center
for health
information
and analysis

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:	**Variation in 30-day readmission risk between high and low-quality inpatient psychiatric facilities**
IRBNet Number:	
Organization Requesting Data (Recipient):	**Brandeis University, Heller School for Social Policy and Management**
Organization Website:	
Authorized Signatory for Organization:	Stanley M. Bolotin
Title:	Director, Pre-Award Services, Research Admin.
E-Mail Address:	bolotin@brandeis.edu
Address, City/Town, State, Zip Code:	Office of Research Administration, MS 116, Brandeis University, 415 South Street, Waltham, MA 02453-2728
Data Custodian: **(individual responsible for ogranizing, storing, and archiving Data)**	**Dominic Hodgkin**
Title:	Professor
E-Mail Address:	Hodgkin@brandeis.edu
Telephone Number:	954-907-0099
Address, City/Town, State, Zip Code:	Brandeis University, 415 South Street, Waltham, MA 02453-2728
Primary Investigator: **(individual responsible for the research team using the Data)**	**Dominic Hodgkin**
Title:	Professor
E-Mail Address:	Hodgkin@brandeis.edu
Telephone Number:	9549070099
Names of Co-Investigators:	Morgan Shields, MS, MA
E-Mail Addresses of Co-Investigators:	mshields@brandeis.edu

IV. PROJECT INFORMATION

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

☐ Epidemiological
☐ Longitudinal Research
☐ Reference tool
☐ Surveillance
☐ Inclusion in a product
☐ Health planning/resource allocation
☐ Quality of care assessment
☐ Research studies
☒ Student research
☐ Other (describe in box below)
☐ Cost trends
☐ Rate setting
☐ Severity index tool
☐ Utilization review of resources

This project is part of a dissertation describing variation in quality of inpatient psychiatric care.

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.

Research on variation in quality of inpatient psychiatric care and its relationship with post-discharge outcomes (e.g., community tenure, readmission) is limited. Research examining post-discharge outcomes and utilization following inpatient psychiatric care has primarily focused on patient characteristics -- identifying diagnoses (e.g., alcohol and

other substance use disorders) and prior utlization as predictors (Sfetcu et al., 2017; Roque et al., 2017; Durbin et al., 2007). Variation in outcomes explained by community characteristics and the quality in hospital care, especially, is scarce (Sfetcu et al., 2017 & Kalseth et al., 2016).

This project will focus on Massachusetts inpatient psychiatric care provided in 2017. The aims of this study are to create variations in composite measures of quality including targeted indicators in CMS' Inpatient Psychiatric Facility Quality Reporting (IPFQR) program as well as non-targeted indicators (complaints made to the Department of Mental Health and counts of restraint episodes submitted to the Department of Mental Health). These composite measures will be used to examine the extent to which overall facility-level quality performance, as opposed to performance on the discharge planning measures specifically, predicts post-discharge 30-day readmission, ED stays, and observation stays, after accounting for the moderating role of patient and community characteristics. Data will be linked across Hospital Inpatient Discharge Database, Outpatient Observation Database, Emergency Department Database from the Massachusetts Acute Hospital Case Mix Database, 2019 IPFQR data (for performance year 2017), American Hospital Association's Annual Survey, American Community Survey, and indicators for Health Professional Shortage Areas for both primary care and mental health care.

We hypothesize that overall faciality-level quality performance will predict 30-day readmission, ED stay, or observation stay, but that this will be driven by the discharge measures as these are the most proximal measures to post-discharge utilization and because of prior research suggesting such a relationship (Steffan et al., 2009 & Vigod et al., 2013). We also hypothesize that performance on the discharge measures will have the greatest effect among patients with co-occurring alcohol or other substance use conditions because there are specific process measures focused on this sub-group for care provided during their inpatient stay as well as post-discharge referral to substance use disorder treatment. Further, there is potentially greater opportunity to improve post-discharge utilization for this sub-group given previously documented low rates of follow-up and readmission risk (nationally, 18.4% of those with alcohol use disorder and 15.1% of those with other substance use disorder have a 30-day all-cause readmission; Elixhauser, 2013).

The intended product of this project will be at least one peer-reviewed publication.

References

Durbin J, Lin E, Layne C, Teed M. Is readmission a valid indicator of the quality of inpatient psychiatric care? *The journal of behavioral health services & research.* 2007;34(2):137-150

Elixhauser A, Steiner C. Readmissions to US hospitals by diagnosis, 2010: statistical brief# 153. 2013.

Kalseth J, Lassemo E, Wahlbeck K, Haaramo P, Magnussen J. Psychiatric readmissions and their association with environmental and health system characteristics: a systematic review of the literature. *BMC psychiatry.* 2016;16(1):376.

Steffen, S., Kösters, M., Becker, T., & Puschner, B. (2009). Discharge planning in mental health care: a systematic review of the recent literature. *Acta Psychiatrica Scandinavica*, *120*(1), 1-9.

Sfetcu R, Musat S, Haaramo P, et al. Overview of post-discharge predictors for psychiatric re-hospitalisations: a systematic review of the literature. *BMC psychiatry.* 2017;17(1):227.

