

Application for Massachusetts Case Mix and Charge 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 casemix.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 Case Mix and Charge Data.
2. After reviewing the Fee Schedule, if you have any questions about the application or data fees, contact casemix.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:	Assessing the health impacts of climate change in Massachusetts
IRBNet Number:	2220634
Organization Requesting Data (Recipient):	Trustees of Boston University, School of Public Health – Department of Environmental Health
Organization Website:	https://www.bu.edu/sph/about/departments/environmental-health
Authorized Signatory for Organization:	William, Segarra, JD, MPH
Title:	Sr. Director, Industry Contracts and Agreements
E-Mail Address:	segarra@bu.edu
Telephone Number:	617-353-6151
Address, City/Town, State, Zip Code:	25 Buick Street, Suite 200, Boston, MA, 02215
Data Custodian: (individual responsible for organizing, storing, and archiving Data)	Chad Milando, PhD, MS
Title:	Research Scientist
E-Mail Address:	cmilando@bu.edu
Telephone Number:	617
Address, City/Town, State, Zip Code:	715 Albany Street, Boston MA, 02118
Primary Investigator (Applicant): (individual responsible for the research team using the Data)	Chad Milando, PhD, MS
Title:	Research Scientist
E-Mail Address:	cmilando@bu.edu
Telephone Number:	617
Address, City/Town, State, Zip Code:	715 Albany Street, Boston MA, 02118
Names of Co-Investigators:	Emma Gause, MS Gregory Wellenius, PhD Kirwa Kipruto, PhD
E-Mail Addresses of Co-Investigators:	egause@bu.edu, kirwa@bu.edu, wellenius@bu.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 (the “Project”). 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, 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

- | | | |
|---|--|---|
| <input type="checkbox"/> Reference tool | <input checked="" type="checkbox"/> Research studies | <input type="checkbox"/> Severity index tool (or other derived input) |
| <input type="checkbox"/> Surveillance | <input checked="" type="checkbox"/> Student research | <input type="checkbox"/> Utilization review of resources |
| <input type="checkbox"/> Inclusion in a product | <input type="checkbox"/> 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 world has warmed approximately 1.5 degrees Fahrenheit over the past 150 years, with the highest rates of temperature increases in the last 40 years. Comprehensive evidence indicates that climate change is largely caused by human emissions of carbon dioxide and other greenhouse gases, and that it is already posing profound threats to human and planetary health. Extreme weather events such as heat waves, wildfires, hurricanes, droughts, and severe storms have increased in frequency and intensity over the last century, with documented short-term and long-term adverse health effects. For example, it is estimated that more than 2,200 people die each year due to extreme heat in the United States. Similarly, an abundance of evidence has linked outdoor air pollution to morbidity and mortality due to many causes worldwide, accounting for approximately 1 in 6 deaths per year.

In the US, much of the epidemiologic research into the health effects of a changing climate has focused on mortality or hospital admissions among elderly Medicare beneficiaries. The CHIA case-mix data present a novel opportunity to assess the health impacts of climate change, extreme weather events, and air pollution across all age groups and for many outcomes. The objective of this project is therefore to use CHIA case-mix data for emergency department visits to examine the association between human health and acute changes in extreme weather in Massachusetts.

This project will yield evidence that can be used to: **1)** provide novel insights into the links between present-day climatic hazards and health risk as measured through healthcare utilization, **2)** generate robust estimates of the present-day and future burden of disease attributable to climatic hazards, **3)** identify individuals, populations, or communities particularly susceptible to the effects of climate change, and **4)** determine the effectiveness of specific adaptation or intervention strategies for reducing the potential health harms associated with climatic hazards. Together, this information will be useful in efforts aimed at mitigating climate change-related health risks, informing adaptation interventions, and reducing the socioeconomic burden associated with a warming climate.

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 states the Project objectives and/or identifies 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.

The overarching purpose of this study is to quantify the health impacts of present-day hazards related to continued climate change in order to provide critical evidence to better protect public health. The specific objectives of this project are:

1. Quantify the association between hazards expected to become more frequent or severe due to continued climate change and healthcare utilization. These hazards include, but are not limited to, meteorological conditions (e.g., high outdoor temperature, heavy precipitation, drought), air pollution (e.g., days with high ozone concentrations), and discrete severe weather events (e.g. coastal storms, wildfires).
2. Identify characteristics of individuals (e.g., age, sex) or communities (e.g., neighborhood measures of socioeconomic status) that place some people at greater risk of harm from these climatic hazards.
3. Assess the effectiveness of local, regional, or national adaptation measures (e.g., heat early warning systems) at reducing healthcare utilization during climatic hazards.

