

**AGREEMENT FOR USE OF CENTER FOR HEALTH INFORMATION AND ANALYSIS (CHIA) DATA
CONTAINING PROTECTED HEALTH INFORMATION**

This Data Use Agreement (“Agreement”), dated as of August 1, 2018 (“Effective Date”), is executed by and between the Center for Health Information and Analysis (“CHIA”) and Trustees of Boston University, a Massachusetts not-for-profit corporation (“Recipient”).

This Agreement addresses the conditions under which CHIA will release and the Recipient will obtain, use, reuse and disclose data released by CHIA to Recipient, including but not limited to, any derivative file(s) created by the Recipient, copies of CHIA data, subsets of CHIA data, and additional years or release versions of CHIA data (“Data”). This Agreement pertains to all Data Application(s) under which CHIA releases Data to Recipient. Each Data Application approved by CHIA will be noted in an amendment to this Agreement and attached hereto as **Exhibit A, A-1, A-2**, and so on.

This Agreement supersedes any and all verbal or written agreements between the parties with respect to the use of any Data in the possession of Recipient and preempts and overrides any instructions, directions, agreements, or other understanding between the parties with respect to the Data, including prior Data Use Agreements entered into by the parties. See **Attachment 1** for a list of prior Data Use Agreements superseded by this Agreement.

The following specified Attachments and Exhibits are incorporated herein:

- Attachment 1: Prior Data Use Agreements
- Exhibit A: Data Application(s)
- Exhibit B: Certificate of Continued Need and Compliance
- Exhibit C: Confidentiality Agreement
- Exhibit D: Certificate of Project Completion and Data Destruction

I. Approved Data Applications and Projects; Permitted Uses

1. Each Data Application shall set forth a specific project for which the Data will be used, and that project’s purpose and objective (“Project”). The Recipient represents that the facts and statements made in each Data Application, any study or research protocol or project plan, Data Management Plan(s), and other documents submitted to CHIA in support of each Data Application are complete and accurate. The Recipient affirms that the requested Data under

each Data Application is the minimum necessary to complete the Project set forth in that Data Application.

2. The Data released under a Data Application may only be used solely for the Project set forth in that Data Application, and, unless approved by CHIA under an amendment hereto, for no other Project or use. The Recipient shall not disclose, use or reuse, sell, rent, lease, loan, or otherwise grant access to the Data except as specified in this Agreement or as CHIA may authorize in writing or as otherwise required by law. The Recipient shall not use the Data to attempt to identify individuals. The Recipient shall not disclose to anyone who is not an authorized user of the Data any direct findings, listings, or information derived from the Data, with or without direct identifiers, if such findings, listings, or information can, by themselves or in combination with other data, be used to deduce an individual's identity.

3. Absent express written authorization from CHIA the Recipient shall not attempt to link records included in the Data to any other information, including but not limited to, linkage to other CHIA data file(s). An approved Data Application that includes the linkage of specific elements or files constitutes express authorization from CHIA to link files as described in that Data Application and for the Project set forth in that Data Application only.

4. Recipients may be approved under a Data Application to receive prospective years or release versions of Data. If so approved, the Recipient shall submit a completed Certificate of Continued Need and Compliance, attached hereto as **Exhibit B**, prior to receipt of such years or release versions of Data. The Recipient acknowledges that prospective years or release versions of Data are for use, reuse, and disclosure solely under the Data Application and for the Project set forth in that Data Application. Such Data will be provided by CHIA as available. The Data might not be provided in the same format, with the same Data elements, or during the same timeframe as previous years or release versions of such Data, or at all.

II. Data Privacy and Security Obligations

1. The Recipient shall ensure the integrity, security, and confidentiality of the Data and shall comply with the terms of this Agreement, its Exhibits, the Data Management Plan(s), M.G.L. chapters 93H and 93I and, as applicable, the privacy and security standards set forth in the federal Privacy Act and the Health Insurance Portability and Accountability Act. The Recipient shall permit appropriate disclosure and use of the Data only as permitted by law and by this Agreement and shall not use the Data to attempt to identify individuals.

2. The Recipient shall establish appropriate administrative, technical, and physical safeguards to protect the confidentiality of the Data and to prevent unauthorized use or access to the Data. Recipient shall at all times during the term of this Agreement abide by the Data Management Plan(s) approved by CHIA, attached to each Data Application. The Recipient

acknowledges that the use of unsecured telecommunications, including the Internet, to transmit individually identifiable or deducible information derived from the Data is prohibited. The Data may not be physically moved, transmitted or disclosed in any way from or by the site approved by CHIA without prior written approval from CHIA unless such movement, transmission or disclosure is required by a law, in which case Recipient shall promptly notify CHIA and, as required, amend the Data Management Plan.

3. The Recipient agrees that any use of the Data in the creation of any document (manuscript, table, chart, study, report, etc.) that is shared with anyone who is not an authorized user of the Data shall adhere to CHIA's current cell size suppression policy. **This policy stipulates that no cell (e.g., admittances, discharges, patients, services) less than 11 may be displayed.** Also, no use of percentages or other mathematical formulas may be used if they result in the disclosure of a cell less than 11. Reports and analytics must use complementary cell suppression techniques to ensure that cells with fewer than eleven observations cannot be identified by manipulating data in adjacent rows, columns or other manipulations of the report.

4. If the Recipient receives CHIA's approval to disclose the Data to an agent, contractor, or other third party, the Recipient shall require such agent, contractor, or other third party receiving the Data to agree, in writing, to adhere to the same terms and conditions with respect to the use (the approved Project), disclosure, maintenance, destruction, privacy and security of the Data that apply to the Recipient under this Agreement and Data Management Plan.

5. Within the Recipient organization and the organizations of its agents, access to the Data shall be limited to the minimum amount of data and minimum number of individuals necessary to complete the Project for which the Data was released (i.e., individual's access to the Data will be on a need-to-know basis). The Recipient shall ensure that all individuals, including employees, agents, or contractors, who will use or access the Data sign CHIA's Confidentiality Agreement, attached hereto as **Exhibit C**. The Recipient shall keep such Confidentiality Agreements and an access log on file and shall make such Confidentiality Agreements and access log available to CHIA anytime upon request by CHIA. The access log shall contain a list of names of all individuals who use and/or access the Data, the Project and Data Application under which the individual has access to the Data, the date on which such individuals signed a Confidentiality Agreement and when access to and/or use of Data was granted and, if applicable, terminated.

III. Inspections

The Recipient shall grant reasonable access to its facilities, personnel and the Data, and to any non-Recipient site where the Data is held, to authorized representatives of CHIA for the

purpose of confirming compliance with the terms of this Agreement. Recipient shall promptly respond to any request by CHIA to verify Recipient's compliance with the terms of this Agreement, as well as compliance of any agent, contractor or third party to whom the Recipient disclosed CHIA Data.

IV. Reporting and Treatment of Subpoenas and Unauthorized Uses, Disclosures or Security Incidents

1. The Recipient shall not disclose, use or reuse, sell, rent, lease, loan, or otherwise grant access to the Data except as specified in this Agreement or as CHIA may authorize in writing or as otherwise required by law, in which case Recipient shall promptly notify CHIA. In the event the Data is subpoenaed or becomes the subject of a court or administrative order or other legal process, the Recipient shall consult with CHIA prior to responding to any such request or demand and provide CHIA with reasonable opportunity to assert to the requestor, court, or administrative agency any objections to disclosure as may be legally available to CHIA. Until CHIA responds to the Recipient's notice of legal process given in accordance with this provision, the Recipient shall assert objections to disclosure of such records and data on grounds as may be legally available to the Recipient.

2. In the event CHIA determines or has a reasonable belief that the Recipient has made or may have made a use, reuse or disclosure of the Data that is not authorized by this Agreement or other written authorization from CHIA, CHIA, at its sole discretion, may require the Recipient to: (a) promptly investigate and report to CHIA the Recipient's determinations regarding any alleged or actual unauthorized use, reuse or disclosure; (b) promptly resolve any issues identified by the investigation; (c) if requested by CHIA, submit a formal response to an allegation of unauthorized use, reuse or disclosure in the time frame specified by CHIA; (d) if requested by CHIA, submit a corrective action plan with steps designed to prevent any future unauthorized uses, reuses or disclosures in the time frame specified by CHIA; and (e) if requested by CHIA, return the Data to CHIA or destroy the Data and any copies thereof. As a result of CHIA's determination or reasonable belief that unauthorized uses, reuses or disclosures have taken place, CHIA may in its sole discretion refuse to release further CHIA data to the Recipient.

3. The Recipient shall report loss of the Data or disclosure to any unauthorized persons to CHIA within three business days of such loss or unauthorized disclosure and shall cooperate fully in any CHIA incident response process. While CHIA retains all ownership rights to the Data, the Recipient shall bear the sole cost and liability for any privacy and security breaches related to the Data while the Data are entrusted to the Recipient. Furthermore, if CHIA determines that the risk of harm requires notification to affected individuals of the security breach and/or other

remedies, the Recipient shall be solely liable to carry out these remedies at its sole cost and expense.

V. Data Ownership

CHIA retains all ownership rights in and to the Data; the Recipient does not obtain any right, title, or interest in or to the Data. The Recipient shall cite the Center for Health Information and Analysis as the source of the Data in any studies, reports or products in which the Data are used.

VI. Data Retention and Destruction

Except set forth herein, the Data released under a Data Application may be retained by the Recipient until the Project approved under such Data Application is complete ("Project Completion"). The Recipient shall notify CHIA within 30 days of Project Completion. Upon Project Completion, the Recipient shall promptly destroy the Data received under the Data Application, including all copies thereof. The Recipient shall promptly, but no later than 30 days of Project Completion, send written certification of the destruction of the Data to CHIA, using the form attached hereto as **Exhibit D**. The Recipient shall not retain Data received under that Data Application after Project Completion unless authorized in writing by CHIA. The Recipient acknowledges its affirmative obligation to destroy the Data upon Project Completion, and that such obligation is not contingent upon action by CHIA.

VII. Term and Termination of Agreement

1. The Agreement may be terminated by either party at any time for any reason upon 30 days written notice. Upon notice of termination by Recipient, CHIA will cease releasing Data to the Recipient, and Recipient will within 15 days destroy all Data. Upon notice of termination by CHIA, Recipient will within 15 days of such notice destroy the Data. Upon destruction, Recipient will promptly send a completed Data Destruction Form to CHIA. Further, CHIA may, at any time and in its sole discretion, require the Data in whole or in part to be returned to CHIA. Recipient shall promptly comply with any such instructions from CHIA.

2. This Agreement shall remain in full force and effect at all times while Recipient or its agent maintains any Data. This Agreement will terminate upon CHIA's receipt of the Data Destruction Forms for all Data in Recipient possession. Articles I, II, III, IV, V, VI, VII, IX, X, and XI shall survive termination of this Agreement.

VIII. Amendment

The terms of this Agreement can be changed only by written amendment to this Agreement or by the parties adopting a new agreement.

IX. Violations and Penalties

A violation of this Agreement or 957 CMR 5.00, may result in penalties and remedies allowed by law, including but not limited to M.G.L. c. 214 § 1B and M.G.L. c. 93A. CHIA may notify state and federal law enforcement officials, as applicable, of any data breaches in connection with any violation of this Agreement. It is the sole responsibility of the Recipient to ensure compliance with all other local, state, and federal laws and regulations.

X. No Representations or Warranties

CHIA MAKES NO REPRESENTATIONS OR WARRANTIES TO ANY PERSON OR ENTITY WITH RESPECT TO CHIA DATA, THE SOFTWARE, OR ANY OTHER INFORMATION PROVIDED BY CHIA OR ITS AGENTS WITH RESPECT TO ANY OF THE FOREGOING, AND HEREBY DISCLAIMS ALL IMPLIED WARRANTIES WITH RESPECT TO CHIA DATA, INCLUDING WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. FURTHER, CHIA MAKES NO WARRANTY, GUARANTEE OR REPRESENTATION REGARDING THE USE, OR ANY INTENDED, EXPECTED, OR ACTUAL RESULTS OF THE USE, OF CHIA DATA, THE SOFTWARE, OR ANY OTHER INFORMATION PROVIDED BY CHIA IN TERMS OF CORRECTNESS, ACCURACY, RELIABILITY, OR OTHERWISE. CHIA DOES NOT MAKE ANY WARRANTIES THAT CHIA DATA, SOFTWARE, OR ANY OTHER INFORMATION PROVIDED BY CHIA WILL BE ERROR-FREE. CHIA SPECIFICALLY DISCLAIMS ALL EXPRESS WARRANTIES NOT STATED HEREIN AND ALL IMPLIED WARRANTIES, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. NO CHIA AGENT OR EMPLOYEE IS AUTHORIZED TO MAKE ANY EXPANSION, MODIFICATION, OR ADDITION TO THE LIMITATION AND EXCLUSION OF WARRANTIES IN THIS AGREEMENT.