Vigod, S. N., Kurdyak, P. A., Dennis, C. L., Leszcz, T., Taylor, V. H., Blumberger, D. M., & Seitz, D. P. (2013). Transitional interventions to reduce early psychiatric readmissions in adults: systematic review. *The British Journal of Psychiatry*, *202*(3), 187-194.

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**: 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.*

Quality and safety of inpatient psychiatric care in Massachusetts has received considerable scrutiny from outlets such as the Boston Globe following incidents of patient death (e.g., Kowalczyk, 2017). Substantiated complaints related to patient's rights vary from death to abuse (physical, sexual, verbal; Shields, Stewart, & Delaney, 2018). According to analyses conducted by the The Health Policy Commission, behavioral health-related emergency department (ED) visits increased by 22% from 2011 to 2016, with a much greater increase specifically among those with alcohol use disorder (40%) and other substance use disorders (54%; The Health Policy Commission, 2017). Moreover, patients presenting to the ED primarily for a behavioral health complaint in Massacshuetts are much more likely to board in the ED, which has been an issue of focus for the state (Blue Cross Blue Shield of Massachusetts Foundation, 2017). gAmong Medicaid patients from June 2013-July 2014, about 21% of those with a behavioral health comorbidity discharged from an acute care hospital were readmitted (compared to 9% of those without a behavioral health diagnosis) with the greatest readmission rate among those with co-occurring mental health and substance use disorder (26.6%; CHIA, 2016). Therefore, patients of inpatient psychiatric facilities as well as taxpayers and citizens of the Commonwealth in general stand to gain from increased understanding into variation in quality and post-discharge acute-care utilization.

References

Blue Cross Blue Shield of Massachusetts Foundation (July, 2017). Access To Behavioral Health Care In Massachusetts: The Basics. Retrived from: https://bluecrossmafoundation.org/sites/default/files/download/publication/BH_basics_Final.pdf

CHIA. (2016) Behaivoral Health and Readmissions. Retrived from: http://www.chiamass.gov/assets/docs/r/pubs/16/Behavioral-Health-Readmissions-2016.pdf

Kowalczyk , L. (2017, June). Families trusted this hospital chain to care for their relatives. It systematically failed them. Retrived from: https://www.bostonglobe.com/metro/2017/06/10/arbour/AcXKAWbi6WLj8bwGBS2GFJ/story.html

Shields, M. C., Stewart, M. T., & Delaney, K. R. (2018). Patient safety in inpatient psychiatry: a remaining frontier for health policy. *Health Affairs*, *37*(11), 1853-1861.

The Health Policy Comission. (March, 2017). 2017 Annual Health Care Cost Trends Report. https://www.mass.gov/files/documents/2018/03/28/2017%20CTR%20Chartpack.pdf

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 ☒ 2017

Describe how your research objectives require Inpatient Discharge data:

These data will be used to identify index admissions as well as readmissions.

☒ Outpatient Hospital Observation Stay Data

☐2004 ☐2005 ☐2006 ☐2007 ☐2008 ☐2009 ☐2010 ☐2011 ☐2012 ☐2013 ☐2014 ☐2015 ☐ 2016 ☒ 2017

Describe how your research objectives require Outpatient Hospital Observation Stay data:

These data will be used to observe post-discharge acute-care utilization, as well as to descriptively understand acute-care utilization in the months prior to the index admission.

☒ Emergency Department Data

☐2004 ☐2005 ☐2006 ☐2007 ☐2008 ☐2009 ☐2010 ☐2011 ☐2012 ☐2013 ☐2014 ☐2015 ☐ 2016 ☒ 2017

Describe how your research objectives require Emergency Department data:

These data will be used to observe post-discharge acute-care utilization, as well as to descriptively understand acute-care utilization in the months prior to the index admission.

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:**

A goal of this analysis is to isolate the effect of facility-level quality performance on post-discharge acute-care utilization. There are key unobserved patient characterizes that could influence where patients receive care as well as risk for post-discharge acute care utilization. For example, the available data will not finely capture nuances related to the disposition of a patient when presenting to the ED, which could influence where they are eventually placed. Our ideal method for controlling for these other unobserved factors is to use distance or travel time to a high-performing or low-performing facility as an instrumental variable. Therefore, the patients' 5-digit zip-code with city and town will allow us to calculate distance/travel time. Moreover, this study will examine and control for community characteristics which will be linked at to patients using their zip code.

Demographic Data

Selcect *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:**

Disparities in access to behavioral health care and severity of psychiatric distress has been documented. Because we will be trying to isolate the effect of the hospital as well as understanding the moderating role of patient and community characteristics, race and ethnicity will be important identifiers to examine as patient-level moderators.

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:**
We are constructing index admissions around a 3-month period and then assessing 30-day acute-care utilization. It is therefore important for us to be able to have the specific dates of admission and discharge.

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:**

We will need to be able to track the patient in order to observe post-discharge readmission, ED stay, and observation stay.

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.

At the facility level: All the variables in the CHIA database will be linked to the IPFQR data for year 2017 (reporting year 2019). All measures of the IPFQR program will be linked to the inpatient psychiatric facilities where patients are hospitalized for their index admission using the Medicare National Provider ID (NPI). Because the case-mix data do not contain the NPI, we will first create a crosswalk file for NPIs by using the names of the facilties in the case-mix file to look up NPIs.

