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

I.   INSTRUCTIONS

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

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

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

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

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

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

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

II.   FEE INFORMATION

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

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

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

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

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

III. ORGANIZATION & INVESTIGATOR INFORMATION

Project Title:	Economic analysis of the implementation of a community health worker-delivered intervention to enhance antihypertensive medication adherence in Community Health Centers in an Accountable Care Organization
IRBNet Number:	1918890
Organization Requesting Data (Recipient):	University of Massachusetts Chan Medical School
Organization Website:	**https://umassmed.edu/**
Authorized Signatory for Organization:	Milagros Rosal, PhD
Title:	Professor
E-Mail Address:	milagros.rosal@umassmed.edu
Telephone Number:	508-856-3173
Address, City/Town, State, Zip Code:	368 Plantation Street, Worcester, MA 01605
Data Custodian: (individual responsible for organizing, storing, and archiving Data)	**Christine Frisard**
Title:	Biostatistician III
E-Mail Address:	Christine.frisard@umassmed.edu
Telephone Number:	508-856-4140
Address, City/Town, State, Zip Code:	368 Plantation Street, Worcester, MA 01605
Primary Investigator (Applicant): (individual responsible for the research team using the Data)	Milagros Rosal, PhD
Title:	Professor
E-Mail Address:	Milagros.rosal@umassmed.edu
Telephone Number:	508-856-3173
Address, City/Town, State, Zip Code:	368 Plantation Street, Worcester, MA 01605
Names of Co-Investigators:	Stephenie Lemon, PhD; Karen Clements, ScDCxt.
E-Mail Addresses of Co-Investigators:	Stephenie.lemon@umassmed.edu; Karen.Clements@umassmed.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 <u>no</u> other purposes. Use of CHIA Data for other purposes requires a separate Data Application to CHIA written request to CHIA, with approval being subject to CHIA's regulatory restrictions and approval process. Unauthorized use is a material violation of your institution's Data Use Agreement with CHIA.

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

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

☐ Inclusion in a product   ☐ Other (describe in box below)

> We will be evaluating an intervention aimed at increasing anti-hypertensive medication adherence in community health centers.

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.

This project is an implementation study of the evidence-based Approach for Lowering blood pressure through Medication Adherence (ALMA) intervention, which was developed by members of our team. ALMA is a systems-based intervention that alerts medical assistants to identify patients with uncontrolled hypertension and facilitates referrals to a community health worker-delivered coaching intervention that promotes medication adherence. Implementation will be facilitated by leadership support and CHC-based medical and operations champions. Using a quasi-experimental design, we will conduct the study in partnership with federally-qualified community health centers (CHCs) that are members of an Accountable Care Organization (ACO) in Massachusetts. The intervention sites will be the Edward M. Kennedy Community Health Center and Family Health Center of Worcester, long-standing partners of our PRC. Five CHCs with similar patient profiles will serve as a comparison condition. Outcomes will include return on investment and cost-effectiveness, blood pressure control among sub-populations and implementation process outcomes. Findings will be used to promote the translation of ALMA into practice.

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

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

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

V.   PUBLIC INTEREST

1. Briefly explain why completing this Project is in the public interest. Use quantitative indicators of public health importance where possible, for example, numbers of deaths or incident cases; age-adjusted, age-specific, or crude rates; or years of potential life lost. *Uses that serve the public interest under CHIA regulations include, but are not limited to: health cost and utilization analysis to formulate public policy; studies that promote improvement in population health, health care quality or access; and health planning tied to evaluation or improvement of Massachusetts state government initiatives.*

This project will focus on promotion of adherence to antihypertensive medications to reduce high rates of uncontrolled hypertension. This has been determined a critical health priority by members of our Community Advisory Board and is a Healthy People 2020 health priority.[4] Hypertension affects 85.7 million[6] Americans and disproportionately affects low socioeconomic and racial/ethnic minority groups.[7, 8] Uncontrolled hypertension is a major factor driving the high rates of cardiovascular-related morbidity and mortality and health care expenditures in the US.[9] The transition toward an Accountable Care Organization model of care demands interventions that effectively promote adherence to antihypertensive medications to reduce uncontrolled hypertension in routine care settings that serve at-risk populations, and that are low cost, sustainable and scalable.

4. Healthy People 2020. Office of Disease Prevention and Health Promotion. (website). Available at: www.healthypeople.gov. Updated June 22, 2018. Accessed June 23, 2018.

6. Massachusetts Department of Elementary and Secondary Education. School and District Profiles - Worcester. Available at: http://profiles.doe.mass.edu/general/general.aspx?topNavID=1&leftNavId=100&orgcode=03480000&orgtypecode=5. Accessed June 22, 2018.

7. Stebbins S. Cities Hit Hardest by Extreme Poverty. 24/7 Wall St website. Available at: https://247wallst.com/special-report/2018/04/17/cities-hit-hardest-by-extreme-poverty-4/. Published April 17, 2018. Accessed June 22, 2018.