CHIA USES AVAILABLE TECHNOLOGY TO MATCH PATIENT IDENTITIES WITH THEIR HEALTH INFORMATION. BECAUSE PATIENT INFORMATION IS MAINTAINED IN MULTIPLE PLACES, NOT ALL OF WHICH ARE ACCESSIBLE TO CHIA, AND BECAUSE NOT ALL PATIENT INFORMATION IS KEPT IN A STANDARD FASHION OR IS REGULARLY UPDATED, IT IS POSSIBLE THAT FALSE MATCHES MAY OCCUR OR THAT THERE MAY BE ERRORS OR OMISSIONS IN THE INFORMATION. CHIA DOES NOT AND CANNOT INDEPENDENTLY VERIFY OR REVIEW THE INFORMATION TRANSMITTED FOR ACCURACY OR COMPLETENESS.

XI. Data Custodian

The following named individual is designated as Custodian of the file(s) on behalf of the Recipient and is the person responsible for the observance of all conditions of use and for establishment and maintenance of security arrangements as specified in this Agreement and the approved Data Management Plan to prevent unauthorized use. The Recipient shall notify CHIA within fifteen (15) days of any change of custodianship. CHIA may disapprove the appointment of a custodian or may require the appointment of a new custodian at any time.

The Custodian hereby acknowledges his/her appointment as Custodian of the aforesaid file(s) on behalf of the Recipient, and agrees to comply with all of the provisions of this Agreement on behalf of the Recipient.

Name of Custodian: <u>Eric Jacobsen</u>		Organization: <u>Trustees of Boston University</u>	
Street Address: <u>930 Commonwealth Ave.</u>	City: <u>Boston</u>	State: <u>MA</u>	Zip Code: <u>02215</u>
Office Telephone (Include Area Code): <u>617-353-8284</u>		E-Mail Address: <u>jacobsen@bu.edu</u>	
Signature: <u>Eric Jacobsen</u>	Title: <u>Director, Information Security, Information Services & Technology</u>	Date: <u>8/28/2018</u>	

IN WITNESS WHEREOF, the parties by their duly authorized representatives have executed this Agreement as of the Effective Date.

CENTER FOR HEALTH INFORMATION AND ANALYSIS

Name of CHIA Representative: <u>William Bailey</u>		Title: <u>Chief Privacy Office</u>	
Street Address: <u>501 Boylston Street, 5th Floor</u>	City: <u>Boston</u>	State: <u>MA</u>	ZIP Code: <u>02116</u>
Office Telephone (Include Area Code): <u>(617) 701-0134</u>		E-Mail Address: <u>william.bailey@state.ma.us</u>	
Signature: <u>Will</u>		Date: <u>8/30/18</u>	

RECIPIENT

Name of authorized signatory: <u>William P. Segarra, JD, MPH</u>		Organization: <u>Trustees of Boston University</u>	
Street Address: <u>25 Buick Street, Suite #200</u>	City: <u>Boston</u>	State: <u>MA</u>	Zip Code: <u>02467</u>
Office Telephone (Include Area Code): <u>617-353-4365</u>		E-Mail Address: <u>industry@bu.edu</u>	
Signature: <u>William P. Segarra, JD, MPH</u>	Title: <u>Director, Industry Contracts & Agreements</u>	Date: <u>8/28/2018</u>	

Digitally signed by William P. Segarra, JD, MPH
DN: cn=William P. Segarra, JD, MPH,
o=Trustees of Boston University, ou=Sponsored
Programs, email=segarra@bu.edu, c=US
Date: 2018.08.28 12:11:17 -0400

ATTACHMENT 1
PRIOR DATA USE AGREEMENTS SUPERSEDED BY THIS AGREEMENT

A-1. Understanding Insurance, Provider Networks, and Outcomes

Dept: School of Management

Primary Investigator: Keith Ericson (Professor)

Data Custodian: Greg Defronzo (Information Technology Services Director, Boston University School of Management)

Co-Investigators: Jim Rebitzer (Professor), Benjamin Lubin (Professor), Kimberley Geissler (Research Associate) Brigham Frandsen (Brigham Young Univ.), Amanda Strac (UPenn)

Data Use Agreement: 9/29/14

A-2. Does Physician Leadership Play a Role in Increasing ACO Efficiency? – Evidence from the Alternative Quality Contract

Dept: School of Public Health

Primary Investigator: Kathleen Carey (Professor)

Data Custodian: Meng-Yun Lin (PhD Candidate)

Co-Investigators: Meng-Yun Lin, James Burgess (Professor) , Austin Frakt (Professor)

Data Use Agreement BU 5/24/16 CHIA 6/7/16

A-3. Evaluation Services to Support the Community Hospital Acceleration, Revitalization and Transformation (CHART) Investment Program

Dept: School of Public Health

Primary Investigator: Christopher Louis (Professor)

Data Custodian: Christopher Louis

Co-Investigators: Sally Bachman, David Rosebloom, Kathleen Cary, Vicky Parker, Alan Sager, Rani Elwy

Data Use Agreement: BU 9/12/16 CHIA 10/27/16 (amended 10/4/2017 and 2/9/18)

A-4. Adoption of Non-Invasive Prenatal Testing in Diverse Populations: A Multilevel Approach

Dept: School of Public Health – Community Health Sciences

Primary Investigator: Catherine Wang (Professor)

Data Custodian: Catherin Wang

Co-Investigators: Amresh Hanchate, Christina Yarrington

Data Use Agreement: BU 3/6/17 CHIA 8/8/17

EXHIBIT B
CERTIFICATE OF CONTINUED NEED AND COMPLIANCE
 (complete and submit to CHIA when requesting new data for approved Project)

The Recipient has been approved under a Data Application entitled, _____ to receive additional years or versions of Data. All use of Data shall be governed by that certain Data Use Agreement, dated as of _____, by and between CHIA and Recipient (the "Agreement").

Recipient wishes to receive the additional years or release versions of the Data and CHIA is willing to provide such Data under the terms of the Agreement and the terms herein.

Name and title of Primary Investigator (Applicant):	
Organization Requesting Data (Recipient):	
Project Title:	
Year or Version of Data Requested:	

The Recipient hereby certifies:

- 1.) The Recipient is in full compliance with the Agreement;
- 2.) The year or release version of Data, identified above, is necessary to complete the Project;
- 3.) No changes have been made to the Project.

The undersigned further acknowledges:

- 1.) Prospective years or release versions of Data will be provided as available: the Data may not be provided in the same format, with the same data elements, or during the same timeframe as previous years or versions of Data, or at all;
- 2.) The additional years or version of Data released under a Data Application may only be used solely for the Project set forth in that Data Application, and, unless approved by CHIA under an amendment hereto, for no other Project or use; and
- 3.) The Recipient must remit any applicable Data fees prior to extraction and release of the Data; Data fees may be subject to change.

Capitalized terms used herein and not defined shall have the same meanings assigned to them in the Agreement. This Certificate is effective as of the date below.

Name of authorized signatory:		Organization:		
Street Address:		City:	State:	Zip Code:
Office Telephone (Include Area Code):			E-Mail Address:	
Signature:	Title:	Date:		

**EXHIBIT C
CONFIDENTIALITY AGREEMENT**

I, _____, hereby acknowledge that, in connection with a request for All-Payer Claims Database data and/or Hospital Discharge Database data under an agreement (the "Agreement") with CHIA, I may acquire or have access to confidential information or individually identifiable information of patients. This information includes, but is not limited to, patient level protected health information (PHI - eligibility, claims, providers), health insurance coverage information, financial institution match information, as well as "personal data" as defined in G.L. c. 66A (collectively, the "Information").

I will comply with all of the terms of the Agreement regarding my access, use, and disclosure of any Information.

I will at all times maintain the confidentiality of the Information. I will not inspect or "browse" the Information for any purpose not approved in the Agreement. I will not access, or attempt to access, my own Information for any purpose. I will not access, or attempt to access, Information relating to any individual or entity with which I have a personal or financial relationship, for any reason. This includes family members, neighbors, relatives, friends, ex-spouses, their employers, or anyone not necessary for the work assigned. I will not, either directly or indirectly, disclose or otherwise make the Information available to any unauthorized person at any time.

I understand that any violations of this Agreement, M.G.L. c. 93H (regarding data breaches), M.G.L.c. 93I (regarding data destruction), and other laws protecting privacy and data security may subject me to criminal or civil liability. I further understand that CHIA may notify state and federal law enforcement officials, as applicable, of any data breaches in connection with any violation of this Agreement.

Name:		Organization:	
Street Address:		City:	State: Zip Code:
Office Telephone (Include Area Code):		E-Mail Address:	
Signature:	Title:	Date:	

EXHIBIT D
CERTIFICATION OF PROJECT COMPLETION & DATA DESTRUCTION

CHIA Data must be destroyed so that it cannot be recovered from the electronic storage media. Acceptable methods include the use of file wiping software implementing at a minimum DoD.5200.28-STD (7) disk wiping, and the degaussing of backup tapes. Electronic storage media such as floppy disks, CDs, and DVDs used to store data must be made unusable by physical destruction. All data destruction must comply with the requirements of M.G.L. c. 93I.

The undersigned hereby certifies that the Project entitled:

_____ approved under a Data Application approved on _____ and subject to the Data Use Agreement dated _____ is complete as of this date: _____.

The undersigned further certifies as follows (check the appropriate section):

I/we certify that I/we have destroyed all Data received from CHIA in connection with this Data Application and Project, in all media that was used during the Project. This includes, but is not limited to, Data maintained on hard drives and other storage media.

I/we certify that I/we will continue to hold Data pending any request for an extended retention date (which request may or may not be granted by CHIA in its discretion.)

Name of Custodian:		Organization:	
Street Address:	City:	State:	Zip Code:
Office Telephone (Include Area Code):		E-Mail Address:	
Signature:	Title:	Date:	

**EXHIBIT A
DATA APPLICATION(S)**

A-1

Attachments included after template Exhibit D

**EXHIBIT A
DATA APPLICATION(S)**

A-1 - Ericson

**Commonwealth of Massachusetts
Center for Health Information & Analysis (CHIA)
Non-Government Agency Application for Data**

This application is to be used by all applicants, except Government Agencies, as defined in 957 CMR 5.02.

NOTE: In order for your application to be processed, you must submit the required application fee. Please consult the fee schedules for APCD and Case Mix data for the appropriate fee amount. A remittance form with instructions for submitting the application fee is available on the CHIA website.

I. GENERAL INFORMATION

APPLICANT INFORMATION	
Applicant Name:	Keith Marzilli Ericson (primary applicant)
Title:	Assistant Professor of Markets, Public Policy, & Law and Faculty Research Fellow
Organization:	Boston University School of Management and National Bureau of Economic Research
Co-Investigator:	Jim Rebitzer
Title:	Professor of Management, Economics and Public Policy; Everett J. Lord Distinguished Scholar; Research Associate
Organization:	Boston University School of Management and National Bureau of Economic Research
Co-Investigator:	Benjamin Lubin
Title:	Assistant Professor of Information Systems
Organization:	Boston University School of Management
Co-Investigator:	Brigham Frandsen
Title:	Assistant Professor of Economics
Organization:	Brigham Young University
Co-Investigator:	Kimberley Geissler
Title:	Research Associate
Organization:	Boston University School of Management
Co-Investigator:	Amanda Starc
Title:	Assistant Professor of Health Care Management
Organization:	University of Pennsylvania
Project Title:	Understanding Insurance, Provider Networks, and Outcomes
Date of Application:	October 2014
Project Objectives (240 character limit)	We examine characteristics of provider networks and insurance policies and relationships with patient outcomes to better understand provider and enrollee behaviors. We use regression techniques, network analysis, and simulation.
Project Research Questions	We investigate how consumers value insurance plan designs and provider

	<p>networks, and examine the links between plan design, network structure, and outcomes. Specifically, we ask the following questions:</p> <ol style="list-style-type: none"> 1. What are the consequences of broader versus narrower insurance plan choice set (i.e. variation in deductibles, actuarial value, etc.)? 2. Can more complex insurance contracts improve outcomes and patient welfare by linking cost-sharing to more information (e.g. provider quality, patient health status)? 3. What is consumer willingness-to-pay for additional network access from their employer’s plan menu, and how does this affect insurance plan design? 4. Do consumers with greater medical utilization gravitate towards certain kinds of plans or networks of providers? 5. What do professional networks of shared patients among physicians look like, and how do such networks vary by type of insurance plan (e.g. HMO v PPO vs. Medicaid)? 6. What is the relationship between professional networks of shared patients among physicians, resource use, and patient outcomes?
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I. PROJECT SUMMARY

Briefly describe the purpose of your project and how you will use the requested CHIA data to accomplish your purpose.

This project investigates how consumers value insurance plans and networks. This requires we establish links between plan design, network structure, and health/utilization outcomes. We will use the CHIA data to first examine the link between characteristics of insurance plans and the utilization of health care, including particular procedures and total spending. We then examine the provider networks available to consumers in each plan/insurance type. We estimate models of demand for particular providers (e.g. hospitals, using measures of geographical distance) and then for insurer-specific networks. We also examine how network structure is associated with outcomes. We associate network-breadth measures with price levels, utilization patterns, and enrollee composition. We also model the structure of provider-provider connections (e.g. referral networks) using insights from network theory (e.g. concepts of connectedness, centrality, etc). We examine how this structure varies by insurance plan design, and how these structures are associated with measures of health outcomes and process quality.

These analyses will use standard forms of regression analysis, hazard models, simulated method of moments, models of consumer choice (e.g. differentiated product demand models) and welfare (e.g. expected utility models), and network structure modeling (e.g., clustering coefficients, betweenness, and spectral analysis).

