center for health information and analysis

# Non-Government Application for Massachusetts All-Payer Claims Data [Exhibit A]

#### I. INSTRUCTIONS

This form is required for all Applicants, except Government Agencies as defined in <u>957 CMR 5.02</u>, requesting protected health information. All Applicants must also complete the <u>Data Management Plan</u>, attached to this Application. The Application and the Data Management Plan must be signed by an authorized signatory of the Organization. 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 <u>Data</u> <u>Use Agreement</u>. Applicants 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.

All attachments must be uploaded to IRBNet with your Application. All Application documents can be found on the <u>CHIA website</u> in Word and in PDF format or on <u>IRBNet</u> in Word format. If you submit a PDF document, please also include a Word version in order to facilitate edits that may be needed.

Applications will not be reviewed until the Application and all supporting documents are complete and the required application fee is submitted. A <u>Fee Remittance Form</u> with instructions for submitting the application fee is available on the CHIA website and IRBNet. If you are requesting a fee waiver, a copy of the Fee Remittance Form and any supporting documentation must be uploaded to IRBNet.

#### **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 <a href="mailto:apcd.data@state.ma.us">apcd.data@state.ma.us</a>.

3. If you believe that you qualify for a fee waiver, complete and submit the <u>Fee Remittance Form</u> and attach it and all required supporting documentation with your application. Refer to the <u>Fee Schedule</u> (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:	Integrating Behavioral Health Into the Pediatric Medical Home for Low-Income Children
IRBNet Number:	1327778-1
Organization Requesting Data (Recipient):	Trustees of Boston University
Organization Website:	http://www.bumc.bu.edu/
Authorized Signatory for Organization:	William P. Segarra, JD, MPH
Title:	Director, Industry Contracts & Agreements
E-Mail Address:	industry@bu.edu
Address, City/Town, State, Zip Code:	25 Buick Street, Suite #200, Boston, MA 02215
Data Custodian:	Megan Cole, PhD, MPH
(individual responsible for organizing, storing, and archiving Data)	
Title:	Assistant Professor
E-Mail Address:	<u>mbcole@bu.edu</u>
Telephone Number:	617-358-1901
Address, City/Town, State, Zip Code:	715 Albany Street Talbot Building, 240W Boston, MA 02118
Primary Investigator (Applicant):	Megan Cole, PhD, MPH
(individual responsible for the research team using the Data)	
Title:	Assistant Professor
E-Mail Address:	mbcole@bu.edu
Telephone Number:	617-358-1901
Names of Co-Investigators:	Megan Bair-Merritt, MD, MSCE
E-Mail Addresses of Co-Investigators:	mbairme1@bu.edu

### **IV. PROJECT INFORMATION**

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

Epidemiological

□ Health planning/resource allocation □Cost trends □ Quality of care assessment

- ⊠ Longitudinal Research □ Reference tool
- $\boxtimes$  Research studies
- □ Surveillance
- □ Inclusion in a product
- □ Student research
- □ Other (describe in box below)
- □ Rate setting
- □ Severity index tool
- □ Utilization review of resources

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.

#### Background

Approximately 1 in 5 US children have a behavioral health problem, with low-income children bearing a disproportionate burden of risk.<sup>1</sup> Children with behavioral health problems, particularly those that are under-diagnosed or under-treated, may be more likely to visit the emergency department,<sup>2 3</sup> and mood disorders are the most common

primary diagnosis amongst hospitalized children.<sup>4</sup> Despite the availability of evidence-based treatments for child behavioral health conditions, there are many systemic barriers to receiving adequate mental health care, especially for low-income and minority populations.<sup>5</sup>

