry (provider NPI link) – to add provider variables such as additional taxonomy codes and gender for individuals. Childhood Opportunity Index (COI) (member zip code link) – to add variables related to healthy child development that characterize the neighborhoods in which they live. The index is based on 29 indicators from 3 domains: education, health/environment, social/economic.

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.

All linkages will be deterministic (exact matches to zip code or NPI).

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.

See attached worksheet: Variables for APCD.xlsx

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

Patient data is linked to external data sources using a 5-digit zip code. The data sources only contain aggregate data for zip code or zip code tabulation areas. Individual patients cannot be identified in these linked sources. The data files from external sources will be copied to encrypted servers behind the hospital firewall. No patient data will leave these servers to link to these additional data sources.

X. PUBLICATION / DISSEMINATION / RE-RELEASE

1. Do you anticipate that the results of your analysis will be published or made publicly 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.

Results of our analyses will be published in academic journals and/or presented at academic conferences. All publications arising from CHIA data will comply with the policies in the Data Use Agreement. Only aggregated results will be published, and no statistical tabulations will disclose cell counts less than 11 or percentages that enable calculating a cell size less than 11.

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.

No plans to disclose results of our analyses of CHIA data in a non-public setting.

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 levels, if any, would either be state or groups of states, e.g., MA, New England states, other states, or region, e.g., metro-Boston, western MA, etc. We are requesting zip codes to acquire the summary statistics and descriptive variables associated with those areas for further analysis. But we do not plan to publish maps or results by zip code.

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 input to develop a product (i.e., severity index tool, 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.

Kenneth Mandl, PI, has led many projects using claims data from the APCD, Aetna, and Blue Cross Blue Shield. As PI for a PCORI Clinical Data Research Network, he co-leads the application for and use of a large CMS dataset across multiple hospitals. These projects have resulted in numerous publications.
Rena Xu has experience with the Pediatric Health Information System and other large databases.
Karen Olson has extensive experience analyzing claims data, including the APCD and the MA Hospital Case Mix Database, and several large, national-scale claims databases, including the Federal Employees Health Benefits plan, the Pediatric Health Information System, and a private insurance database with >85 million enrollees over a 12-year period.

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.

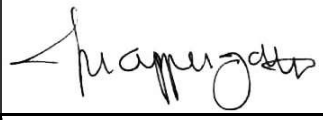
[INSERT A NEW SECTION FOR ADDITIONAL AGENTS/CONTRACTORS AS NEEDED]

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)	
Printed Name:	**Theresa Applegate**
Title:	Senior Director, Office of Sponsored Programs
Date:	01/26/2023

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.