Non-Governmental Application for Massachusetts Case Mix and Charge Data [Exhibit A]

I. INSTRUCTIONS

This form is required for all Applicants, except Government Agencies as defined in 957 CMR 5.02, requesting protected health information. *All Applicants must also complete the Data Management Plan, 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 Data Use Agreement. 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 casemix.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 CHIA website in Word and in PDF format or on IRBNet 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 Fee Remittance Form 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 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 AND INVESTIGATOR INFORMATION

Project Title:	National Estimates of the Impact of the Affordable Care Act on Healthcare Utilization, Outcomes & Quality among Hispanics
IRBNet Number:	
Organization Requesting Data (Recipient):	Boston Medical Center
Organization Website:	**https://www.bmc.org/**
Authorized Signatory for Organization:	**Todd Erceg**
Title:	Director of Sponsored Programs
E-Mail Address:	Todd.erceg@bmc.org
Address, City/Town, State, Zip Code:	660 Harrison Avenue, Boston, MA 02118
Data Custodian: **(individual responsible for ogranizing, storing, and archiving Data)**	**Amresh D. Hanchate**
Title:	Associate Professor
E-Mail Address:	hanchate@bu.edu
Telephone Number:	617-638-8889
Address, City/Town, State, Zip Code:	801 Mass. Ave. 2nd floor, Boston, MA 02118
Primary Investigator: **(individual responsible for the research team using the Data)**	Amresh D. Hanchate
Title:	Associate Professor
E-Mail Address:	hanchate@bu.edu
Telephone Number:	617-638-8889
Names of Co-Investigators:	Michael Paasche-Orlow, Karen Lasser, Souvik Banerjee
E-Mail Addresses of Co-Investigators:	MPO@bu.edu, Karen.lasser@bmc.org, Souvikb@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
☒ Longitudinal Research	☐ Quality of care assessment	☐ Rate setting
☐ Reference tool	☒ Research studies	☐ Severity index tool
☐ Surveillance	☐ Student research	☐ Utilization review of resources
☐ Inclusion in a product	☐ Other (describe in box below)	

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.

1. SPECIFIC AIMS

One of the central policy assumptions in the U.S. today is that expanding health insurance coverage will improve access to health care, improve health outcomes, and make each more equitable for all Americans. Evidence from randomized control and natural experimental settings indicates that insurance coverage

increases healthcare access and utilization, improves self-reported health status, and decreases mortality.[1-10] Despite its uncertain future, the **Affordable Care Act (ACA)** of 2010, "the most important legislation in health care since the passage of Medicare and Medicaid",[11] is a multifaceted effort to expand insurance coverage, restructure healthcare reimbursement, and improve quality and value of healthcare.[12-14] Beyond expanding coverage – 17.7 million adults aged 18-64 gained insurance by early 2016[15] – the ACA holds great promise for reducing disparities in healthcare access, utilization and outcomes between vulnerable subgroups – racial/ethnic minorities and low-income persons – and others.[16,17]

With the **objective of evaluating the impact of the 2014 ACA reforms on healthcare access, utilization and quality of care among Hispanics**, the proposed study has three foci. First, we will examine outcomes based on actual healthcare utilization. Second, to better focus on Hispanics, the racial/ethnic minority with the highest uninsurance rate (41%), we will develop a near-national database by combining state inpatient discharge data from 22 states that together account for 88 percent of the national Hispanic population; emergency department (ED) data will be obtained from 13 states. Third, far from being an uniform intervention, ACA expansion engendered wide variation in implementation, particularly across states; we will evaluate how reform effects among Hispanics are modified by language barriers, national origin, baseline uninsurance, state Medicaid generosity, and provider availability.