II. FILES REQUESTED

Please indicate the databases from which you seek data, the Level(s) and Year(s) of data sought.

ALL PAYER CLAIMS DATABASE	Level 1 ¹ or 2 ²	Single or Multiple Use	Year(s) Of Data Requested Current Yrs. Available 2009 - 2012

¹ Level 1 Data: De-identified data containing information that does not identify an individual patient and with respect to which there is no reasonable basis to believe the data can be used to identify an individual patient. This data is de-identified using standards and methods required by HIPAA.

² Level 2 (and above) Data: Includes those data elements that pose a risk of re-identification of an individual patient.

X Medical Claims	<input type="checkbox"/> Level 1 ³ x Level 2	Select... Single	X 2009 X 2010 x 2011 X 2012
X Pharmacy Claims	X Level 2	Select... Single	X2009 X2010 X2011 X2012
<input type="checkbox"/> Dental Claims X Member Eligibility X Provider X Product	<input type="checkbox"/> Level 2 X Level 2 X Level 2 X Level 2	Select... Single Select... Single Select... Single Select... Single	X 2009 X 2010 x 2011 X 2012

CASEMIX	Level 1 - 6	Fiscal Years Requested
Inpatient Discharge	<input type="checkbox"/> Level 1 – No Identifiable Data Elements <input type="checkbox"/> Level 2 – Unique Physician Number (UPN) <input type="checkbox"/> Level 3 – Unique Health Information Number (UHIN) <input type="checkbox"/> Level 4 – UHIN and UPN <input type="checkbox"/> Level 5 – Date(s) of Admission; Discharge; Significant Procedures <input type="checkbox"/> Level 6 – Date of Birth; Medical Record Number; Billing Number	<u>1998-2013 Available</u> (limited data 1989-1997)
Outpatient Observation	<input type="checkbox"/> Level 1 – No Identifiable Data Elements <input type="checkbox"/> Level 2 – Unique Physician Number (UPN) <input type="checkbox"/> Level 3 – Unique Health Information Number (UHIN) <input type="checkbox"/> Level 4 – UHIN and UPN <input type="checkbox"/> Level 5 – Date(s) of Admission; Discharge; Significant Procedures <input type="checkbox"/> Level 6 – Date of Birth; Medical Record Number; Billing Number	<u>2002-2012 Available</u> (2013 available 8/1/14)
Emergency Department	<input type="checkbox"/> Level 1 – No Identifiable Data Elements <input type="checkbox"/> Level 2 – Unique Physician Number (UPN) <input type="checkbox"/> Level 3 – Unique Health Information Number (UHIN) <input type="checkbox"/> Level 4 – UHIN and UPN; Stated Reason for Visit <input type="checkbox"/> Level 5 – Date(s) of Admission; Discharge; Significant Procedures <input type="checkbox"/> Level 6 – Date of Birth; Medical Record Number; Billing Number	<u>2000-2012 Available</u> (2013 available 9/1/14)

³ Please note that Level 1 APCD data is not available as of 4/30/2014. This is scheduled to be available later in 2014.

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III. FEE INFORMATION

Please consult the fee schedules for APCD ([Administrative Bulletin 13-11](#)) and Case Mix data ([Administrative Bulletin 13-09](#)) and select from the following options:

APCD Applicants Only

- Academic Researcher
 Others (Single Use)
 Others (Multiple Use)

Case Mix Applicants Only

- Single Use
 Limited Multiple Use
 Multiple Use

Are you requesting a fee waiver?

- XXX Yes
 No

If yes, please submit a letter stating the basis for your request. Please refer to the fee schedule for qualifications for receiving a fee waiver. If you are requesting a waiver based on the financial hardship provision, please provide documentation of your financial situation. Please note that non-profit status alone isn't sufficient to qualify for a fee waiver.

IV. REQUESTED DATA ELEMENTS [APCD Only]

State and federal privacy laws limit the use of individually identifiable data to the minimum amount of data needed to accomplish a specific project objective. Please use the [APCD Data Specification Workbook](#) to identify which data elements you would like to request and attach this document to your application.

V. MEDICAID DATA [APCD Only]

Please indicate here whether you are seeking Medicaid Data:

- Yes
 No

Federal law (42 USC 1396a(a)7) restricts the use of individually identifiable data of Medicaid recipients to uses that are directly connected with the administration of the Medicaid program. If you are requesting Medicaid data from Level 2 or above, please describe in detail why your use of the data meets this requirement. Applications requesting Medicaid 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 Medicaid program. MassHealth may impose additional requirements on applicants for Medicaid data as necessary to ensure compliance with federal laws and regulations regarding Medicaid.

<p>This project will identify how insurance plans can be designed to improve individuals' health outcomes and welfare, and how to increase health system efficiency. The results of our analyses will inform</p>
--

market regulators as they evaluate policies, particularly those that affect network coverage in MassHealth. Our results will identify patterns of provider networks that patients value and that deliver effective care, giving more information to the Medicaid program about efficient allocation of providers. Additionally, many studies have examined the effects of limited provider networks for Medicaid – we will look at the structure of these networks and their relationships with patient outcomes, particularly as compared to other types of insurance including HMOs. This will potentially inform Medicaid as to the value of expanding networks (if any) in terms of outcomes including cost and utilization measures such as hospitalizations or emergency department visits.

VI. REQUESTS PURSUANT TO 957 CMR 5.04

If you are a payer, provider, provider organization or researcher seeking access to Level 1 (de-identified) data, please describe how you will use such data for the purposes of lowering total medical expenses, coordinating care, benchmarking, quality analysis or other administrative research purposes. Please provide this information below.

VII. FILTERS

If you are requesting APCD elements from Level 2 or above, describe any filters you are requesting to use in order to limit your request to the minimum set of records necessary to complete your project. (For example, you may only need individuals whose age is less than 21, claims for hospital services only, or only claims from small group projects.)

APCD FILE	DATA ELEMENT(S) FOR WHICH FILTERS ARE REQUESTED	RANGE OF VALUES REQUESTED
Medical Claims		
Pharmacy Claims		
Dental Claims		
Membership Eligibility		
Provider		
Product		

VIII. PURPOSE AND INTENDED USE

1. Please explain why completing your project is in the public interest.

This project will identify how insurance plans can be designed to improve individuals' health outcomes and welfare, and how to increase health system efficiency. The results of our analyses will inform market regulators as they evaluate policies that affect network coverage and plan generosity in the health insurance exchanges, as well as in the individual and group markets. Our results will identify patterns of provider networks that patients value and that deliver effective care, which will be of use to providers and insurance plans/carriers that desire to improve care.

2. **Attach** a brief (1-2 pages) description of your research methodology. (This description will not be posted on the internet.)
3. Has your project received approval from your organization's Institutional Review Board (IRB)? Please note that CHIA will not review your application until IRB documentation has been received (if applicable).
X Yes, and a copy of the approval letter is attached to this application.
 No, the IRB will review the project on _____.
 No, this project is not subject to IRB review.
 No, my organization does not have an IRB.

IX. APPLICANT QUALIFICATIONS

1. Describe your qualifications to perform the research described or accomplish the intended use of CHIA data.

Keith Marzilli Ericson holds a PhD in Economics from Harvard University and a BA in economics and political science from Williams College. He is an Assistant Professor of Markets, Public Policy, and Law in the Boston University School of Management, teaching courses in econometrics and optimization theory. He is also a Faculty Research Fellow at the National Bureau of Economic Research.

Jim Rebitzer holds a Ph.D. in economics from the University of Massachusetts at Amherst and a BS in biology from the University of Illinois in Urbana Illinois. He is a professor of Management, Economics and Public Policy at the Boston University School of Management where he is also an Everett J. Lord distinguished scholar as well as being a research associate at the National Bureau of Economic Research. He has considerable experience working with confidential commercial insurance records in empirical, health services research.

Benjamin Lubin holds a PhD in Computer Science from Harvard University and an AB in Computer Science from Harvard University. He is an Assistant Professor of Information Systems in the Boston University School of Management, teaching courses in computer science. He is also a Hariri Institute junior faculty fellow.

Brigham Frandsen holds a PhD in Economics from the Massachusetts Institute of Technology and a BS in economics and physics from Brigham Young University. He is an Assistant Professor of Economics at Brigham Young University, teaching courses in econometrics. He also was a Robert Wood Johnson Scholar in Health Policy Research at Harvard University.

Kimberley Geissler holds a PhD in Health Policy and Management from the University of North Carolina Gillings School of Global Public Health and a BA in chemistry and economics from Williams College. She is a Research Associate in the Boston University School of Management. She is also an Adjunct Assistant Professor of Health Policy and Management at the University of North Carolina.

Amanda Starc holds a PhD in Business Economics from Harvard University and a BA in Economics from Case Western Reserve. She is an Assistant Professor of Health Care Management in the Wharton School, University of Pennsylvania.

Ericson and Starc have examined the Massachusetts Health Insurance Exchange (Connector) in a series of papers (2013 American Economic Review, 2013 Inquiry, 2012 National Bureau of Economic Research Working Paper, 2013 Working Paper). All investigators have worked with sensitive health data

previously (Ericson: Marketscan; Rebitzer: numerous datasets including commercial insurance claims data; Frandsen: confidential medical and drug claims data from a large private insurer; MEPS Insurance Component; Census Long Form (confidential 1:6 sample); Lubin: Marketscan; Starc: Medigap; Geissler: State Hospital Discharge Datasets, Marketscan).

2. Attach résumés or curricula vitae of the applicant/principal investigator, key contributors, and of all individuals who will have access to the data. (These attachments will not be posted on the internet.)

X. DATA LINKAGE AND FURTHER DATA ABSTRACTION

1. Does your project require linking the CHIA Data to another dataset?
 - Yes
 - No
2. If yes, will the CHIA Data be linked to other patient level data or with aggregate data (e.g. Census data)?
 - Patient Level Data
 - Aggregate Data
3. If yes, please identify all linkages proposed and explain the reasons(s) that the linkage is necessary to accomplish the purpose of the project. Please be specific in describing vvhich data elements will be linked to outside datasets and how this will be accomplished.

4. We propose to link CHIA data to the following aggregate datasets, described here:

- 1) Hospital linkages – We will link hospitals to the American Hospital Association Annual Survey Database (AHA) for hospital characteristics; to the Medicare Hospital Compare dataset for quality and aggregate health outcome data. We will use information on the service provider name and location to identify hospitals from the medical claims data (MC027, MC028, MC029, MC030, MC031, MC033, MC034, MC035), linked with location information from the provider file based on the National Service Provider ID (MC026 or MC024 if MC026 is missing). We will link using the hospital name and location we derive from the APCD fields to hospital name and location in the AHA and Hospital Compare datasets. This is needed to describe provider networks and model patient choice of hospital.
- 2) Provider linkages – We will link providers to the American Medical Association Physician Masterfile for provider specialty and demographic data (using the MC026, National Service Provider ID; if MC026 is missing, we will use MC024 and the provider file to link to the AMA Masterfile by physician name and service location); to tiering (quality/cost-efficient care) measures for specialist providers participating in the GIC UniCare plans (using the MC026, MC028, MC029, MC030, and MC035 to link by National Provider ID if possible, or by name and location if not; if the information is not available in the medical claims, we will use MC024 and the provider file to conduct the linkage); and to the

Massachusetts Health Quality Partners (MHQP) provider dataset to accurately link providers to practices for determination of practice level measures and to link to quality data (ambulatory physician group practice linkages) [This linkage will be done using the MCO26, National Service Provider ID; if MCO26 is missing, we will use MCO24 and the provider file to link to the MHQP provider dataset by physician name and service location]. To link to provider information, we need a number of provider identifiers. In published analyses and reports, we will not identify providers or report information where deductive disclosure would be possible (e.g., we will mask small cells, etc.). This is needed to characterize provider networks (e.g. are more efficient doctors more likely to be in the same network) and model patient choice of provider.

- 3) Ambulatory physician group practice linkages – We will link provider data to MHQP quality data on clinical and patient experience measures for primary care physicians (We will do this using provider IDs, names, and practice locations from the medical claims files and the provider file. We will use MCO24, MCO26, MCO28, MCO29, MCO30, MCO35 and the provider file to find the address and practice location if necessary for the linkage. We will use the physician group information from the MHQP provider dataset linkage). This is needed to characterize provider networks and model patient choice of provider.

- 4) Geographic area linkages – We will link member geographic data (ZIP, city, county from the member eligibility file – ME3, ME4, ME6, ME017) to the corresponding geographic indicator in the Area Resource File and the American Communities Survey/Census data to get information on healthcare supply, socioeconomic status, and regional characteristics. This is needed to account for variation in patient characteristics that might affect patient use of medical care or outcomes; we do not identify individual patients, merely link to characteristics of their ZIP code.

- 5) Carrier and/or insurance plan linkages – We will link carrier and/or insurance plan data (ME030, ME040 to link to product file, and then PR003, PR004) to market share and premium data from Mass Connector, as well as to the network definition of plans in the Connector (by looking up particular providers to determine if they are in-network for a given plan). This is needed to model insurer price setting (which is jointly determined with patient demand for insurance), how prices move with plan generosity, and to model consumer choice of insurance plan.