8. Centers for Disease Control and Prevention. Prevention Research Centers. Available: https://www.cdc.gov/prc/about-prc-program/index.htm. Updated September 8, 2016. Accessed June 22, 2018.

9. Schoenthaler A, De La Calle F, Barrios-Barrios M, et al. A practice-based randomized controlled trial to improve medication adherence among Latinos with hypertension: Study protocol for a randomized controlled trial. Trials. 2015;16:290.

VI.   DATASETS REQUESTED

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

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

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

   ☐ One-Time Request   **OR**   ☒ Subscription

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

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

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

☒ **Medical Claims**
Describe how your research objectives require Medical Claims data: Claims data is required so we are able to determine diagnosis of hypertension, number and type of hospital visits and provider visits and amount paid for each claim

☒ **Pharmacy Claims**
Describe how your research objectives require Pharmacy Claims data: Pharmacy claims are required to determine whether or how often a patient is filling their prescribed antihypertensive medications.

☐ **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 will be required to calculate person-time observation of individuals receiving care at intervention and control sites

☒ **Provider**
Describe how your research objectives require Provider data: Provider data will be used to identify claims from community health center pratitioners

☒ **Product**
Describe how your research objectives require Product data: Data on insurance products will help inform our cost analyses and allow us to test intervention effects across insurance products.

VII.   DATA ENHANCEMENTS REQUESTED

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

All-Payer Claims Database data is released in Limited Data Sets (LDS). All Organizations receive the "Core" LDS, but may also request the data enhancements listed below for inclusion in their analyses. Requests for

enhancements will be reviewed by CHIA to determine whether each represents the minimum data necessary to complete the specific Project objective.

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

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

a. Geographic Subdivisions

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

☐ 3-Digit Zip Codes (standard)	☒ 5-Digit Zip Codes***
***If requested, provide justification for requesting 5-Digit Zip Code. Refer to specifics in your methodology: 5 digit zip codes are needed to link the APCD data to demographic indicators in the census so we are able to assess differences in controlled hypertension by subgroups.	

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: It is necessary for us to determine blood pressure status at each provider visit. If visits occur more than once in a month's time, we will need the month and day to determine order of visits.		

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: Click here to enter text.	

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.

As a significant proportion of community health center patients are on Medicaid. Our cost analyses will help determine the cost of administering this intervention with Medicaid patients.

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

IX.   DATA LINKAGE

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

1. Do you intend to link or merge CHIA Data to other data?
    ☒ Yes

     No linkage or merger with any other data will occur

2. If yes, please indicate below the types of data to which CHIA Data will be linked. [Check all that apply]
    ☐ Individual Patient Level Data (e.g. disease registries, death data)
    ☐ Individual Provider Level Data (e.g., American Medical Association Physician Masterfile)
    ☐ Individual Facility Level Data (e.g., American Hospital Association data)
    ☒ Aggregate Data (e.g., Census data)
    ☐ Other (please describe):

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

The APCD data will be linked to census data by 5-digit zip code so we are able to differences in controlled hypertension by several area-level variables, including categories of income level, poverty status, educational attainment, race/ethnicity and % non-US born in participants' zip code

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.

Deterministic linkage will be conducted, matching 5-digit zip code

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 list of census fields we would use to create the above categories is included in attached.

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

Data will be linked at the zip code level only; linked data will report area-level socio-demographic characteristics of population subgroups. All cell sizes below 11 will be suppressed.

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 of our analyses will be published in scientific journals, poster and conference presentations. Results will be stratified by subgroups (age, gender, insurance status) where appropriate. Data suppression rules will be adhered to.

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?

Data will not be presented by geographical divisions, but rather summarized by patient population for the four participating community health centers

4. Will you be using CHIA Data for consulting purposes?
 ☐ Yes
 ☒ No

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

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

7. Will you be using CHIA Data as in input to develop a product (i.e., severity index took, risk adjustment tool, reference tool, etc.)

☐ Yes
☒ No

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

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

Click here to enter text.

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

Click here to enter text.

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

Click here to enter text.

XI.   APPLICANT QUALIFICATIONS

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

Karen Clements, ScD is the Co-Investigator who will be overseeing the claims analysis. Dr. Clements has extensive experience using claims data. She is currently leading a project with the Massachusetts Department of Public Health Bureau of Infectious Disease and Laboratory Science that uses APCD data to examine screening and treatment patterns for hepatitis C virus (HCV), HIV, chlamydia, and latent tuberculosis infection. She previously co-led an NIH funded analyses of APCD data to examine perinatal healthcare utilization among individuals with disabilities. Dr. Clements is currently leading analyses using Medicaid claims data from Massachusetts and other states to examine healthcare utiliziton, costs and outcomes in the areas of HCV and substance use disorder, and has previously led Medicaid claims analyses to measure healthcare utilization and costs among indivduals with severe mental illness and with asthma.

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:	Milagros Rosal, PhD
Title:	Professor
Date:	5/23/2022

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.==