To estimate changes associated with the 2014 ACA insurance expansion by race/ethnicity, we will use a natural experimental design, wherein pre-expansion (2010-2013) to post-expansion (2014-2018) changes in the study outcome measures will be contrasted with those in a comparison cohort with no expansion.[18,19] As indicators of **access to care**, we will examine admissions for ambulatory care sensitive conditions (ACSC), such as asthma and diabetes,[9,20,21] and ED visits.[22,23] **Utilization** will be measured by population rates of use of major elective surgical procedures, such as knee replacement, hysterectomy and gastric bypass.[24,25] Lower quality of care among racial/ethnic minorities has been associated with hospitals where care is received; as insurance accords choice among providers, we will examine for shifts across hospitals and change in quality.[17,26,27] **Quality of care** will be measured by inpatient mortality and 30-day readmissions for selected conditions, such as heart failure (HF).[26-28] We will compare changes in outcomes (a) among Hispanics vs. other racial/ethnic groups (non-Hispanic whites and blacks), and (b) among Hispanic subgroups by sex, national origin, English language proficiency and socioeconomic status (SES). Our **specific aims** are to

Aim 1: Estimate the change in rates of ACSC admissions, ED use and major elective procedure use, and disparities in such rates by race/ethnicity, associated with ACA coverage expansion.

H1a: Insurance expansion is associated with a larger reduction in ACSC admission and ED use, and a larger increase in major elective procedure use among Hispanics compared to whites, blacks and Asians.

H1b: Hispanics in Medicaid expansion states will experience larger reduction in ACSC admission and ED use, and larger increase in major elective procedure use compared to Hispanics in non-expansion states.

Aim 2: Estimate the changes in ACSC admissions, ED use and major elective procedure use associated with ACA coverage expansion among Hispanics by sex, national origin and English language fluency.

H2a: Hispanics with good English language proficiency will experience larger reduction in ACSC admission and ED use, and larger increase in major elective procedure use than Hispanics with poor proficiency.

Aim 3: Estimate the changes in use of safety-net hospitals associated with ACA expansion by race/ethnicity and among Hispanics by sex, national origin and English language proficiency.

H3a: Hispanics with good English language proficiency will experience larger increase in inpatient care received in non-safety-net hospitals compared to Hispanics with poor proficiency.

Aim 4: Estimate the changes in rates of inpatient mortality and 30-day readmissions associated with ACA expansion by race/ethnicity, and among Hispanics by sex, national origin and English language proficiency.

H4a: Hispanics in Medicaid expansion states will experience larger reduction in rates of inpatient mortality and 30-day readmissions compared to Hispanics in non-expansion states.

This proposal is highly significant: using comprehensive discharge data on actual utilization for a near-national population of Hispanics, our findings will inform stakeholders – policy makers, patient groups, providers – on the realized changes, especially in reducing disparities in healthcare access, utilization and quality among Hispanics overall and subgroups by national origin and English language proficiency.