The pediatric medical home is an ideal location to deliver behavioral health prevention and treatment because of the near universality of well-child visits, and because of the longitudinal relationship between providers and families. Charged with caring for 6 million low-income children each year, federally-qualified Community Health Center (CHC) providers in particular recognize the consequences of under-diagnosed and under-treated behavioral health problems, and are amenable to changing care delivery.<sup>7</sup> As such, starting in 2017, three Boston-based pediatric medical home CHC sites began implementing TEAM UP, a complete behavioral health integration model. The initiative includes: (1) provider and staff training focused on recognizing and diagnosing child behavioral health problems, engaging families in appropriate self-care, and providing evidence-based therapeutic interventions when necessary and (2) full integration of behavioral health providers, care coordinators, community health workers, psychologists and psychiatrists into the medical team, allowing for "in the moment" support and intervention with families. Specific aims & hypotheses

Our specific aims are threefold: (1) to examine the impact of receiving primary care at an intervention site on rates of health care utilization in children, including primary care and other outpatient behavioral health visits, all-cause emergency department (ED) visits, behavioral health ED visits, inpatient admissions, and inpatient admissions with a primary diagnosis of a mental health condition, (2) to examine the impact of receiving primary care at an intervention site on quality of care for children, including rates of psychotropic medication use and evidence of 7- and 30-day follow-up visit after discharge, and (3) to examine the impact of receiving primary care at an intervention site on total cost of care for children. We hypothesize that receipt of integrated behavioral health services will reduce ED visits and hospitalizations that are sensitive to behavioral health, while potentially reducing total care of care for patients served by intervention sites.

# Products

Results from this project will be disseminated through manuscripts, conference presentations, and presentations to key stakeholders involved in the project. This information will be used to make key decisions about whether or not to scale up the intervention to other community health centers in the greater Boston area. Results may also inform similar interventions across the state and across the US.

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

☑ Yes [If yes, a copy of the approval letter and protocol <u>must</u> be included with the Application package on IRBNet.]
 □ No, this Project is not human subject research and does not require IRB review.

4. **<u>Research Methodology</u>**: Applicants must provide 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 your 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.

Completing this project is of public interest for four main reasons. First, one objective of our project is to reduce avoidable health care utilization for children, particularly for ED visits and inpatient admissions related to mental health. This is of particular interest to the public, as pediatric inpatient admissions have increased substantially across the US in recent years (Health Cost Institute, 2012) and many ED visits are preventable. This would be of particular benefit to MassHealth, as nearly all patients in our intervention are MassHealth enrollees.

Second, if ED visits and hospitalizations are successfully reduced, this may ultimately reduce total cost of care over the long run. This is of particular interest to the public because in the US, approximately 20% of children have a diagnoses mental health disorder (Perou R, Bitsko RH, Blumberg SJ, et al, 2013) with associated inpatient and outpatient costs of about \$247 billion per year (Centers for Disease Control and Prevention, 2013). Reductions in total cost of care for these children will directly benefit the state's Medicaid program.

Third, the proposed project includes a measurable population health benefit, as the ultimate objective is to improve behavioral health outcomes for low-income children served by community health centers. If our findings are positive, then the intervention may be scaled up to additional primary care sites in the greater Boston area and throughout the state, thus increasing the population-level impact, especially for the MassHealth population.

Finally, as the state transitions the majority of its MassHealth enrollees into accountable care organization (ACO) arrangements, one critical aspect of ACO success is to integrate behavioral health services into medical care, including medical care for children. In fact, 10 of the proposed 22 MassHealth ACO Quality Payment Program Measures focus on behavioral health specifically. Thus, findings from our study may inform future behavioral health integration efforts for these ACOs and will be complementary to the ongoing ACO efforts to better integrate behavioral health services.

# VI. DATA 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. Data requests will be fulfilled using the most current Release Version. For more information about the most current APCD Release Version, 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 <u>CHIA's website</u>.

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. Applicants who anticipate a need for future years of data may request to be considered for a subscription. Approved subscriptions will receive, upon request, the <u>same data files and data</u> <u>elements</u> included in the initial Release annually or as available. Please note that approved subscription request will be subject to the Data Use Agreement, will require payment of fees for additional Data, and subject to the limitation that the Data can be used only in support of the approved Project.