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.*

Completing this project will allow for highly localized science to inform policies and actions that address the present and future extreme weather/pollution-related challenges that residents of Massachusetts cities face. The comprehensive emergency department data from the Center for Health Information Analysis (CHIA) will allow us to investigate acute causes of emergency room visits for all causes. The data will also permit highly localized assessment of extreme heat-related health events. The results of this pilot will help identify specific vulnerable populations most at risk from climate change, and therefore inform the design of effective, well-targeted interventions to reduce the health burden due to extreme weather among the most vulnerable residents of Massachusetts cities.

VI. DATASETS REQUESTED

The Massachusetts Case Mix and Charge Data (“Case Mix”) are comprised of Hospital Inpatient Discharge, Emergency Department and Outpatient Hospital Observation Stay Data collected from Massachusetts’ acute care hospitals, and satellite emergency facilities. Case Mix Data are updated each fiscal year (October 1 – September 30) and made available to approved data users. For more information about Case Mix Data, including a full list of available elements in the datasets 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 years of data not yet available. 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 same data files and data elements 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. 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. Specify below the dataset(s) and year(s) of data requested for this Project, and your justification for requesting *each* dataset. Data prior to 2004 is not available.

<input type="checkbox"/> Hospital Inpatient Discharge Data <input type="checkbox"/> 2004 <input type="checkbox"/> 2005 <input type="checkbox"/> 2006 <input type="checkbox"/> 2007 <input type="checkbox"/> 2008 <input type="checkbox"/> 2009 <input type="checkbox"/> 2010 <input type="checkbox"/> 2011 <input type="checkbox"/> 2012 <input type="checkbox"/> 2013 <input type="checkbox"/> 2014 <input type="checkbox"/> 2015 <input type="checkbox"/> 2016 <input type="checkbox"/> 2017 <input type="checkbox"/> 2018 <input type="checkbox"/> 2019 <input type="checkbox"/> 2020 <input type="checkbox"/> 2021
Describe how your research objectives require Inpatient Discharge data: Click here to enter text.
<input type="checkbox"/> Outpatient Hospital Observation Stay Data <input type="checkbox"/> 2004 <input type="checkbox"/> 2005 <input type="checkbox"/> 2006 <input type="checkbox"/> 2007 <input type="checkbox"/> 2008 <input type="checkbox"/> 2009 <input type="checkbox"/> 2010 <input type="checkbox"/> 2011 <input type="checkbox"/> 2012 <input type="checkbox"/> 2013 <input type="checkbox"/> 2014 <input type="checkbox"/> 2015 <input type="checkbox"/> 2016 <input type="checkbox"/> 2017 <input type="checkbox"/> 2018 <input type="checkbox"/> 2019 <input type="checkbox"/> 2020 <input type="checkbox"/> 2021
Describe how your research objectives require Outpatient Hospital Observation Stay data: Click here to enter text.
<input checked="" type="checkbox"/> Emergency Department Data <input type="checkbox"/> 2004 <input type="checkbox"/> 2005 <input type="checkbox"/> 2006 <input type="checkbox"/> 2007 <input type="checkbox"/> 2008 <input type="checkbox"/> 2009 <input checked="" type="checkbox"/> 2010 <input checked="" type="checkbox"/> 2011 <input checked="" type="checkbox"/> 2012 <input checked="" type="checkbox"/> 2013 <input checked="" type="checkbox"/> 2014 <input checked="" type="checkbox"/> 2015 <input checked="" type="checkbox"/> 2016 <input checked="" type="checkbox"/> 2017 <input checked="" type="checkbox"/> 2018 <input checked="" type="checkbox"/> 2019 <input checked="" type="checkbox"/> 2020 <input checked="" type="checkbox"/> 2021
Describe how your research objectives require Emergency Department data: These data will allow us to investigate emergency room visits for all causes associated with changing climate in MA. Emergency Department data specifically are useful as a signal for the impact of acute extreme weather and/or pollution events. The data will also permit highly localized assessment of extreme weather/pollution-related health events.

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.

Case Mix Data are 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 enhancements), please refer to [release layouts, data dictionaries](#) and similar documentation included on CHIA’s website.

Please note that CHIA Case Mix Data contain reports produced using proprietary computer software created, owned, and licensed by the 3M Company. All Copyrights in and to the 3M APR™ Software, and to the 3M APR™ DRG classification system(s) (including the selection, coordination and arrangement of all codes) are owned by 3M. All rights reserved.