These databases will then be linked to the American Hospital Association's Annual Survey using the NPI.

At the area level: The dataset will be linked to the American Community Survey to characterize the 5-year average of area-level characteristics such as poverty, race and ethnicity, income, and education attainment. Indicators for the Health Professional Shortage Areas for both primary care and mental health care will also be linked to patients' zip-code as an indicator for community-provider capacity.

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.

For facility level data, we will use the NPI. For area-level, we will use the zip-code. Both of these linkages are deterministic. Patient-specific data will not be linked.

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

Inpatient Psychiatirc Facility Quality Reporting Program

- HBIPS-2: Hours of Physical Restraint Use
- HBIPS-3: Hours of Seclusion Use
- HBIPS-5: Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification
- SUB-1: Alcohol Use Screening
- SUB-2: Alcohol Use Brief Intervention Provided or Offered and SUB-2a: Alcohol Use Brief Intervention
- TOB-1: Tobacco Use Screening
- TOB-2: Tobacco Use Treatment Provided or Offered and TOB-2a Tobacco Use Treatment
- TOB-3: Tobacco Use Treatment Provided or Offered at Discharge and TOB-3a: Tobacco Use Treatment at Discharge
- SUB-3 and SUB-3a: Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge and the subset, Alcohol and Other Drug Use Disorder Treatment at Discharge
- Screening for Metabolic Disorders (among those on antipsychotics)
- Timely Transmission of Transition Record
- Transition Record with Specified Elements Received by Discharged Patients
- IMM-2: Influenza Immunization
- Influenza Vaccination Coverage Among Healthcare Personnel
- Use of Electronic Health Record
- Assessment of Patient Experience of Care

American Hospital Association's Annual

- Ownership
- Facility type
- Overall beds
- Psychiatric beds
- Payer mix

American Community Survey

- 5-year average poverty rate
- 5-year average income
- 5-year average mix of race and ethnicity
- 5-year average percent of individuals with a college degree

Health Professional Shortage Areas

- Indicator for MH shortage

- Indicator for primary care shortage

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

Identification of patients is highly unlikely as we will not be linking individual patient information to the CHIA database, only aggregate area-level information as well as facility-level information. Further, we will not attempt to describe variation in patient characteristics across specific identifiable regions/zip-codes. The zip-code will be used for purposes of a travel distance analysis as well as linking to area-level demographic measures. These demographic measures are aggregate area attributes associated with where patients live.

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.

The results of this study will be published in a peer-reviewed journal and presented at conferences via poster or oral presentation. All analyses will be presented in aggregate form. Specific facilities will not be disclosed in these publications. We do not anticipate having cell sizes of patients less than 11 as groups of this size would not permit proper statistical analysis. We will be characterizing patients based on broad classes of diagnoses, such as: co-occurring mental health and substance use; mental health only; substance use only and demographic data will similarly be characterized in broad categories to support statistical analyses. Further, we do not plan to present descriptions of patient-level aggregate information at the zip-code level. We are only using the zip-code to create distance/travel time variables and to link aggregate community characteristics to patients.

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.

The results will be presented in a PhD-level dissertation, academic journal publications and scientific conferences. Only aggregate level information and results from bivariate and multivariate analyses will be presented. The

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 do not anticipate reporting any geographical information other than the fact that facilities are located in Massachusetts. We will likely include aggregate information about the percentage of facilities in rural versus urban areas and aggregate information about community characteristics, but these will not be identified in our products by specific geography in the state.

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, provide the name and a description of the 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.

Morgan Shields, M.Sc., M.A., is a Ph.D. Candidate at the Heller School for Social Policy and Management concentrating in Behavioral Health. She has used the Healthcare Cost and Utilization Project's National Inpatient Sample to examine hospital utilization and costs for self-injurious behavior among autistic adults. She has used the CMS' IPFQR data and the American Hospital Association's Annual Survey to examine variation in performance by ownership, the effect of the IPFQR reporting program on quality, and variation in use of health information exchange at discharge from inpatient psychiatric facilities.

Dominic Hodgkin, Ph.D. Dr. Hodgkin, a health economist and Professor at IBH, has 25 years' experience of working on economic issues in behavioral health, including benefits design, managed care and psychotropic medication prescribing. He has used hospital discharge abstract data from Maine and New Hampshire to analyze cardiac care utilization patterns; survey data from the American Hospital Association to examine hospital cost trends; and hospital claims data from Medicaid and private health plans to analyze how different financing arrangements affect utilization of hospital care.

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 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:	
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:	
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.

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.

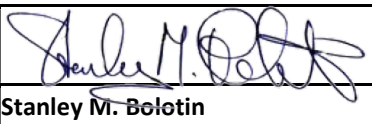
[INSERT A NEW SECTION FOR ADDITIONAL AGENTS/CONTRACTORS AS NEEDED]

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 :	**Stanley M. Bolotin**
Title:	Director, Pre-Award Services, Office of Research Administration

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]