1. List years of data requested (only list years available in the <u>current Release Version</u>): <u>2014-2017 (will wait until 2017</u> is available)

2. Please indicate below whether this is a one-time request, or if the described Project will require a subscription.

# $\Box$ One-Time Request **OR** $\boxtimes$ Subscription

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 will be used to capture utilization measures (i.e. ED visits, hospitalizations), total cost of care measures, patient follow-up visits after hospitalizations, and patient diagnoses. Medical claims will also be used in conjunction with the member eligibility files and provider files to attribute members to a primary care site, based on where they receive the majority of their primary care services.

### Pharmacy Claims

#### Describe how your research objectives require Pharmacy Claims data:

Pharmacy claims will be used to capture psychotropic medication use and will contribute to the pharmacy portion of total cost of care.

#### **Dental Claims**

Describe how your research objectives require Dental Claims data:

NA

# Member Eligibility

#### Describe how your research objectives require Member Eligibility data:

Member eligibility files will be used to capture key patient demographics as well as important inclusion and exclusion criteria. This includes member age, gender, zip code, plan type, product type, cost sharing information if any, attributed PCP, the Physician Group of the Member's PCP, and dates of eligibility.

#### Provider

#### Describe how your research objectives require Provider data:

The provide file will be used to assess the location and thus the practice of the provider if it is the attributed primary care provider. This will allow us to identify intervention sites versus non-intervention sites when creating our intervention and control groups.

#### Product

#### Describe how your research objectives require Product data:

The product file will give us information about the product type and deductible amount, which will be used to ensure that these characteristics are balanced in our intervention and control groups and further adjusted for in our models if needed.

# VII. DATA ENHANCEMENTS REQUESTED

State and federal privacy laws limit the release and use of 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 applicants 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 <u>release layouts</u>, <u>data dictionaries</u> 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 <u>each</u> enhancement.

### Geographic Subdivisions

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

□ 3-Digit Zip Code (standard)	⊠ 5-Digit Zip Code***

\*\*\*If requested, provide justification for requesting 5-Digit Zip Code. Refer to specifics in your methodology:

Our study will require 5 digit zip code for two reasons. First, understanding each enrollee's zip code will allow us to more accurately assign enrollees to intervention sites. Second, it is critical that the intervention and control groups have similar demographic make-up, including zip code of residence. For example, when creating our propensity matched control group, for every enrollee receiving care at an intervention site, we will select another enrollee *not* receiving care at an intervention site who is from the same five-digit zip code. It is important that the zip codes are as precise as possible given that demographics vary widely across zip codes.

We also require zip codes for providers, as this will allow us to assign practice designations.

#### Date Resolution

Select <u>one</u> 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:		
Knowing specific dates is necessary for capturing several outcomes. All claim dates, inclusive of day, are needed to identify		
number of days from hospital discharge	to follow-up visit; to identify the length	n of stay for hospital visit; and to ensure the
sequence of claims is understood for claims occuring in the same month. Product start and end dates are also necessary to		
determine specific number of eligible da	ys in a given time period (month, quart	ter).

National Provider Identifier (NPI) Select *one* of the following options.

Encrypted National Provider Identifier(s) (standard)	Decrypted National Provider Identifier(s)***	
*** If requested, provide justification for requesting decrypted National Provider Identifier(s). Refer to specifics in your		
methodology:		

As appropriate attribution to intervention versus non-intervention sites is critical for our analyses, we are requesting NPIs so as to link NPI with CMS' NPI database. This will allow us to link each provider with their practice location. In turn, we can more accurately assign providers and their patients to practices.

### 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 <u>directly connected to the administration of the Medicaid program</u>. 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 Data without approval from MassHealth. This may introduce significant delays in the receipt of MassHealth Data.

MassHealth data are critical for our analyses, as nearly all children served by our intervention sites, and by community health centers generally, are enrolled in MassHealth.

The public benefits described in Section V apply almost entirely to the MassHealth program and its enrollees, as described below.

Completing this project is of direct benefit to the Medicaid program for four main reasons. First, one objective of our project is to reduce avoidable health care utilization within children, particularly for ED visits and inpatient admissions related to mental health. This is of particular interest to the public, as pediatric inpatient admissions have increased substantially across the US in recent years (Health Cost Institute, 2012) and many ED visits are preventable. This would be of particular benefit to MassHealth, as nearly all patients in our intervention are MassHealth enrollees.