1. Specify below which enhancements you are requesting in addition to the “Core” LDS.

Geographic Subdivisions

State code, five-digit ZIP code, and 3-digit ZIP code are available for patients residing in CT, MA, ME, NH, RI, VT, and NY. City or Town of residence is available for residents of MA only. States outside of this region will be coded as XX (“Other”).

Select *one* of the following options:

<input type="checkbox"/> 3-Digit Zip Code (Standard)	<input type="checkbox"/> 3-Digit Zip Code & City/Town ***	<input type="checkbox"/> 5-Digit Zip Code ***	<input checked="" type="checkbox"/> 5-Digit Zip Code & City/Town ***
<p>***If requested, provide justification for requesting 5-Digit Zip Code or City/Town. Refer to specifics in your methodology:</p> <p>Such granularity will allow us to identify and analyze variations in exposure to climate-related risks and health outcomes across different communities. Zipcode-level data enable the study of specific factors, such as socioeconomic status, access to healthcare, and local environmental conditions, which can vary significantly even within a small geographic area. By examining these data, we can develop targeted interventions and policies to mitigate health risks and improve resilience in the most vulnerable populations.</p>			

Demographic Data

Select *one* of the following options:

<input type="checkbox"/> Not Requested (Standard)	<input checked="" type="checkbox"/> Race & Ethnicity***
<p>** If requested, provide justification for requesting Race and Ethnicity. Refer to specifics in your methodology:</p> <p>One of the main objectives of the research proposed in this application is an investigation into differences in vulnerability to climate hazards today and into the future in order to better understand health disparities faced by Massachusetts populations. We intend to use patient Race and Ethnicity information to characterize individuals’ potential exposure to racism. One of the specific aims of the research is to fit a Multilevel Analysis of Individual Heterogeneity and Discriminatory Accuracy (MAIHDA) model to understand the potential multiplicative risk of several co-occurring individual categories of vulnerability and resilience; We’ll investigate neighborhood data on historic redlining and individual sociodemographic characteristics such as Race and Ethnicity to understand risk for each combined identity (e.g.) the specific risk for a White male between 25-35 years old living in a historically redlined neighborhood, or for a Black woman aged 55-65 years old living in a historically advantaged neighborhood. We believe this approach will provide unique, new information to the heat vulnerability conversation by recognizing that individuals simultaneously exist as members of multiple social and contextual spheres, all of which affect their potential risk.</p>	

Date Resolution

Select *one* of the following options for dates of admissions, discharges, and significant procedures.

<input type="checkbox"/> Year (YYYY)(Standard)	<input type="checkbox"/> Month (YYYYMM) ***	<input checked="" type="checkbox"/> Day (YYYYMMDD)***
<p>***If requested, provide justification for requesting Month or Day. Refer to specifics in your methodology:</p> <p>Many of our climate and climate hazard exposures are relevant only at a daily timescale – for example, daily temperatures, or days with extreme storms. In order to assess the acute health impacts from these climate hazards, we must also have outcome data with a daily temporal resolution. This work would not be possible without exact dates.</p>		

Practioner Identifiers (UPN)

Select *one* of the following options.

<input checked="" type="checkbox"/> Not Requested (Standard)	<input type="checkbox"/> Hashed ID ***	<input type="checkbox"/> Board of Registration in Medicine Number(BORIM) ***
***If requested, provide justification for requesting Hashed ID or BORIM Number. Refer to specifics in your methodology: Click here to enter text.		

Unique Health Information Number (UHIN)

Select one of the following options.

<input type="checkbox"/> Not Requested (Standard)	<input checked="" type="checkbox"/> UHIN Requested ***
*** If requested, provide justification for requesting UHIN. Refer to specifics in your methodology: Having this allows us to track patients over time, and to assign medical history as potential modifier of the exposure disease relationship (e.g., are people with prior medical histories more at risk of climate-related ED visits).	

Hashed Mother's Social Security Number

Select one of the following options:

<input checked="" type="checkbox"/> Not Requested (Standard)	<input type="checkbox"/> Hashed Mother's SSN Requested ***
*** If requested, provide justification for requesting Hashed Mother's SSN. Refer to specifics in your methodology: Click here to enter text.	

VIII. 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 assign environmental exposures and neighborhood-level covariates at the spatial area unit-level (so zipcode or county).

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.

The linkage will be deterministic, as our climate models predict a single value for each spatial unit and time. The primary key is ZCTA or county FIPS code.