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

As these datasets do not increase the ability or likelihood of identification of individual patients

in the linked datasets, these linkages would not jeopardize patient confidentiality. As discussed in the data security and integrity section, we will take great care to ensure the confidentiality of the data.

XI. PUBLICATION / DISSEMINATION / RE-RELEASE

1. Describe your plans to publish or otherwise disclose CHIA Data, or any data derived or extracted from such data, in any paper, report, website, statistical tabulation, seminar, conference, or other setting.

We will submit the results of our study for academic publication in peer-reviewed journals and present in seminars and conferences as necessary. We will have summary statistics and analyses completed using the data, but no identification of patients will be possible. If there are small cells in the analysis (<10 patients), we will censor these cells to maintain confidentiality.

2. Will the results of your analysis be publicly available to any interested party? Please describe how an interested party will obtain your analysis and, if applicable, the amount of the fee.

The results will be available for no fee at the researchers' websites or upon email request.

3. Will you use the data for consulting purposes?

- Yes
- XX No**

4. Will you be selling standard report products using the data?

- Yes
- XX No**

5. Will you be selling a software product using the data?

- Yes
- XX No**

6. If you have answered "yes" to questions 3, 4 or 5, please describe the types of products, services or studies.

XII. USE OF AGENTS AND/OR CONTRACTORS

Third-Party Vendors. Provide the following information for all agents and contractors who will work with the CHIA Data.

Company Name:	
Contact Person:	
Title:	
Address:	

Telephone Number:	
E-mail Address:	
Organization Website:	

7. Will the agent/contractor have access to the data at a location other than your location or in an off-site server and/or database?

- Yes
 No

8. Describe the tasks and products assigned to this agent or contractor for this project.

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9. Describe the qualifications of this agent or contractor to perform such tasks or deliver such products.

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10. Describe your oversight and monitoring of the activity and actions of this agent or subcontractor.

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Information provided from this page forward will NOT be posted publicly on the internet.

XIII. APPLICANT CONTACT INFORMATION

Applicant Name:	Keith Marzilli Ericson (primary applicant)
Title:	Assistant Professor of Markets, Public Policy, & Law and Faculty Research Fellow
Organization:	Boston University School of Management and National Bureau of Economic Research
Address:	595 Commonwealth Ave, Boston, MA 02215
Telephone Number:	617-575-9074
E-mail Address:	kericson@bu.edu
E-mail Addresses of ALL Co-	rebitzer@bu.edu ; frandsen@byu.edu ; blubin@bu.edu ; geissler@bu.edu ; astarc@wharton.upenn.edu

Investigators: **XIV. DATA SECURITY AND INTEGRITY**

(Information provided in this section is confidential and not a public record.)

Complete this section for each location where the data will be stored or accessed. If you plan to use an agent/contractor that has access to the data at a location other than your location or in an off-site server and/or database, the agent/contractor should complete this section.

1. *Physical Location of the data:* Please provide the delivery address for the data, as well as the full address, including building and floor, of each location where data will be stored.

Boston University School of Management
 595 Commonwealth Ave
 Boston, MA 02215
 Servers are located on the 5th floor of the building, hard copies will be stored in a locked file cabinet in a locked office on the 5th or 6th floor of the BU School of Management.

If the storage location above is managed by a third party then answer the following:

- a) Will the data be stored by the third party on a system in the cloud (reachable via the Internet) [Y/N]? ___
 - b) If you answered yes to (a): Has this Cloud Service Provider passed a FedRAMP 3PAO assessment *for the specific cloud system* which will host the data [Y/N]? ___
 - c) If you answered yes to (b): What is the FedRAMP level the specific cloud system hosting the data is operating at? ___
2. *Person Responsible for securing the data:* Please provide the name and contact information of the individual responsible for securing the data.

Greg DeFronzo, Information Technology Services Director
 Boston University School of Management
 Phone: (617) 353 - 5162
 Email: gdefronz@bu.edu

3. *Data Privacy Training and Awareness:* Has every individual who will access the data received training on the proper handling of protected health information and/or personal data within the last two (2) years [Y/N]? ___
 _Yes If yes, please provide the name of the training event, location where given, and who provided it (name of the instructor or sponsor).

All individuals accessing the data will complete the "HIPAA Security and Privacy Training" training module offered by Boston University IT (an online training course) before they access the data.

All individuals accessing the data will also complete the "Data Security Training for APCD

Data Use” training module developed by Boston University School of Management.

Dates of training: Oct 30th, Kimberly Geissler (Boston University Sponsor)

Dates of training: Oct 31th, Keith Ericson and Benjamin Lubin (Boston University Sponsor)

Any other Investigators listed on the application will be required to complete the training before they are given access the data.

4. *Encryption of copied data:* Will the APCD data or any copy of the data be copied from the encrypted hard drive to another storage medium [Y/N]? Y_ If yes, is the storage medium encrypted[Y/N]? Y_ With what level of encryption (e.g., AES 256 bit)?

Archives of the APCD will be stored on encrypted media. Our external storage is an Apricorn Aegis ADT-3PL128-2000 Padlock DT HW Encrypted Hard Drive, using 256-bit AES encryption via a keyed password on the device. The media is then physically locked in a secure cabinet in a locked office. The archive on the server is stored on an encrypted drive using the Linux dm-crypt protocols which are also based on 256-bit AES encryption.

1. *Software Applications Accessing the Data:* What is the provider (company, etc.), product name, and version of the software application used to access and manipulate the data? If this software application is a *custom* application (i.e., developed in-house or by a third party specifically for your organization) then attach all development documentation relevant to its authorization, authentication, and other security features and capabilities (functional specification(s), security design review, security architecture and workflow diagrams, security test plan(s), security code review(s), etc.).

Stata 12.1 and 13.1
 SAS 9.3
 R 3.1.1
 Python 3.4.1
 MySQL 5.6

2. *Technical Safeguards:* What additional specific technical safeguards (not mentioned in prior answers) will be used to *mitigate* the risk of unauthorized access to each of the following:

- a) The original data media and subsequent copies of the data, including backups of the data.

(BU-100-003) The data media will be immediately uploaded to the secure server upon receipt. It will be protected after it is uploaded to the server by being stored in a locked file cabinet in a locked office at BU School of Management. After completion of the study, the data will be shredded and disposed of as described in Section XVII.

- b) Any work, scratch, or temporary files generated from the data.

(BU100-001A, BU100-001, BU100-002, and BU100-003) Work files will be maintained on the same

dedicated server with access restricted as described in the previous section. Work files will not be downloaded from the server until they are the completely deidentified summarizations that are the output of our analysis.

- c) Any device (appliances, workstations, servers, et al) with Internet connectivity which can also connect internally to any other device containing the data or a copy of the data.

(BU 100-001A) The dedicated server will be established on its own independent subnet protected by a router/firewall. All access to the server will be through a secure and controlled channel using the ssh protocols.

3. *Portable Computing Devices:* How will you prevent *all* portable computing devices (laptops, tablets, notebooks, netbooks, smartphones et al), whether owned or issued by your organization or other parties or persons, from gaining access to, or storing, the data or copies of the data?

(BU100-001 and BU100-002) Data will not be stored on PCs. The only files that will be downloaded related to the data will be deidentified summary files after analysis is complete.

4. *Administrative Safeguards:* If your agency has a Written Information Security Program (WISP) or information security policy(ies) that contains data security provisions, please attach the document(s) and refer to the applicable sections in your response to the questions below.

Please see references to the Boston University WISP in bold in the sections above.

5. List any additional technical information security or privacy safeguards your organization has pertinent to mitigating the risk of unauthorized access to or use of the data.

(BU 00000SP, BU000-001, BU-000-004A, and BU-000-005C) Great care will be taken to prevent unauthorized access to or use of the data. Access will be limited to researchers covered by the confidentiality agreement and essential IT personnel. The physical copies of the data will be immediately uploaded to the server and stored in a locked file cabinet in a locked office. The electronic copies of the data will be stored on a dedicated server with electronic access limited to researchers covered by the confidentiality agreement and essential IT personnel. This will be accomplished using secure passwords meeting restrictions described. Administrator passwords will be complex and will not be the same across servers; they will be changed every 90 days. IT personnel will conduct periodic user account and access validation.

The dedicated server will be a dedicated system on an isolated network segment with current antivirus protection running at all times. It will be located in a locked room with access limited to essential IT personnel. Logs will be stored for the duration of the project showing all access to the CHIA data, these logs will be available for audit by CHIA upon request. In the event that CHIA desires an audit of the data security measures, we will make available Greg DeFronzo (or equivalent personnel) and documentation related to the access, use, and disclosure of CHIA data. In the unlikely event there is a security breach, notification will be made to appropriate CHIA

<p>personnel immediately by phone and in writing within three days of becoming aware of such disclosure.</p>	
<p>(BU 000-001) IT personnel will perform periodic audits of the machine, checking logs and configuration to look for anomalies that might indicate unauthorized access. Any findings will be immediately investigated, and if any breach should be found, immediately reported as per section 3 above.</p>	
<p>(BU-100-003) When the study is completed, hard copies of the data will be destroyed using a crosscut shredder. Electronic copies of the data stored on the secure server will be destroyed. This will be accomplished using data tools that clear the data by performing 1-3 overwrites, ensuring that the data is appropriately and fully destroyed. This destruction will be conducted by someone with authorized access to the CHIA data. We will maintain a log documenting the completion of this destruction.</p>	

6. *Enterprise Information Security* (to be completed by an employee responsible for Information Security in the organization):

a. Name: Jamison Kissh

b. Title: Network Administrator

c. Has every individual who will access the data received training on their user cyber security responsibilities within the last two (2) years [Y/N]? Yes If yes, please provide the name of the training event, location where given, and who provided it (name of the instructor or sponsor):

All individuals accessing the data will complete the "HIPAA Security and Privacy Training" training module offered by Boston University IT (an online training course) before they access the data.

All individuals accessing the data will also complete the "Data Security Training for APCD Data Use" training module developed by Boston University School of Management.

Dates of training: Oct 30th, Kimberly Geissler (Boston University Sponsor)

Dates of training: Oct 31th, Keith Ericson and Benjamin Lubin (Boston University Sponsor)

Any other Investigators listed on the application will be required to complete the training before they are given access the data.

d. Has the IT organization in scope for this application experienced a breach of PHI or PII in the last seven (7) years [Y/N]? N If yes, then what was the resolution?

e. Regarding the system that will host the data is an audit log maintained of all user logons to the system [Y/N]? Y If yes, then how many days of activity are preserved in the log? Planned 1 year (box has only existed since 12/5)

- f. Regarding the system that will host the data: Describe the authentication technical security controls you employ to defend the system against unauthorized logon, e.g. maximum failed login attempts, lockout period, etc.:

Hosted on a non-routable subnet accessible only on BU's campus or via the BU VPN through which all activity is monitored by intrusion detection systems by Boston University Information Systems and Technology's Information Security group. Physical access to the server room is limited to server/network administrators and I controlled by key and centrally monitored security system. User's connections are dropped for 60 seconds after three consecutive login failures.

- g. Are all the user accounts that log on to any machine (server or endpoint) that accesses the data uniquely assigned to individual users (i.e., the user accounts are not shared)? [Y/N] Y
- h. What is the minimum password length and character complexity (uppercase, lowercase, numeric, and special characters) required for new passwords on the user accounts logging on to the system accessing the APCD data? Password requirements are at least 8 characters, 1 upper case character, 1 lower case character, 1 number, 1 special character, and must not contain dictionary words or your username
- i. Do you run an anti-virus or anti-malware product on the server that will host the data [Y/N]? Yes If yes, is the software at a current patch/revision/version level? Yes If no, what is the product name and patch/revision/version number? _____

The APCD data will be stored and used on a Linux-based server which is less susceptible to malicious software than Windows-based systems. We will employ standard best-practices for maintaining the health and security of this server. We will install and run the ClamAV Linux-based anti-virus scanner to ensure no malicious software is running on our server. We will also use of the "chkrootkit" package for detecting malicious software and unauthorized access.

- j. Check all the security features of the room containing the server hosting the APCD data or a copy of it:
- i. Continuous recorded video with server in field view
 - ii. Access log of all individuals entering the room
(Log of security panel arms/disarms is available and tied to individuals)
 - iii. Secure server rack
 - iv. Locked room
- k. When was the last information security risk assessment performed in your enterprise? _____ Who conducted it? May 2014 performed by BU Internal Audit. The last vulnerability scan was run on 9/27.
- l. When was the last IT audit performed in your enterprise? _____ Who conducted it?
May 2014 performed by BU Internal Audit

XV. DATA RETURN OR DESTRUCTION

Applicants are required to attest that the original released CHIA Data and all copies of the CHIA Data used by the Applicant or its employees, contractors or agents will be destroyed upon completion of the project described in this Application. All data destruction must conform to the requirements of M.G.L. c. 93I. Specify the measures you will use to meet these requirements.

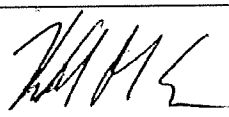
(BU-100-003) When the study is completed, hard copies of the data will be destroyed using a crosscut shredder. Electronic copies of the data stored on the secure server will be destroyed. This will be accomplished using data tools that clear the data by performing 1-3 overwrites, ensuring that the data is appropriately and fully destroyed. This destruction will be conducted by someone with authorized access to the CHIA data. We will maintain a log documenting the completion of this destruction.