References

1. Manning WG, Newhouse JP, Duan N, Keeler E, Leibowitz A, Marquis MS. Health Insurance and the Demand for Medical Care: Evidence from a Randomized Experiment. *American Economic Review.* 1987;77(3):251-277.
2. Finkelstein A, Taubman S, Wright B, et al. The Oregon Health Insurance Experiment: Evidence from the First Year*. *The Quarterly Journal of Economics.* 2012;127(3):1057-1106.
3. Baicker K, Taubman SL, Allen HL, et al. The Oregon Experiment — Effects of Medicaid on Clinical Outcomes. *New England Journal of Medicine.* 2013;368(18):1713-1722.
4. Sommers BD, Baicker K, Epstein AM. Mortality and Access to Care among Adults after State Medicaid Expansions. *New England Journal of Medicine.* 2012;367(11):1025-1034.
5. Sommers BD, Long SK, Baicker K. Changes in Mortality After Massachusetts Health Care ReformA Quasi-experimental StudyChanges in Mortality After Massachusetts Health Care Reform. *Annals of Internal Medicine.* 2014;160(9):585-593.
6. Lasser KE, Hanchate AD, McCormick D, Manze MG, Chu C, Kressin NR. The effect of Massachusetts health reform on 30 day hospital readmissions: retrospective analysis of hospital episode statistics. *BMJ.* 2014;348.
7. Hanchate AD, Kapoor A, Katz JN, et al. Massachusetts health reform and disparities in joint replacement use: difference in differences study. *BMJ.* 2015;350:h:440.
8. McCormick D, Hanchate AD, Lasser KE, et al. Effect of Massachusetts healthcare reform on racial and ethnic disparities in admissions to hospital for ambulatory care sensitive conditions: retrospective analysis of hospital episode statistics. *BMJ.* 2015;350:h1480.
9. Miller S. The Effect of the Massachusetts Reform on Health Care Utilization. *Inquiry.* 2012;49(4):317-326.
10. Levy H, Meltzer D. The Impact of Health Insurance on Health. *Annual Review of Public Health.* 2008;29(1):399-409.
11. Altman D. The Affordable Care Act After Six Years. *The Wall Street Journal.* May 23, 2016.
12. Patient Protection and Affordable Care Act. H.R. 3590. Public Law 111-48; 2010.
13. Obama B. United states health care reform: Progress to date and next steps. *JAMA.* 2016.
14. Kaiser Family Foundation. *Health Reform Implementation Timeline.* http://kff.org/interactive/implementation-timeline/ July 17, 2015 2016.
15. Uberoi N, Finegold K, Gee E. *Health Insurance Coverage And The Affordable Care Act. 2010–2016.* Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation;2016.
16. Agency for Healthcare Research and Quality. *2015 National Healthcare Quality and Disparities Report and 5th Anniversary Update on the National Quality Strategy.* Rockville, MD: Agency for Healthcare Research & Quality; September 12, 2016 2016.
17. Andrulis DP, Siddiqui NJ. Health Reform Holds Both Risks And Rewards For Safety-Net Providers And Racially And Ethnically Diverse Patients. *Health Affairs.* 2011;30(10):1830-1836.
18. Dimick JB, Ryan AM. Methods for Evaluating Changes in Health Care Policy: The Difference-in-Differences Approach. *Jama.* 2014;312(22):2401-2402.
19. Ryan AM, Burgess JF, Jr., Dimick JB. Why We Should Not Be Indifferent to Specification Choices for Difference-in-Differences. *Health Serv Res.* 2015;50(4):1211-1235.
20. Kolstad JT, Kowalski AE. The Impact of Health Care Reform on Hospital and Preventive Care: Evidence from Massachusetts. *Journal of Public Economics.* 2012;96(11):909-929.
21. McDonough JE, Adashi EY. REalizing the promise of the affordable care act—january 1, 2014. *Jama.* 2014.

22. Miller S. The Effect of Insurance on Outpatient Emergency Room Visits: An Analysis of the 2006 Massachusetts Health Reform. *Journal of Public Economics.* 2012;96:893-908.
23. Smulowitz PB, O'Malley J, Yang X, Landon BE. Increased Use of the Emergency Department After Health Care Reform in Massachusetts. *Annals of emergency medicine.* 2014.
24. Billings J. Using Administrative Data to Monitor Access, Identify Disparities, and Assess Performance of the Safety Net. In: Weinick RM, Billings J, eds. *Tools for Monitoring the Health Care Safety Net.* Vol AHRQ Publication No. 03-0027. Rockvill,e MD: Agency for Healthcare Research and Quality; 2003.
25. Hanchate AD, Lasser KE, Kapoor A, et al. Massachusetts Reform and Disparities in Inpatient Care Utilization. *Medical Care.* 2012;50:569-577.
26. Jha AK, Orav EJ, Epstein AM. Low-Quality, High-Cost Hospitals, Mainly In South, Care For Sharply Higher Shares Of Elderly Black, Hispanic, And Medicaid Patients. *Health Affairs.* 2011;30(10):1904-1911.
27. Rodriguez F, Joynt KE, Lopez L, Saldana F, Jha AK. Readmission rates for Hispanic Medicare beneficiaries with heart failure and acute myocardial infarction. *Am Heart J.* 2011;162(2):254-261 e253.
28. Joynt KE, Orav EJ, Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. *JAMA: The Journal of the American Medical Association.* 2011;305(7):675-681.

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.

See IRB approval letter and protocol attached

4. **Research Methodology**: 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.*

In its landmark report, *Unequal Treatment*, the Institute of Medicine (IOM) reported that "a central concern of the committee ... has been the relative paucity of data on non-African-American racial and ethnic minority groups." We propose a unique study, titled "**National Estimates of the Impact of the Affordable Care Act on Healthcare Utilization, Outcomes & Quality among Hispanics**", that examines actual healthcare utilization to evaluate the post-ACA experience (2014-2019) among Hispanics and non-Hispanic blacks. With particular focus on Hispanics, the minority group with the highest uninsurance rate and other access barriers, we will assemble a near-national data of inpatient and ED utilization data covering pre- and post-ACA periods

VI. DATASETS REQUESTED

The Massachusetts Case Mix and Charge Data 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 and Charge Data are updated each fiscal year (October 1 – September 30) and made available to approved data users. For more information about Case Mix and Charge 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.