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.

Redlining HOLC scores, SOURCE: Mapping Inequality, University of Richmond
 Race, SOURCE: ACS 5-year
 Median Household Income in past 12 months, SOURCE: ACS 5-year
 Educational attainment for the Population 25 years and over, SOURCE: ACS 5-year
 Ratio of Income to Poverty Level in the Past 12 Months, SOURCE: ACS 5-year
 Hispanic or Latino Origin by Race, SOURCE: ACS 5-year
 Employment Status for the Population 16 Years and Over, SOURCE: ACS 5-year
 Median Home Value (Dollars), SOURCE: ACS 5-year
 Housing Units, SOURCE: ACS 5-year
 Housing tenure (renter/owner), SOURCE: ACS 5-year
 Median Gross Rent (Dollars), SOURCE: ACS 5-year
 Occupancy Status (vacancy), SOURCE: ACS 5-year
 Gross Rent as a Percentage of Household Income in the Past 12 Months, SOURCE: ACS 5-year
 Gini Index of Income Inequality, SOURCE: ACS 5-year
 Population by Sex by Age, SOURCE: ACS 5-year
 Year Structure Built, SOURCE: ACS 5-year
 NDVI, SOURCE: Google Earth Engine
 Daily temperatures & WBGT, SOURCE: ERA-5 Reanalysis Satellite data
 City spatial Boundaries, SOURCE: Census TIGER/LINE
 ZCTA spatial boundaries, SOURCE: Census TIGER/LINE
 Types of Health Insurance Coverage by Age, SOURCE: ACS 5-year
 Daily temperatures, SOURCE: NLDAS
 Daily air pollution (PM2.5, PM10, Ozone), SOURCE: Estimates from Joel Sewartz's Lab, Harvard University
 Historic storms, SOURCE: NOAA
 Flooding, SOURCE: Dartmouth Flood Observatory
 Blackout, SOURCE: MA Department of Public Utilities
 Impervious Surfaces, SOURCE: Google Earth Engine
 Albedo, SOURCE: Google Earth Engine
 Urban Heat Islands, SOURCE: Yale Center for Earth Observations
 Air conditioning, SOURCE: Article data from Romitti et al. 2022

Zoning codes, SOURCE: Massachusetts Zoning Atlas, and MassGIS
 Subsidized housing / housing affordability, SOURCE: Housing Navigator Massachusetts

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

No data will be linked at the individual patient level and no attempt will be made to identify individuals within the data. We intend to use ZCTA/zip codes to merge a number of contextual or compositional areal variables that describe local neighborhoods' built environment and climate or environmental hazards as well as their potential community-level susceptibility to such hazards. These ZCTA-level joins are essential to our ability to conduct this research to address the impact of current and historic neighborhood disinvestment with current vulnerability to climate hazards for our local Massachusetts communities, which could not be conducted otherwise. We will leverage our combined years of experience working with personal health information to safeguard against the accidental identification of individuals through the combination of areal measures. All results will be presented in the aggregate, and cells fewer than 11 outcomes will always be suppressed in presentation.

IX. 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 will ensure that in our published works and public presentations we adhere to the cell suppression rules in place for proper use of CHIA data – We will always suppress cells that have fewer than 11 outcomes and additionally ensure that it is not possible to calculate the number of the suppressed cell using row or column totals. In any spatial or map-based presentations of data, in addition to suppressing cells with fewer than 11 outcomes, we will additionally bin counts into categories so it is not possible to identify the exact counts for every geography. Prior to publication, we will conduct a thorough review of all tables, graphs, maps, figures, and text to ensure that we are adequately protecting the privacy of participants in our dataset.

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.

None

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 present zipcode maps, but otherwise, only incidence rates and exposure response curves. No zipcode-level raw data will be presented. We may present results that are specific to Massachusetts cities.

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 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?

NA

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.

NA

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?

NA

X. APPLICANT QUALIFICATIONS

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

All investigators have experience using hospital data. Dr Milando and Ms Gause currently using both OPTUM and HCAI data, Dr Kirwa has used CHIA data before and Dr Wellenius has used/overseen projects in OPTUM and MEDICARE.

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.)

XI. 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.

NA

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.

NA

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 #2 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.

NA

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.

NA

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.

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

XII. 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)	<i>William P. Segarra, MA, JD, MPH</i> Drag signature image here or delete and physically sign
Printed Name:	William P. Segarra
Title:	Sr. Director, Industry Contracts
Date:	August 15, 2024

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.