XVI. ASSURANCES

Applicants requesting and receiving data from CHIA pursuant to 957 CMR 5.00 (“Data Recipients”) will be provided with data following the execution of a data use agreement that requires the Data Recipient to adhere to processes and procedures aimed at preventing unauthorized access, disclosure or use of data.

Data Recipients are further subject to the requirements and restrictions contained in applicable state and federal laws protecting privacy and data security, including but not limited to the Massachusetts Fair Information Practices Act, M.G.L. c. 66A; M.G.L. c. 93H (data breaches); and M.G.L. c. 93I (data destruction).

Data Recipients must notify CHIA of any unauthorized use or disclosure of CHIA data.

Signature: 	
Printed Name: Keith Marzilli Ericson	
Title: Assistant Professor	
Agency: Boston University	
Date: 9/30/2014	

Boston University Charles River Campus Institutional Review Board

25 Buick Street
Room 157
Boston, Massachusetts 02215
T 617-358-6115
www.bu.edu/irb



Notification of IRB Review: Exemption Request

August 19, 2013 - corrected

Keith Marzilli Ericson
School of Management
595 Commonwealth Avenue
Boston, MA 02215

Protocol Title: Understanding Insurance, Provider Networks, and Outcomes
Protocol #: 3243X
Funding Agency: Robert Wood Johnson Foundation/BU Internal Research Funds
IRB Review Type: Exempt (4)

Dear Professor Ericson:

On July 15, 2013, the IRB determined that the above-referenced protocol meets the criteria for exemption in accordance with CFR 46.101(b)(4). Per the protocol, you will use health insurance claims data from Massachusetts, New Hampshire, and Kansas in the form of a limited data set that has removed direct patient identifiers (but still may contain service dates, geographic information at the level of zip code or coarser, and a masked member id and/or masked social security number).

Additional review of this study is not needed unless changes are made to the current version of the study. Any changes to the current protocol must be reported and reviewed by the IRB. If you have any changes, please submit the *Clarification Form* located at <http://www.bu.edu/irb/>. No changes can be implemented until they have been reviewed by the IRB.

If you have any questions, please contact me at 617-358-6115.

Sincerely,

A handwritten signature in cursive script that reads "Mary McCabe".

Mary McCabe
IRB Analyst
Charles River Campus IRB

Understanding Insurance, Provider Networks, and Outcomes Research Methodology

We examine how consumers value insurance plan designs and provider networks, and how these plan designs and networks affect quality of care and health outcomes. We will examine how changing the design of cost-sharing would affect health care utilization levels, choice of provider, and outcomes, ultimately allowing us to estimate consumer welfare. Specifically, we will consider changes in provider networks, time horizons of insurance contracts, and information used in the calculation of cost-sharing (e.g. what would be the impact of using disease-specific deductibles or of limiting/expanding the range of plan actuarial values available to consumers). Provider networks play an important role in our analysis, since insurance plans are differentiated in part based on what providers are in network. We will examine both the breadth of insurance plan networks (i.e. how many providers are included, and contrasting limited/tiered networks with wider networks) as well as the structure of relationships between providers (i.e. what do referral patterns look like, how many patients do a particular pair of providers have in common).

To answer these questions, we will construct theoretical models that will guide our empirical analyses. The empirical analyses will use details of existing insurance plan structures (e.g., deductibles, copayments) and networks (e.g., HMO, PPO, Medicaid) in the commercial and MassHealth claims data for children and adults.

First, we will examine variation in the financial characteristics of insurance plans. Using observed spending patterns and price data, we will calculate out-of-pocket spending and expected utility under a variety of plan designs. For instance, we will consider the range of plans currently offered in the Massachusetts Connector (bronze, silver, and gold), the range of permissible parameters under the Affordable Care Act, and permutations of value-based insurance design. We will compare these menus to the range of choice typically found in employer-sponsored insurance. We will also examine the impact of plans that are either currently not permitted or simply infrequently seen: for instance, deductibles that depend on the diseases an individual already has, alternative ways of defining cost sharing for care for chronic conditions, and contracts that are shorter in duration than the current standard of one year.

We will simulate utility within a plan under a variety of individual choice models, and model the distribution of spending risk under a variety of assumptions about consumers' private information. We will account for moral hazard in utilization using existing estimates from the academic literature and, potentially, estimates from the APCD data itself. These analyses will allow us to simulate consumer choice of plans from a variety of insurance plan menus, and estimate consumer utility from such menus. Ultimately, these results will allow us to examine the impact of insurance market regulations that affect the types of menus consumers are offered.

Crucial information for analyses of insurance contracts will be the ability to track individual plan specific spending; the ability to construct total household/contract level information; information on the plans themselves (e.g., deductibles, etc.); and spending data by enrollees and insurers. We will use statistical software, including SAS, Stata, and Matlab, for our empirical analyses and simulations. These analyses will use standard forms of regression analysis, hazard models, simulated method of moments, and models of consumer choice (e.g. differentiated product demand models) and welfare (e.g. expected utility models).

We will then turn to variation in provider networks. Provider networks are quite important for consumer welfare, but are harder to measure and quantify than cost-sharing parameters. Our first step will be to model consumer valuation of particular providers, including access to particular hospitals or specialists. Based on our

models of consumer choice developed above, we will derive consumer willingness-to-pay (WTP) for additional network access using spending and premium data (taken from the Massachusetts Connector). To identify WTP, we will use information on geographic distance to providers, as well as patterns of utilization associated with individuals in different plans. In order to model consumer choice, we must determine plan choices available to employees of a particular firm; major changes in plan offerings for an employer will allow us to evaluate the causal relationship between plan type and outcomes. Once we have modeled how consumers value access to particular providers, we can extend these models to examine how consumers value networks of providers. These analyses allow us to examine network breadth.

However, networks differ in more than just breadth: they differ in structure as well. Physician network structures incorporate formal and informal referrals (i.e., shared patients) as well as formal and informal information sharing. We will use network analytic techniques to address three major questions about network structure:

1. What do professional networks of shared patients among physicians look like, and how do such networks vary by type of insurance plan (e.g. HMO vs. PPO vs. Medicaid)?
2. What is the relationship between physicians' networks of shared patients with process measures and patient outcomes (e.g., resource use, quality of care, etc.)?
3. Do consumers with greater medical utilization gravitate towards certain kinds of plans or providers?

We will start by analyzing the number of patients shared by each pair of physicians (e.g. if doctors Smith and Jones both saw patients Tom and Mary, that implies that Smith and Jones have 2 shared patients) and use this relationship to construct a network graph of physicians linked by the patients they have in common. We will also construct a measure of care continuity by measuring how concentrated a patient's care is across primary care providers. Using multiple regression methods, we then examine how care discontinuity affects quality and costs, and whether any negative effects are ameliorated by the frequency with which physicians share patients.

We will apply network analysis including calculating the clustering coefficients and betweenness as well as conducting spectral analysis to determine differences in characteristics of networks across insurance carriers and plans. We will also examine whether differences in the network structures related to insurance plans are related to patient outcomes. We are interested in a variety of patient outcomes, including spending, hospitalizations, emergency department use, intensity of healthcare use, health/process outcomes, and quality of care. We will conduct analyses for the full insurance carrier/plan networks as well as for particular subgroups of patient types and diagnoses (e.g., patients with diabetes, obstetrics). The third question will link analyses on network structure with those related to insurance contract design, giving information on both components.

Crucial information for the analysis of physician networks is the ability to identify physicians across plans/carriers and observe them over time; linking individual demographics and spending data; information on spending and resource use; information on provider specialty, location, and practice group; information on provider affiliation with hospitals; and information on hospitals and practice groups that would allow linkages to publicly available quality data (e.g., MHQP indicators for primary care providers, GIC tiering data for specialists, and Hospital Compare for hospitals) and information about hospitals (e.g., teaching status, safety net status from American Hospital Association data).

The results of our analyses will inform market regulators, providers, MassHealth, and commercial insurance plans/carriers by providing information related to policies affecting network coverage, plan generosity, physician referrals, and continuity of care.

**EXHIBIT A
DATA APPLICATION(S)**

Exhibit A-2 - Carey

**Commonwealth of Massachusetts
Center for Health Information & Analysis (CHIA)
Non-Government APCD Request for Data**

This form is to be used by all applicants, except Government Agencies, as defined in 957 CMR 5.02.

Please note: CHIA is undertaking a number of key measures to help ensure that the processing of MA APCD applications is done as efficiently as possible. As such, we will only be accepting applications from Massachusetts based payers and providers who submit Case Mix and APCD data as well as Massachusetts-based students and researchers. Applications from others will not be accepted from May 13, 2015 to November 1, 2015. All applications received prior to May 13, 2015 will be processed.

In order for your application to be processed, you must submit the required application fee. Please consult the fee schedules for APCD data for the appropriate fee amount. A remittance form with instructions for submitting the application fee is available on the CHIA website.

I. GENERAL INFORMATION

APPLICANT INFORMATION	
Applicant Name:	Kathleen Carey
Title:	Professor
Organization:	Boston University School of Public Health
Project Title:	Does Physician Leadership Play a Role in Increasing ACO Efficiency?—Evidence from the Alternative Quality Contract
Mailing Address:	715 Albany Street, Boston, MA 02118
Telephone Number:	(781) 687-2140
Email Address:	kcarey@bu.edu
Names of Co-Investigators:	Meng-Yun Lin, James Burgess, Austin Frakt
Email Addresses of Co-Investigators:	mylin@bu.edu, jfburges@bu.edu, frakt@bu.edu
Original Data Request Submission Date:	10-22-2015
Dates Data Request Revised:	04-25-2016
Project Objectives (240 character limit)	We seek to understand the impacts of physician leadership on performance of Accountable Care Organizations (ACOs) in cost containment and quality improvement by studying provider entities signing the Alternative Quality Contract (AQC) with Blue Cross Blue Shield of MA (BCBS).
Project Research Questions (if applicable)	<p>We will investigate whether physician-led ACOs are more efficient in controlling costs and improving quality of care under incentive global payment—a bundled payment with sizable quality bonuses. Specifically, we will study 16 provider organizations that are governed by either physicians or affiliated hospitals and paid by BCBS under AQC (hereafter AQC groups).</p> <p>The specific aims of our research project are as follows: Aim 1: Evaluate differences in efficiency improvement between physician-led and hospital-led AQC groups.</p>

	<p>Aim 2: Identify major areas of efficiency improvement achieved by physician-led and hospital-led AQC groups.</p>
--	--

II. PROJECT SUMMARY

Briefly describe the purpose of your project and how you will use the requested CHIA data to accomplish your purpose.

The creation and operation of an ACO requires involvement of various providers. The major providers that sponsor and manage ACOs are hospitals and physician groups. Though previous studies have documented the strong role of physicians in funding and leading ACOs and expressed opinions about how crucial physician leadership is to ACO performance, it is not yet clear the extent to which physician leadership may influence the success of ACOs in reality. To answer this question, there is a need to evaluate variations in quality improvement and cost containment among ACOs under leadership of different providers. We seek to do so through studies of 16 AQC groups using data from the Massachusetts All-Payer Claims Database (APCD) for the following two research aims.

Aim 1: Evaluate differences in efficiency improvement between physician-led and hospital-led AQC groups.

AQC was only implemented among health maintenance organization (HMO) and point-of-service (POS) enrollees because these plans require enrollees to designate PCPs who can therefore be held accountable for the health of their patients. APCD data makes it possible to identify patient population whose health outcomes and costs are attributable to providers of AQC groups. We will use APCD provider, member eligibility, and product files to identify our study sample--BCBS members who enrolled in a HMO or POS plan and designate a PCP who is affiliated with an AQC group. Specially, to examine efficiency, we will measure length of stay of inpatient admission, costs per covered member, and racial/ethnic disparities in health outcomes using APCD medical and pharmacy claim data.

Aim 2: Identify major areas of efficiency improvement achieved by physician-led and hospital-led AQC groups.

To better understand the mechanism of efficiency improvement, the study will decompose efficiency into cost and quality components. We hypothesize that hospital-led AQC groups achieve greater cost containment in the inpatient dimension; while physician-led AQC groups achieve greater quality improvement in outpatient dimension. We will use APCD data to construct measure of inpatient spending and admission rates for ambulatory care sensitive conditions of AQC groups run by different leadership. Also, APCD data will allow us to conduct risk adjustment that relies on diagnoses in claims record to produce individual risk scores.

As ACOs are still a work in process, findings of this study can influence how payers, providers, and policymakers experiment with future iterations of health care delivery reform.

III. FILES REQUESTED

Please indicate the databases from which you seek data, and the year(s) of data requested.