Second, if ED visits and hospitalizations are successfully reduced, this may ultimately reduce total cost of care over the long run. This is of particular interest to the public because in the US, approximately 20% of children have a diagnoses mental health disorder (Perou R, Bitsko RH, Blumberg SJ, et al, 2013) with associated inpatient and outpatient costs of about \$247 billion per year (Centers for Disease Control and Prevention, 2013). Reductions in total cost of care for these children will directly benefit the state's Medicaid program.

Third, the proposed project includes a measurable population health benefit, as the ultimate objective is to improve behavioral health outcomes for low-income children served by community health centers. If our findings are positive, then the intervention may be scaled up to additional primary care sites in the greater Boston area and throughout the state, thus increasing the population-level impact, especially for the MassHealth population.

Finally, as the state transitions the majority of its MassHealth enrollees into ACO arrangements, one critical aspect of ACO success is to integrate behavioral health services into medical care, including medical care for children. In fact, 10 of the proposed 22 MassHealth ACO Quality Payment Program Measures focus on behavioral health specifically. Thus, findings from our study may inform future behavioral health integration efforts for these ACOs and will be

# complementary to the ongoing ACO efforts to better integrate behavioral health services.

#### 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?

 $\boxtimes$  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)

 $\Box$  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 link NPI identifiers to the national NPI database and/or to the MA Registration of Provider Organizations (RPO) database to verify practice locations.

Please note that <u>we will not</u> link, stack, merge, or otherwise combine CHIA Data with claims data that the study team has from the RI APCD or from BMC HealthNet.

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 use a one-to-many merge based on NPI number – a common identifier. No algorithm is necessary.

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

The variables linked from the NPI file will include the following: Provider Organization Name (Legal Business Name); Provider Other Organization Name; Provider First Line Business Practice Location Address; Provider Second Line Business Practice Location Address; Provider Business Practice Location Address City Name; Provider Business Practice Location Address State Name; Provider Business Practice Location Address Postal Code; Provider Enumeration Date; Last Update Date; NPI Deactivation Date; NPI Reactivation Date

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

No linked data will be at the patient-level. Linked data are for providers only.

# 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.

Results from this project will be publically disseminated through manuscripts and conference presentations. Results will be reported in <u>aggregate</u>, where we will compare outcomes for all patients in the intervention group versus the control group. Tens of thousands patients will comprise these two respective groups.

We do not anticipate small cell sizes for any outcomes or subanalyses. However, we will ensure that no reported results will have a cell size less than 11. We will ensure this by reporting all sample sizes by cell. If any analyses were to result in a cell size <11, then we would not report that finding. Instead, we would include a note indicating that the cell size was insufficient for reporting.

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.

Results from this project will also be made available through presentations to key stakeholders involved in the project, including project funders (The Smith Family Foundation) and project participants (the three intervention sites). Patient-level data will never be shared in such a format. The smallest level of reporting for this purpose would be at the site level, though site-level results will not be shared publically. All results presented to these groups will be reported in aggregate and in accordance with cell size guidelines as described above.

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?

We will not report any results by geographical level. All public results will be grouped by intervention site (all three sites) versus non-intervention site (3-6 comparison sites). The smallest unit of reporting for non-public results will be the site-level.

To ensure that individuals cannot be identified, all results will be reported in aggregate (by intervention group or by

site) and in accordance with cell size guidelines as described above. No patient-level data will be shared. We anticipate that all or nearly all outcomes will have underlying denominator sizes of tens of thousands of patients.

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

- $\Box$  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?

9. If you have answered "yes" to questions 5, 6, 7 or 8, please describe the types of products, software, services, or tools.

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?