☒ **Hospital Inpatient Discharge Data** ☐2004 ☐2005 ☐2006 ☐2007 ☐2008 ☐2009 ☐2010 ☐2011 ☒2012 ☒2013 ☒2014 ☒2015 ☒ 2016
Describe how your research objectives require Inpatient Discharge data: As an indicator of access to care, we will examine admissions for ambulatory care sensitive conditions. Utilization will be measured by rates of elective surgical procedures. Quality of care will be measured by inpatient mortality and 30-day readmission. We will estimate the change in the rates of these indicators over time by race/ethnicity to estimate the effect of insurance expansion on these indicators.
☒ **Outpatient Hospital Observation Stay Data** ☐2004 ☐2005 ☐2006 ☐2007 ☐2008 ☐2009 ☒2010 ☒2011 ☒2012 ☒2013 ☒2014 ☒2015 ☒ 2016
Describe how your research objectives require Outpatient Hospital Observation Stay data: CHIA Thinks we may miss many elective procedures by not looking at Observation Data. We plan to review the inpatient Data first + then possibly order the Observation Data at a later time.
☒ **Emergency Department Data** ☐2004 ☐2005 ☐2006 ☐2007 ☐2008 ☐2009 ☐2010 ☐2011 ☒2012 ☒2013 ☒2014 ☒2015 ☒ 2016
Describe how your research objectives require Emergency Department data: We will also use the rate of change of ED use over time is an indicator of access to care.

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 and Charge Data are grouped into six "Levels" or Limited Data Sets (LDS) for release, depending on the fiscal year. Data for FY 2004 – 2014 are organized into Levels. Level 6 Data will be released to Government Applicants only.

CHIA staff will use the information provided in this section to determine the appropriate Level of Data justified for release.

Data for FY 2015 and later are organized into LDS's. 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.

1. Specify below which enhancements you are requesting in addition to the "Core" LDS. CHIA will use this information to determine what Level of data is needed for pre-FY 2015 data requests.

Geographic Subdivisions
State, five-digit zip code, and 3-digit 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.

☐ 3-Digit Zip Code (Standard)	☐ 3-Digit Zip Code & City/Town ***	☒ 5-Digit Zip Code ***	☐ 5-Digit Zip Code & City/Town ***

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

We will use zip-code to characterize (group) patients based on a number of demographic, socioeconomic, and provider availability measures (e.g., proportion of zip code population that is Hispanic, proportion of zip code population with income below poverty line, proportion of zip code population with English not the primary language, etc).

Demographic Data
Choose *one* of the following options.

☐ Not Requested (Standard)	☒ Race & Ethnicity***

**** If requested, provide justification for requesting Race and Ethnicity. Refer to specifics in your methodology:**

Hispanics have the lowest insurance rate among racial/ethnic minorities. We intend to estimate the effect of the 2014 ACA reforms on access to care, healthcare utilization and quality of care with an emphasis on the Hispanic population.

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

☐ Year (YYYY)(Standard)	☐ Month (YYYYMM) ***	☒ Day (YYYYMMDD)***

***If requested, provide justification for requesting Month or Day. Refer to specifics in your methodology:
The dates are necessary for (a) our quality of care measures of repeated hospitalizations (readmissions) and time between hospitalizations, and (b) examining differences in outcomes by weekday/weekend.

Practioner Identifiers (UPN)
Select *one* of the following options.

☒ Not Requested (Standard)	☐ Hashed ID ***	☐ Board of Registration in Medicine Number(BORIM) ***
***If requested, provide justification for requesting Hashed ID or BORIM Number. Refer to specifics in your methodology:		

Unique Health Information Number (UHIN)
Select *one* of the following options.