<p>ALL PAYER CLAIMS DATABASE</p>	<p>Year(s) Of Data Requested Current Yrs. Available 2009 – 2013</p>
---	--

<input checked="" type="checkbox"/> Medical Claims	<input checked="" type="checkbox"/> 2009 <input checked="" type="checkbox"/> 2010 <input checked="" type="checkbox"/> 2011 <input checked="" type="checkbox"/> 2012 <input checked="" type="checkbox"/> 2013
<input checked="" type="checkbox"/> Pharmacy Claims	<input checked="" type="checkbox"/> 2009 <input checked="" type="checkbox"/> 2010 <input checked="" type="checkbox"/> 2011 <input checked="" type="checkbox"/> 2012 <input checked="" type="checkbox"/> 2013
<input type="checkbox"/> Dental Claims	<input type="checkbox"/> 2009 <input type="checkbox"/> 2010 <input type="checkbox"/> 2011 <input type="checkbox"/> 2012 <input type="checkbox"/> 2013
<input checked="" type="checkbox"/> Member Eligibility	<input checked="" type="checkbox"/> 2009 <input checked="" type="checkbox"/> 2010 <input checked="" type="checkbox"/> 2011 <input checked="" type="checkbox"/> 2012 <input checked="" type="checkbox"/> 2013
<input checked="" type="checkbox"/> Provider	<input checked="" type="checkbox"/> 2009 <input checked="" type="checkbox"/> 2010 <input checked="" type="checkbox"/> 2011 <input checked="" type="checkbox"/> 2012 <input checked="" type="checkbox"/> 2013
<input checked="" type="checkbox"/> Product	<input checked="" type="checkbox"/> 2009 <input checked="" type="checkbox"/> 2010 <input checked="" type="checkbox"/> 2011 <input checked="" type="checkbox"/> 2012 <input checked="" type="checkbox"/> 2013

IV. REQUESTED DATA ELEMENTS [APCD Only]

State and federal privacy laws limit the use of individually identifiable data to the minimum amount of data needed to accomplish a specific project objective. Please use the APCD Data Specification Workbook to identify which data elements you would like to request and attach this document to your application.

V. FEE INFORMATION

Please consult the fee schedules for APCD data) and Case Mix data, available at http://chiamass.gov/regulations/#957_5, and select from the following options:

APCD Applicants Only

- Academic Researcher
- Others (Single Use)
- Others (Multiple Use)

Are you requesting a fee waiver?

- Yes
- No

If yes, please submit a letter stating the basis for your request. Please refer to the fee schedule for qualifications for receiving a fee waiver. If you are requesting a waiver based on the financial hardship provision, please provide documentation of your financial situation. Please note that non-profit status alone isn't sufficient to qualify for a fee waiver.

VI. MEDICAID DATA [APCD Only]

Please indicate here whether you are seeking Medicaid Data:

- Yes
- No

Federal law (42 USC 1396a(a)7) restricts the use of individually identifiable data of Medicaid recipients to uses that are directly connected with the administration of the Medicaid program. If you are requesting Medicaid data from Level 2 or above, please describe in detail why your use of the data meets this requirement. Applications requesting Medicaid 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 Medicaid program. MassHealth may impose additional requirements on applicants for Medicaid data as necessary to ensure compliance with federal laws and regulations regarding Medicaid.

NA

VII. FILTERS

If you are requesting APCD elements from Level 2 or above, describe any filters you are requesting to use in order to limit your request to the minimum set of records necessary to complete your project. (For example, you may only need individuals whose age is less than 21, claims for hospital services only, or only claims from small group projects.)

APCD FILE	DATA ELEMENT(S) FOR WHICH FILTERS ARE REQUESTED	RANGE OF VALUES REQUESTED
Medical Claims	MC001	BCBS of MA
Medical Claims	Derived-MC16	Ages 18-64
Pharmacy Claims	PC001	BCBS of MA
Pharmacy Claims	Derived-PC14	Ages 18-64
Membership Eligibility	ME001	BCBS of MA
Membership Eligibility	Derived-ME14	Ages 18-64
Provider	PV001	BCBS of MA
Product	HD002	BCBS of MA

IX. PURPOSE AND INTENDED USE

1. Please explain why completing your project is in the public interest.

This project investigates whether physician leadership helps promote efficacy of ACOs. Specifically, we seek to examine whether physicians are superior in achieving cost containment and quality improvement by investigating the 16 provider entities signing the AQC with BCBS of MA. As the ACO movement is a leader of the volume-to-value transition, impacts of physician leadership in achieving efficiency improvement will need to be demonstrated. The results of our analyses will inform policymakers as they evaluate policies regulating the formation and operation of ACOs, which is crucial to the success of delivery reform in the post-Affordable Care Act era. Also, our results will provide insights about performance of ACOs run by hospitals and physicians, which will be of use to CMS to further tailor its ACO programs.

2. Attach a brief (1-2 pages) description of your research methodology. (This description will not be posted on the internet.)
3. Has your project received approval from your organization's Institutional Review Board (IRB)? Please note that CHIA will not review your application until IRB documentation has been received (if applicable).
 - Yes, and a copy of the approval letter is attached to this application.
 - No, the IRB will review the project on _____.

- No, this project is not subject to IRB review.
- No, my organization does not have an IRB.

X. APPLICANT QUALIFICATIONS

1. Describe your qualifications to perform the research described or accomplish the intended use of CHIA data.

Meng-Yun Lin is a PhD candidate in Health Services Research at Boston University School of Public Health. She is experienced in working with sizable and complex health data (Health Care and Utilization Project Database, Marketscan, and State Hospital Discharge Datasets). She has been working as a Research Data Analyst at Boston Medical Center for four years.

Kathleen Carey holds a PhD in Economics from Boston University. She is a professor at Boston University School of Public Health. She has published extensively on hospitals and on the effects of organizational structure on provider performance. She has authored a number of studies that investigate the effects of organizational change in the hospital industry on competition and cost efficiency.

James Burgess holds a PhD in Economics from Brown University. He is a professor at Boston University School of Public Health and a health economist with more than 25 years of extensive health care management, research, and educational experience. He has served as editors of many academic journals in the fields of health economics and health services research.

Austin Frakt holds a PhD in Statistical and Applied Mathematics from Massachusetts Institute of Technology. He is an associate professor and health economist affiliated with the Boston University School of Medicine and School of Public Health. He also serves on the editorial board for *Health Services Research* and the Translation and Dissemination Institute Advisory Committee for AcademyHealth.

All investigators have worked with sensitive health data previously.

2. Attach résumés or curricula vitae of the applicant/principal investigator, key contributors, and of all individuals who will have access to the data. (These attachments will not be posted on the internet.)

XI. DATA LINKAGE AND FURTHER DATA ABSTRACTION

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

1. Do you intend to link or merge CHIA Data to other datasets?
 - Yes
 - No linkage or merger with any other database will occur
2. If yes, will the CHIA Data be linked or merged to other individual patient level data (e.g. disease registries, death data), individual provider level data (e.g., American Medical Association Physician Masterfile), facility level (e.g., American Hospital Association data) or with aggregate data (e.g., Census data)? [check all that apply]

Individual Patient Level Data

What is the purpose of the linkage:

NA

What databases are involved, who owns the data and which specific data elements will be used for linkage:

NA

Individual Provider Level Data

What is the purpose of the linkage:

NA

What databases are involved, who owns the data and which specific data elements will be used for linkage:

NA

Individual Facility Level Data

What is the purpose of the linkage:

Quality and costs of inpatient care vary by hospital characteristics, such as ownership type, hospital size, teaching affiliation, and community hospital designation. Therefore, to properly evaluate the differences in efficiency between AQC groups led by hospitals and physician groups, it is necessary for us to control for factors that are relevant to patient outcomes.

What databases are involved, who owns the data and which specific data elements will be used for linkage:

We will link hospitals to the *Medicare Hospital Compare* (MHC) dataset which is a public-use file by hospital name and/or location to get information on quality and outcomes for individual hospitals. We will identify hospital discharges from the medical claims file (MC094=002) and link them with facility name and location from the provider file based on provider ID (MC026 or MC024 if MC026 is missing). Then we will link the Medicare Hospital Compare dataset based on hospital name and location.

Aggregate Data

What is the purpose of the linkage:

Variation in health outcomes and costs may be attributable to difference in patient socioeconomic status, which could affect use of care, and area health resources, which could impact referral pattern and utilization of procedures requiring specialists. To properly evaluate the differences in efficiency between AQC groups led by hospitals and physician groups, it is crucial to control for these factors.

What databases are involved, who owns the data and which specific data elements will be used for linkage:

We will link member geographic data (zip code or county, ME017/ME110 and ME3/ME4) from the member eligibility file to the corresponding geographic indicator in the *Area Health Recourses File (AHRF)*, *American Communities Survey (ACS)*, and *Census data* (all are public available data) to get information on health care supply, socioeconomic status, and regional characteristics.

3. If yes, for each proposed linkage above, please describe your method or selected algorithm (e.g., deterministic or probabilistic) for linking each dataset. If you intend to develop a unique algorithm, please describe how it will link each dataset.

We will first identify provider groups of interest along with their affiliated primary care physicians in the APCD provider file based on PV002, PV012, and PV056. The set of selected providers is linked by provider ID (PV002=ME046) with member eligibility data which is further linked to the product file by product ID (ME040=PR001) to get details on health plan. Then, the study will define study population based on plan information and retrieve corresponding medical and pharmacy claims by carrier ID and member ID (ME001=MC001 & ME107=MC137 & ME117=MC141; ME001=PC001 & ME107=PC107 & ME117=PC108). Information on providers who rendered claimed services will be obtained by linking claim data with the provider file by provider ID (MC079=PR001; PC056=PR001). Last, Census data and elements from the AHRF/ ACS will be merged by zip-code and FIPS county-code respectively. Hospital characteristics from the MHC database will be incorporated by hospital name and location.

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

Linking APCD data to the supplementary data above only provide additional information about providers and environment in which a member lives and receives care. It does not increase the likelihood that individuals can be identified. Therefore, the linking of these datasets presents no additional risk of jeopardizing patient confidentiality. However, the confidentiality of individuals in the data is of great importance to us, and we will do all in our power to ensure that individuals not be identified.

5. If yes, and the data mentioned above is not in the public domain, please attach a letter of agreement or other appropriate documentation on restrictions of use from the data owner corroborating that they agree to have you initiate linkage of their data with CHIA data and include the data owner's website.

XII. PUBLICATION / DISSEMINATION / RE-RELEASE

1. Describe your plans to publish or otherwise disclose CHIA Data, or any data derived or extracted from such data, in any paper, report, website, statistical tabulation, seminar, conference, or other setting.

We plan to submit research results for publication in peer-reviewed, academic journals and present findings at research conferences. Our results will consist of averages for large groups of members, so no identification of individual members or providers will be possible. To ensure confidentiality, we will not report results of small sample size (<10 members).

2. Will the results of your analysis be publicly available to any interested party? Please describe how an interested party will obtain your analysis and, if applicable, the amount of the fee.

Our research may result in one or more publications which are generally searchable online and may involve an access fee to the publishers. However, we will make our published findings available for free to any interested party via email.

3. Will you use the data for consulting purposes?

Yes
 No

4. Will you be selling standard report products using the data?

Yes
 No

5. Will you be selling a software product using the data?

Yes
 No

6. Will you be reselling the data?

Yes
 No

If yes, in what format will you be reselling the data (e.g., as a standalone product, incorporated with a software product, with a subscription, etc.)?

NA

7. If you have answered "yes" to questions 3, 4 or 5, please describe the types of products, services or studies.

NA

XIII. USE OF AGENTS AND/OR CONTRACTORS

Third-Party Vendors. Provide the following information for all agents and contractors who will work with the CHIA Data.

Company Name:	NA
Contact Person:	
Title:	
Address:	
Telephone Number:	
E-mail Address:	
Organization Website:	

8. Will the agent/contractor have access to the data at a location other than your location, your off-site server and/or your database?

- Yes
- No

If yes, please provide information about the agent/contractor's data management practices, policies and procedures in your Data Management Plan.

9. Describe the tasks and products assigned to this agent or contractor for this project.

NA

10. Describe the qualifications of this agent or contractor to perform such tasks or deliver such products.

NA

11. Describe your oversight and monitoring of the activity and actions of this agent or subcontractor.

NA

XIV. ASSURANCES

Applicants requesting and receiving data from CHIA pursuant to 957 CMR 5.00 (“Data Recipients”) will be provided with data following the execution of a data use agreement that requires the Data Recipient to adhere to processes and procedures aimed at preventing unauthorized access, disclosure or use of data, as detailed in the DUA and the applicant’s CHIA-approved Data Management Plan.

Data Recipients are further subject to the requirements and restrictions contained in applicable state and federal laws protecting privacy and data security, and will be required to adopt and implement policies and procedures designed to protect CHIA data in a manner consistent with the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

By my signature below, I attest to: (1) the accuracy of the information provided herein; (2) my organization’s ability to meet CHIA’s minimum data security requirements; and (3) my authority to bind the organization seeking CHIA data for the purposes described herein.

Signature:	<i>Dolores Markey</i>
Printed Name:	Dolores Markey
Title	Associate Director
Original Data Request Submission Date:	10-22-2015
Dates Data Request Revised:	04-25-2016



Boston University
Medical Center

BOSTON
MEDICAL

Office of the Institutional
Review Board
560 Harrison Ave, Suite 300
Boston, Massachusetts
02118-2526
Tel: 617-638-7207
Fax: 617-638-7234

Title of Study: Does Physician Leadership Play a Role in Increasing Efficiency of Accountable Care Organization? Evidence from the Alternative Quality Contract
IRB Number: H-34063

RE: New Protocol

Determination: Not Human Subjects Research

Date of Action: May 11, 2015

Funding Source: Unfunded Student Research

INSPIR Application Version #: 1.1

Dear Meng-Yun Lin, MPH,

A qualified member of the BUMC Institutional Review Board (IRB) staff has reviewed the above referenced protocol and has determined that it does not require further review by the BUMC IRB because it does not meet the definition of "human subject research".