# XII. 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.

**Megan B. Cole, PhD, MPH**: For the past seven years of her career, Dr. Cole has worked extensively with claims data in conducting research and analyses. Examples of recent claims experiences include:

- Since 2014, she has used CMS Medicaid Analytic eXtract (MAX) Data. This includes twelve years of
  complete claims from 14 states, including inpatient, long-term care, prescription, or "other therapy"
  claims. For example, using these data, Cole has served as lead analyst and lead author in assessing to
  comorbidities in the HIV Medicaid population. This has included extensive data cleaning, quality checking,
  variable creation, analytic file creation, and statistical analyses.
- Since 2014, she has used multi-payer claims data from all payers in Rhode Island. Using these data, she has served as lead analyst and lead author in assessing the impact of Rhode Island's multi-payer patient centered medical home program on utilization and total cost of care. This has included quality checking, variable creation, analytic file creation, and statistical analyses.
- In more recent (2018) work, she is using the All-Payer Claims Database in RI to assess statewide cost trends and drivers of cost.
- Since 2017, she has led the economic impact evaluation of the TEAM UP intervention. This evaluation uses BMCHealth Net claims data to assess ED visits and inpatient admissions for children receiving care at a TEAM UP intervention site. These claims data are submitted to our study team in APCD format.

In addition, Dr. Cole has prior experience with Medicare's MedPAR files, which consolidates Inpatient Hospital and Skilled Nursing Facility claims data from the National Claims History files into stay level records. Previously, while at The Lewin Group, she also served as a data manager on a long-term CMS contract that required extensive cleaning, review, and analysis of raw claims data submitted by every state Medicaid program. At any given time, Cole oversaw the data for a portfolio of claims data for 4-7 states.

**Megan Bair-Merritt, MD**: Minimal claims experience. Will have access to data but will not conduct analyses, as Dr. Bair-Merritt is the PI of the full TEAM UP evaluation.

2. <u>Resumes/CVs</u>: 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.)

# XIII. USE OF AGENTS AND/OR CONTRACTORS

By signing this Application, the Agency assumes all responsibility for the use, security and maintenance of the CHIA Data by its agents, including but not limited to contractors. The Agency 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 <u>all</u> agents and contractors who will have access to the CHIA Data. [Add agents or contractors as needed.]

AGENT/CONTRACTOR #1 INFORMATION		
Company Name:	Boston Medical Center (BMC)	
Company Website	https://www.bmc.org/	
Contact Person:	Qiuyuan Qin	
Title:	Research Assistant	
E-mail Address:	Qiuyuan.Qin@bmc.org	
Address, City/Town, State, Zip Code:	Vose Hall, 3 <sup>rd</sup> Floor, 10 Stoughton St., Boston, MA 02118	
Telephone Number:	(617) 414-3667	
Term of Contract:		

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.

Qiuyuan Qin is the Research Assistant and statistical programmer on this project. She is employed by BMC, which is organizationally and geographically integrated with Boston University. She is a core member of our team, which meets every week to discuss project progress. Her work is directly overseen by Dr. Cole and Dr. Bair-Merritt, and her office is located right down the fall from Dr. Bair-Merritt. Ms. Qin is held to the same security and monitoring standards as employees of BU. BU IT staff have confirmed that her computer and work environment meet all security standards as outlined in the data management plan.

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 <u>must</u> be completed by the agent or contractor.

AGENT/CONTRACTOR #2	
INFORMATION	
Company Name:	
Company Website:	
Contact Person:	
Title:	
E-mail Address:	
Address, City/Town, State, Zip Code:	
Telephone Number:	
Term of Contract:	

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

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.

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 <u>must</u> be completed by the agent or contractor.

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

### **IVX. 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.

Applicants 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) that the requested Data is the minimum necessary to accomplish the purposes described herein; (3) 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 (4) to my authority to bind the Organization.

Signature:	
(Authorized Signatory for Organization)	
Printed Name:	William P. Segarra, JD, MPH
Title:	Director, Industry Contracts & Agreements

#### **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

 $\boxtimes$  3. CVs of Investigators (upload to IRBnet)

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

[INSERT IRB approval letter and protocol, or research methodology]

### REFERENCES

<sup>7</sup> NACHC. America's Health Centers. 2008.

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