☐ Not Requested (Standard)	☒ UHIN Requested ***
*** If requested, provide justification for requesting UHIN. Refer to specifics in your methodology:	
A unique patient identifier is necessary for (a) identifying repeated hospitalizations, and (b) identifying same person in ED and inpatient data bases	

Hashed Mother's Social Security Number
Select *one* of the following options:

☒ Not Requested (Standard)	☐ Hashed Mother's SSN Requested ***
*** If requested, provide justification for requesting Hashed Mother's SSN. Refer to specifics in your methodology:	

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 data base(s) to which the CHIA Data will be linked, indicate which CHIA Data elements will be linked and the purpose for each linkage.

	Source	*Data elements linked with CHIA data*	*Variables to be included*
1	Census & American Community Survey	Zip code, county	Area level proportion of population by race/ethnicity, poverty, uninsurance, national origin, language proficiency.
2	American Hospital Association (AHA) Annual Survey Database	Hospital	Hospital data on facilities, services offered, revenue from main payers
3	Area Healthcare Resource File (AHRF)	County	County-level data on health resources (hospital beds, physicians by specialty)
4	Behavioral Risk Factors Surveillance System (BRFSS)	County	County-level prevalence of chronic conditions by socio-demographic groups and physician provider availability.

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

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

	Source	*Data elements linked with CHIA data*	*Variables to be included*
1	Census & American Community Survey	Zip code, county	Area level proportion of population by race/ethnicity, poverty, uninsurance, national origin, language proficiency.
2	American Hospital Association (AHA) Annual Survey Database	Hospital	Hospital data on facilities, services offered, revenue from main payers
3	Area Healthcare Resource File (AHRF)	County	County-level data on health resources (hospital beds, physicians by specialty)
4	Behavioral Risk Factors Surveillance System (BRFSS)	County	County-level prevalence of chronic conditions by socio-demographic groups and physician provider availability.

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

We will never report any individual-level data (demographics, diagnosis, dates, zip code, etc. As clarified below all our findings are at group or overall patient cohort (disease/treatment) level.

IX. PUBLICATION / DISSEMINAITON / 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 plan to present research findings at national research meetings such as the Academy Health, Society for General Internal Medicine and AHRQ
- We plan to publish findings in publicly accessible peer-reviewed medical and health policy journals

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.

Findings will be reported in publicly accessible peer-reviewed journals. We will never report any individual-level data (demographics, diagnosis, dates, zip code, etc).

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?

As noted above we will never report any individual identifiable data. We may produce graphs (plots) of measures at group level (age, race/ethnicity, zip code, hospital).

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?

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?

XI. INVESTIGATOR 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.

Amresh Hanchate, Ph.D., Principal Investigator, is an Associate Professor of Medicine, and has extensive experience in the use of large databases for epidemiologic disparities research. He is PI on 3 other ongoing NIH-funded studies that utilize data from the same or similar data sources as those in the proposed research:

1) R01MD007705— National Estimates for Inpatient Care, Outcomes & Hospital Effect among Hispanics--the precursor to the current proposed research that utilized state inpatient data from 15 states and medicare data
2) R01HL127212-- Racial and Ethnic Health Disparities Due to Ambulance Diversion—this study uses medicare data in conjunction with local Boston EMS data
3) R01MD010527-- Unintended Consequences: Medicare Performance Programs and Health Disparities—using medicare data

And several studies that have successfully concluded where Dr. Hanchate was PI or Co-P, some include:

1) One study (R21 NINDS) used state inpatient discharge data from eight states and census population data to estimate population-level incidence rates of ischemic stroke, and evaluate discharge outcomes, by race and ethnicity.
2) Another study (co-PI of NHLBI center grant project) used state inpatient discharge and census data from five states, to evaluate the impact of Massachusetts health reform on racial/ethnic disparities in access to inpatient healthcare utilization and their outcomes.

Dr. Hanchate's research has been published in high-impact peer-reviewed journals, including *Archives of Internal Medicine, Health Services Research, and Medical Care*. He has extensive experience in the design and estimation of hierarchical statistical models involving merged patient-level data with broader level data at the zip code, county and state levels.