The BUMC IRB has made this determination based on the regulatory definitions of Human Subject and Research per the following:

1. According to HHS, Human Subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information (45 CFR 46.102(f)).
2. According to FDA, a Human Subject means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control (21 CFR 50.3(g)).
3. Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 45.102(d)).

Protocol Specific Determinations

This study is not subject to the HIPAA Privacy Rule.

Requirements

This approval corresponds with the version of the protocol indicated above.

All determinations regarding this project have been made based on the information

submitted by the investigator. Any modifications to the research plan (including any changes in funding) must be submitted to the IRB for review and approval prior to initiation, and may change the IRB's determination.

You may retain this letter in your files as documentation of this decision by the BUMC IRB. No progress reports are required for this project as long as no changes are made to the protocol.

It is the responsibility of the PI to ensure that any relevant HIPAA requirements have been met. It is also the responsibility of the PI to ensure that all required institutional approvals have been obtained prior to initiating any protocol related activities.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Matthew Ogrodnik", with a stylized flourish at the end.

Signature applied by Matthew Ogrodnik on 05/11/2015 01:33:04 PM EDT

Senior IRB Analyst

Research Methodology

Project Title

Does Physician Leadership Play a Role in Increasing ACO Efficiency?—Evidence from the Alternative Quality Contract

Methods

Study Design

This study adopts a retrospective observational design using claim data from the MA APCD to evaluate variations in efficiency and performance between hospital-led and physician-led Accountable Care Organizations (ACOs). In addition to descriptive analyses, the study will specify multivariate hierarchical regression models to adjust for patient characteristics (case-mix), provider and facility characteristics, and other covariates including regional levels of health resources and quality of care, a factor potentially confounded with efficiency. The study will conduct main analyses using all-cause hospital admission and subgroup analyses focusing on specific clinical conditions. One condition of interest is cardiovascular (CV) diseases as previous studies have documented that CV conditions consume considerable amount of medical resources.

Settings

The setting is the 16 provider entities that participated in the Alternative Quality Contract (AQC) at various time (hereafter AQC groups). Eight entities including Atrius Health et al are the first provider cohort that entered the AQC in January 2009. Several organizations signed the contract in later years. These provider entities will be grouped into two categories: physician-led versus hospital-led entities based on the sector that dominates the particular organization. *Physician-led entities* are defined as (1) provider entities where physicians are affiliated and contract with hospitals, or (2) entities that are composed of solely physician practice groups. *Hospital-led entities* are hybrid organizations that consist of hospitals and hospital-employed physicians.

Study Population

The study population will include adult (aged 18-64) BCBS beneficiaries whose designated primary care physicians (PCPs) are members of an AQC group. First, enrollees of BCBS HMO or POS plans during January 2009 and December 2013 from the APCD will be identified. Among those, members who were not continuously enrolled for at least one calendar year and those who had Medicare coverage will be excluded. Enrollees whose designated PCPs are not affiliated with an AQC group will be excluded as well. The remaining members will comprise the sample for the main analyses. Subgroup analyses that focus on CV conditions will target all acute care hospitalizations for heart attack (AMI: MS-DRGs 280-285), heart failure (HF: MS-DRGs 290-293), and pneumonia (PN: MS-DRGs 193-195) among study sample. Risk scores will be computed based on current-year diagnoses, claims, and demographic information to control for differences among patients that may affect their health care outcomes.

Analytic Plan

Aim 1: Evaluate difference in efficiency improvement between physician-led and hospital-led AQC groups.

H1: physician-led provider entities achieve greater technical efficiency measured by shorter length of stay (LOS) of index admission compared to hospital-led entities.

Research Methodology

Data structure is cohorts of index admission for any cause and three CV conditions (AMI, CF, and PN). The outcome of interest is LOS during index admissions. I will fit a linear model based on the following equation at the level of discharge i :

$$LOS_i = \beta_0 + \beta_1 MDLED + \beta_3 R30 + \sum \beta_{ki} X_{ki} + \sum \gamma PCP + \sum \delta_j HOPS_j + \sum \lambda Z + YEAR_t + \epsilon_{ijt}$$

where MDLED indicates physician leadership (binary; 1=physician-led entities), X is a set of patient-level demographic and clinical characteristics, PCP and HOPS are a set of provider and hospital characteristics respectively, and Z is a set of environmental factors. R30 indicating the incidence of 30-day readmission is used to adjust for quality of care during the index hospitalization. YEAR is a set of dummies controlling for year fixed effects.

H2: physician-led provider entities achieve greater productive efficiency measured by lower costs per covered member compared to hospital-led entities.

Outcome of interest is annual medical spending (in dollars) per member. I will specify a linear model based on the following equation at the level of member i :

$$SPEND_i = \beta_0 + \beta_1 MDLED + \sum \beta_{ki} X_{ki} + \sum \gamma PCP + \sum \lambda Z + YEAR_t + \epsilon_{it}$$

H3: physician-led provider entities achieve greater social efficiency measured by less racial/ethnic disparities in health outcomes compared to hospital-led entities.

Outcome of interest is the incidence of amputation among subjects with critical limb ischemia. I will perform a logistic regression based on the following equation at the level of discharge i :

$$\Pr(AMPU_i=1) = \beta_0 + \beta_1 MDLED + \beta_3 RACE_i + \beta_{4i} MDLED * RACE_i + \sum \beta_{ki} X_{ki} + \sum \gamma PCP + \sum \delta_j HOPS_j + \sum \lambda Z + YEAR_t + \epsilon_{ijt}$$

where RACE references two dummy variables indicating non-Hispanic black and Hispanic.

Aim 2: Identify major area of efficiency improvement achieved by physician-led and hospital-led ACQ groups.

H1: hospital-led provider entities achieve greater cost containment in inpatient dimension measured by larger decreases in inpatient spending.

Outcome of interest is annual inpatient care spending (in dollars) per member. I will specify a linear model based on the following equation at the level of member i :

$$COST_i = \beta_0 + \beta_1 MDLED + \beta_t TIME_t + \sum \beta_{ki} X_{ki} + \sum \gamma PCP + \sum \lambda Z + \alpha_t MDLED * TIME_t + \epsilon_{it}$$

where TIME is a set of dummies indicating the 2nd, 3rd... year of individual entity participating in the ACQ.

H2: physician-led provider entities achieve greater quality improvement in outpatient dimension measured by lower rates of ACS admissions.

Outcome of interest is the incidence of ACS admissions in a given year. I will perform a linear probability model based on the following equation at the level of member i :

$$\Pr(ACSx_i=1) = \beta_0 + \beta_1 MDLED + \sum \beta_{ki} X_{ki} + \sum \gamma PCP + \sum \lambda Z + YEAR_t + \epsilon_{it}$$

**Commonwealth of Massachusetts
Center for Health Information & Analysis (CHIA)
Data Management Plan for Non-Governmental Data Use**

This Data Management Plan is to be completed by non-governmental applicants for APCD and Case Mix Data, except for applicants seeking de-identified data, as that term is defined in 957 CMR 5. This form should be completed by the applicant's Chief Information Security Officer, Chief Privacy Officer, legal counsel, or an officer with sufficient knowledge of the Applicant's data privacy and security practices and authority to bind the organization.

GENERAL INFORMATION

APPLICANT INFORMATION	
Applicant (principal investigator/project lead)	Meng-Yun Lin
Title:	PhD Candidate
Organization:	Boston University School of Public Health
Project Title:	Does physician leadership play a role in increasing efficiency of accountable care organizations under incentive global payment?—Evidence from the Alternatice Quality Contract
Mailing Address:	715 Albany St, Boston, MA 02118
Telephone Number:	617-414-6796
Email Address:	mylin@bu.edu
CISO/CPO/Counsel/Officer responsible for Data Privacy and/or Security	Eric Jacobsen
Email Address of Officer responsible for Data Privacy and/or Security	Jacobsen@bu.edu
Data Request Submission Date:	October 07, 2015
Data Management Plan Submission Date (if different from Data Request date):	October 07, 2015
DMP Revision Dates:	May 18, 2016

Data Management Plan

A full Data Management Plan should be completed by any collaborating organization that will receive a copy of the CHIA files sought in the Data Request.

If your organization has an approved Data Management Plan on file with CHIA, you may submit that form and annotate it to reflect any proposed changes to the approved practices. Applicants should also note if they are providing to CHIA a Data Management Plan previously approved by CMS.

CHIA's Minimum Security Requirements

Non-governmental applicants must meet the following minimum security requirements before receiving any CHIA data that includes Protected Health Information (Case Mix Level 2 and above and MA APCD data):

- Encryption of any media containing CHIA data;

- Anti-virus software on any server containing CHIA data; and
- Physical access controls, e.g., confidential data must be stored behind locked doors with access to the data limited to the fewest number of people required to achieve the purpose for which such access was granted.

Or

- An attestation by your organization's chief legal officer, or another attorney or officer authorized to bind your organization, that your organization complies with HIPAA privacy and security requirements or, if not a HIPAA-covered entity, has privacy and security practices and policies in place such that the organization is substantially compliant with HIPAA privacy and security rules;

Or

- Documentation sufficient to show that your organization's information security and privacy program has been subject to an independent third-party audit in the last two years and the outside auditor determined that your organization is HIPAA-compliant.

Response:

Workstations storing CHIA data will be encrypted using methods native to the operating system (e.g. Bitlocker or FileVault). Workstations are kept in a locked room. Media storing CHIA data will be protected through the use of an encrypted container (e.g. Bitlocker encrypted VHD or FileVault Encrypted Spare Images). Media will be stored in a locked cabinet when not in use. CHIA data stored on central file server will be stored in an encrypted container (e.g. Bitlocker encrypted VHD or FileVault Encrypted Spare Images). File servers are located in University data centers, protected by locked doors, video cameras and limited access policies.

The workstation(s) storing CHIA data have University provided anti-virus (currently McAfee) installed per University policy. On the central file server the data is encrypted and cannot be examined by a virus scanner, but also cannot be infected. Details of the University policy are available at <http://www.bu.edu/policies/information-security-home/minimum-security-standards/> and <http://www.bu.edu/tech/services/support/desktop/software/removal/security/mcafee/>.

The research team will comply with the policies and guidelines set forth by Boston University.

1. PHYSICAL POSSESSION AND STORAGE OF CHIA DATA FILES

- 1.1. Who will have the main responsibility for organizing, storing, and archiving the data? Please provide name(s) and job title(s).

Response:

The applicant, Meng-Yun Lin, PhD candidate, will have the main responsibility for organizing, storing, and archiving the data.

- 1.2. Describe how your organization maintains a current inventory of CHIA data files, if any.

Response:

BU School of Public Health does not keep a current inventory of CHIA data files. The tracking of CHIA dataset recipients will be managed through IS&T Information Security. This data worksheet (which includes the investigators and their responses to the data management plan), along with relevant dates (approval, renewal) shall be tracked through a central SharePoint site. The research team will follow the policies and guidelines set forth by Boston University to inventory CHIA data files received.

- 1.3. Describe how your organization binds all members (i.e., organizations, individual staff) of research or project teams to specific privacy and security rules in using CHIA data files. This includes, for example, confidentiality agreements and non-disclosure agreements.

Response:

Binding is through this process and the agreement signed with CHIA. Additionally, University faculty, staff, and students are expected to follow University policy on computing code and ethics as well as the Data Protection Standards. Details are available at <http://www.bu.edu/policies/information-security-home/conditions-of-use-policy-on-computing-ethics-2/> and <http://www.bu.edu/policies/information-security-home/data-protection-standards/>. The research team will comply with the policies and guidelines set forth by Boston University.

1.4. Provide details about how, and by whom, your organization will notify CHIA of any project staffing changes.

Response:

This data is being requested for empirical analysis to be conducted by the applicant, Meng-Yun Lin, as part of her dissertation in fulfillment of the Ph.D. degree. Professor Kathleen Carey, Ph.D., Dissertation Committee Chair and Co-Investigator on the project, will notify CHIA of any project staffing changes.

1.5. Describe your organization's training programs that are used to educate staff on how to protect CHIA data files.

Response:

Staff who interact with protected health information are required to complete annual training on handling sensitive information. Staff are also expected to be familiar with the Data Protection Standards. Details are available at <http://www.bu.edu/tech/files/2010/06/BU-000-005-Security-Awareness-Training.pdf> and <http://www.bu.edu/policies/information-security-home/data-protection-standards/>. The research team will comply with the guidelines set forth by Boston University.

1.6. Explain the infrastructure (facilities, hardware, software, other) that will secure the CHIA data files.

Response:

Workstations storing CHIA data will be protected with full disk encryption. CHIA data stored on central file servers will be in an encrypted container. File systems will utilize native security mechanisms (account/group permissions) to restrict access to the file. File servers use DLP software to track access and actions to files and folders. Workstations and file servers storing CHIA data will not have direct access to the Internet. Further details are available at <http://www.bu.edu/policies/information-security-home/data-classification-guide/>, <http://www.bu.edu/policies/information-security-home/data-protection-requirements/>, and <http://www.bu.edu/policies/information-security-home/minimum-security-standards/>. The research team will comply with the guidelines set forth by Boston University.