Dr. Paasche-Orlow is a primary care clinician and a nationally recognized expert in the field of health literacy, he has dedicated his career to improving the care of vulnerable populations. He is currently a co-investigator with five clinical studies that examine health literacy and doctor-patient communication, various modes of patient education, and empowerment. He has been the lead designer of eight patient-oriented interactive behavioral informatics programs. This work has brought attention to the role health literacy plays in racial and ethnic disparities, to the fact that appropriately designed information technologies can be empowering for patients with low health literacy, and improving informed consent. He has served as the guest editor for 10 special issues on health literacy for various journals and is now the founding Editor-in-Chief for the journal *Health Literacy Research and Practice*. He has also helped promote the field of health literacy research as the principal investigator of the Health Literacy Annual Research Conference for each of the past seven years. He has lectured broadly on the role of health literacy in health outcomes and health disparities, including seven times at the NIH at the invitation of the National Institute of Minority Health and Health Disparities and eight times at the National Academies of Sciences, Engineering, and Medicine, where he serves as a member of the Health Literacy Roundtable. He has been an active proponent of improved measurement of health literacy as an advisor for five different health literacy measurement tool projects developed with item response theory methods and curates an on-line evidence-based public resource with >125 health literacy tools. He has had a productive and active collaboration with Dr. Hanchate over the course of the past decade. They have worked together on projects relating to health literacy, health utilization, health disparities, health policy, and health outcomes for Hispanics. The project we currently propose, "National Estimates of the Impact of the Affordable Care Act on Healthcare Utilization, Outcomes & Quality among Hispanics" represents a natural and significant extension of our prior work together

Dr. Lasser is a primary care physician and health disparities researcher with expertise in analyzing large data sets to examine the impact of health policy initiatives on health disparities. She also has experience conducting clinical trials and in developing interventions to reduce disparities and improve quality of care. She is currently Principal Investigator on two randomized controlled trials. The first utilizes patient navigation and financial incentives to promote smoking cessation in primary care. The second is a NIDA-funded project examining the effectiveness of a nurse care managed registry to improve opioid prescribing and monitoring. Dr. Hanchate and Lasser were co-PIs of an NHLBI center grant project which used state inpatient discharge data. The daughter of an immigrant from Bogota, Colombia, I speak fluent Spanish, and my clinical work focuses on caring for a largely Hispanic population at Boston Medical Center. I have extensive research and clinical experience as a safety-net provider, having worked in safety-net settings since 1995. Much of my research has focused on studying and improving quality of care in primary care among underserved patient populations.

Dr. Banerjee is a Research Assistant Professor and is working in the Healthcare Disparities group with Dr. Hanchate as Co-Investigator on three of his R01 grants on healthcare disparities. He has a strong background in health economics. During the course of his dissertation, he worked as a graduate research assistant over a period of two years for Prof Kajal Lahiri and Prof Pinka Chatterji under their NIH R01 grant

on minority health and health disparities. His research interests broadly lie in health economics, with a particular focus on health outcomes research. During the course of my post-doctoral fellowship I have worked on multiple projects with researchers in an inter-disciplinary environment, including the School of Medicine, UW; Group Health Research Institute, Seattle; and Nestle, Switzerland to assess the impact of alternative treatment regimens and interventions on costs and healthcare utilization. In addition, his is interested in modeling the impact of different health interventions and policies on varied outcomes using alternative causal frameworks. In the different projects, he has experience working with different observational data – pharmacy claims, electronic medical records, inpatient hospital databases, administrative, survey – which will be valuable for the current proposed study. He has been actively involved in creating analytical data files from multiple data sources and conducting data analysis with appropriate statistical/econometric tools. In collaboration with Dr. Hanchate, he will participate in all phases of the proposed study, including study design, supervision of data processing, estimation of models, and writing of dissemination materials

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.)

See attached:

Biosketch-Amresh Hanchate
Biosketch-Michael Paasche-Orlow
Biosketch-Karen Lasser
Biosketch-Souvik Banerjee

XII. 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 **all** agents and contractors who will work with the CHIA Data. *[Add agents or contractors as needed.]*

AGENT/CONTRACTOR #1 INFORMATION	
Company Name:	N/A
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 **must** be completed by the agent or contractor.

AGENT/CONTRACTOR #2 INFORMATION	
Company Name:	**N/A**
Company Website:	
Contact Person:	
Title:	
E-mail Address:	
Address, City/Town, 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.

N/A

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.

N/A

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.

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 :	**Todd Erceg**
Title:	Director of Sponsored Programs

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.

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