1.7. Describe the policies and procedures regarding the physical possession and storage of CHIA data files.

Response:

This CHIA data set falls under our Restricted Use classification as it contains identifiable information. Please see the following reference URLs for our policy on handling this type of data: <http://www.bu.edu/policies/information-security-home/data-classification-guide/>, <http://www.bu.edu/policies/information-security-home/data-protection-requirements/>, and <http://www.bu.edu/policies/information-security-home/minimum-security-standards/>. The research team will comply with the guidelines set forth by Boston University.

1.8. Explain your organization's system or process to track the status and roles of the research team.

Response:

This data is being requested for empirical analysis to be conducted by the applicant, Meng-Yun Lin, as part of her dissertation in fulfillment of the Ph.D. degree. Professor Kathleen Carey, Ph.D., Co-Investigator on the project, will be overseeing all related activities. Dr. Carey will be taking responsibility for tracking the status of the project including the roles of all investigators.

1.9. Describe your organization's physical and technical safeguards used to protect CHIA data files (including physical access and logical access to the files).

Response:

Workstations storing CHIA data will be protected with full disk encryption and will reside in a locked room. CHIA data stored on central file servers will be in an encrypted container. File systems will utilize native security mechanisms (account/group permissions) to restrict access to the file. File servers use DLP software to track access and actions to files and folders. Workstations and servers storing CHIA data will not have direct access to the Internet. The applicant will secure any physical media received containing CHIA data in a locked file cabinet behind a locked door accessible only to study investigators.

2. DATA SHARING, ELECTRONIC TRANSMISSION, DISTRIBUTION

2.1. Describe your organization's policies and procedures regarding the sharing, transmission, and distribution of CHIA data files.

Response:

This CHIA data set falls under our Restricted Use classification, as it has identifiable information. Please see the following reference URLs for our policy on handling this type of data:

<http://www.bu.edu/policies/information-security-home/data-classification-guide/>,

<http://www.bu.edu/policies/information-security-home/data-protection-requirements/>, and

<http://www.bu.edu/policies/information-security-home/minimum-security-standards/>.

The applicant has consulted with Boston University Information Security and the research team will adhere to the policies and practices described above.

2.2. If your organization employs a data tracking system, please describe.

Response:

CHIA data stored on the central file server will be tracked/audited through the use of our DLP software. Periodic reports include changes to folder permissions and changes to group memberships assigned to folder.

2.3. Describe the policies and procedures your organization has developed for the physical removal, transport and transmission of CHIA data files.

Response:

This CHIA data set falls under our Restricted Use classification, as it has identifiable information. Please see the following reference URLs for our policy on handling this type of data:

<http://www.bu.edu/policies/information-security-home/data-classification-guide/>,

<http://www.bu.edu/policies/information-security-home/data-protection-requirements/>, and

<http://www.bu.edu/policies/information-security-home/minimum-security-standards/>.

The research team will comply with the guidelines set forth by Boston University.

2.4. Explain how your organization will tailor and restrict data access privileges based on an individual's role on the research team.

Response:

The file system utilizes access control lists based on usernames and group membership to control who can access what data. Access to the CHIA data set will be limited to members of the research team. On central file servers, access will be verified through the use of our DLP software, which will enable us to log who accesses CHIA data. The research team is very small, with full access to the data granted for all members. Members of the larger institution will not have access to this data.

2.5. Explain the use of technical safeguards for data access (which may include password protocols, log-on/log-off protocols, session time out protocols, and encryption for data in motion and data at rest).

Response:

Workstations storing CHIA data will utilize full disk encryption via the native disk encryption tool, Bitlocker. Bitlocker uses the AES-128 cipher. CHIA data stored on central file servers will be in an encrypted container created using Bitlocker. All systems utilize NTFS/share-based permissions for access control and leverages the University Active Directory for authentication. Access to data stored on central file server will be verified through the use of our DLP software, which will enable us to log who accesses CHIA data. Details are available at <http://www.bu.edu/policies/information-security-home/access-management-and-authentication-requirements/>. The workstation locally hosting the data is not backed up. Data stored on the central file servers would be backed up as encrypted file and would still be encrypted when restored from backup. The research team will comply with the guidelines set forth by Boston University.

2.6. Are additional organizations involved in analyzing the data files provided by CHIA?

Response:

No additional organizations will be involved in analyzing the data files provided by CHIA.

If so, please review the Collaborator Checklist (see attached) for guidance and considerations to include in the Data Management Plan, and indicate below how these organizations' analysts will access the data files:

- VPN connection
- Will travel to physical location of data files at requesting organization
- Request that a copy of the data files be housed at second location
- Other:

2.7. If an additional copy of the data will be housed in a separate location, please describe how the data will be transferred to this location. (Also, please ensure you have included information on how the data will be managed at this location under the appropriate subsections of the Data Management Plan.)

Response:

Data will not be stored in other locations.

3. DATA REPORTING AND PUBLICATION

3.1. Who will have the main responsibility for notifying CHIA of any suspected incidents wherein the security and privacy of the CHIA data may have been compromised? Please describe and identify your organization's policies and procedures for responding to potential breaches in the security and privacy of the CHIA data.

Response:

Dr. Kathleen Carey, Ph.D., Committee Chair for the applicant (see 1.8 above) will take responsibility for informing CHIA of any suspected incidents of breaches in data security and privacy. Any unauthorized disclosure or loss of this information must be reported to the BU Incident Response Team (irt@bu.edu or 617-358-1100) and will be conveyed to the Information Security Program Director.

3.2. Explain how your organization's data management plans are reviewed and approved by your organization.

Response:

The Boston University Medical Campus Office of Information Technology reviews and approves the data management plan, working with the data applicant. Data management plans for grants must be submitted through the Institutional Review Board (IRB). Research requiring the processing or storage of sensitive data is coordinated through BUMC IT.

3.3. Explain whether and how your organization's data management plans are subjected to periodic updates during the DJA period.

Response:

For data acquired by Ph.D. students for their dissertations, data management and review is conducted by the dissertation committee chair. Professor Carey will review the plan and update as needed. Significant changes to the architecture or implementation of a service or supporting hardware prompts an information security architecture review. Upon completion of this review, a re-assessment of data management plans shall occur.

3.4. Please attest to the CHIA cell suppression policy of not publishing or presenting tables with cell sizes less than 11 to anyone who is not an authorized user of the data.

Response:

The research team will only report summary statistics. To maintain confidentiality, the research team will reduce the number of strata (say, from quartiles to two strata) in case of small cells (<11 cases). If there are still small cells in the analysis, these cells will be censored.

ML I agree. (Please place your initials on the line.)

4. COMPLETION OF RESEARCH TASKS AND DATA DESTRUCTION

4.1. Describe your organization's process to complete the Certificate of Destruction form and policies and procedures to dispose of data files upon completion of its research.

Response:

When the study has concluded, the applicant will bring physical media received containing original CHIA data to BUMC IT for data destruction. BUMC IT will certify the destruction of active identified data stored on central resources under their control. This will be done by using a tool, such as 'sdelete', to scrub the data as it exists on disk. Data stored in snapshots will expire over time and can not be actively deleted. BUMC IT may assist in the destruction of identified data on other media, workstations or laptops.

4.2. Describe your organization's policies and procedures used to protect CHIA data files when individual staff members of project teams (as well as collaborating organizations) terminate their participation in projects (which may include staff exit interviews and immediate access termination).

Response:

Dr. Kathleen Carey, Ph.D., Committee Chair for the applicant (see 1.8 above) will notify BUMC IT for any changes in project staff, including termination of participation in the research. Data classified as Restricted Use per the BU Data Classification Guide must be protected in a manner consistent with requirements outlined in the Data Protection Guide and Minimum Security Standards. Further details are available at <http://www.bu.edu/policies/information-security-home/data-classification-guide/>, <http://www.bu.edu/policies/information-security-home/data-protection-requirements/>, and <http://www.bu.edu/policies/information-security-home/minimum-security-standards/>.

4.3. Describe policies and procedures your organization uses to inform CHIA of project staffing changes, including when individual staff members' participation in research projects is terminated, voluntarily or involuntarily.

Response:

There are not written policies or procedures, per se. Dr. Kathleen Carey, Ph.D., Committee Chair for the applicant (see 1.8 above) will take responsibility for informing CHIA of any changes in project staff, including voluntary or involuntary termination.

4.4. Describe your organization's policies and procedures to ensure that CHIA data and any derivatives or parts thereof are not used following the completion of the project.

Response:

The research team will not make any physical or electronic copies of the CHIA data files in addition to those stored on the central file server. The applicant will bring the physical media containing original CHIA data to BUMC IT for data destruction following the completion of the project. BUMC IT will certify destruction of CHIA data stored on central resources.

5. ASSURANCES

Applicants requesting and receiving data from CHIA pursuant to 957 CMR 5.00 ("Data Recipients") will be provided with data following the execution of a data use agreement that requires the Data Recipient to adhere to processes and procedures aimed at preventing unauthorized access, disclosure or use of data, including the processes and procedures outlined in this Data Management Plan.

Data Recipients are further subject to the requirements and restrictions contained in applicable state and federal laws protecting privacy and data security, and will be required, as a condition of receipt of CHIA data, to agree to establish and maintain appropriate administrative, technical, and physical safeguards to protect the confidentiality of the data and to prevent unauthorized use or access to it. The safeguards shall provide a level and scope of security that is consistent with 45 CFR § 164.530(c) and not less than the level and scope of security requirements established by the Office of Management and Budget (OMB) in OMB Circular No. A-130, Appendix III--Security of Federal Automated Information Systems (<http://www.whitehouse.gov/omb/circulars/a130/a130.html>) as well as Federal Information Processing Standard 200 entitled "Minimum Security Requirements for Federal Information and Information Systems" (<http://csrc.nist.gov/publications/fips/fips200/FIPS-200-final-march.pdf>); and, Special Publication 800-53 "Recommended Security Controls for Federal Information Systems" (<http://csrc.nist.gov/publications/nistpubs/800-53-Rev2/sp800-53-rev2-final.pdf>).

Data Recipients must notify CHIA, as soon as practicable, of any unauthorized use or disclosure of CHIA data.

The undersigned agrees that the Applicant and any collaborating organizations will adhere to the Data Management Plan described herein and will notify CHIA of any material changes in Data Management pertaining to an approved project that involves the use of CHIA Data.

CISO/CPO/Counsel Signature:	<i>Eric Jacobsen</i>
Title	Director of Information Security
Printed Name:	Eric Jacobsen
Authorized Agent Signature	<i>Eric Jacobsen</i>
Authorized Agent Title	Director of Information Security
Printed Name:	Eric Jacobsen
Original DMP Submission Date:	October 07, 2015
Dates DMP Revised:	May 18, 2016

COLLABORATOR CHECKLIST

Please note –this checklist is for guidance purposes only and for organizations that are involving an additional organization as part of their project. The checklist identifies data safeguard practices and considerations of the collaborating organization that should be indicated in the data requestor’s Data Management Plan. All questions may not apply but are dependent upon the data sharing arrangement between the organizations involved in the research project.

Information should be indicated for each collaborating organization that will have access to CHIA data files.

A. Access to Identifiable and De-identifiable Files

1. What is the name of the collaborating organization?
2. How will the collaborating organization access the CHIA data (secure VPN, a physical copy on site at the collaborating organization, traveling to the DUA holder’s site, etc.)?
3. Who are the project staff from the collaborating organization? Indicate if each project staff member will have access to raw data, analytic files, or output with cell sizes less than 11. (*Please ensure that these individuals and data access rights are listed in the Project Staff list.*)
4. What binding agreements are required of the project staff members from the collaborating organization?
5. What training is required of project staff members from the collaborating organization?
6. How will the collaborating organization notify the DUA holder of changes in staff who are participating on the project team?
7. Will the researchers from the collaborating organization abide by the DUA holder’s project rules or the policies of their employing organization?

B. Access to Protected Health Information

1. Will the collaborating organization have access to PHI?
If yes, please provide the following required details:
 - a. Will the collaborating organization have the ability to download and store a copy of the CHIA data?
 - b. Does the collaborating organization intend to backup the data? If so, has the collaborating organization developed a backup arrangement and are the back-up copies maintained at a second location?
 - c. Who is responsible for maintaining the security and distribution of the CHIA data at the collaborating organization?
 - d. Does the collaborating organization maintain an inventory of the CHIA data?
 - e. How will the collaborating organization tailor and restrict data access?

- f. Please describe the collaborating organization's physical and technical safeguards used to protect CHIA data files (including physical access and logical access to the files).
- g. Please describe the collaborating organization's infrastructure, operating systems, and hardware that will be used to secure the CHIA data.
- h. How will the collaborating organization dispose of electronic copies of the data?

C. *Physical Copies of CHIA Data*

Please note - If the collaborating organization will maintain a separate copy of the CHIA data, the collaborating organization is required to complete a full Data Management Plan.

1. Will a separate copy of the CHIA data be housed at the collaborating organization's location?
2. How will the collaborating organization receive the CHIA data?

**EXHIBIT A
DATA APPLICATION(S)**

Exhibit A-3 - Louis

**Commonwealth of Massachusetts
Center for Health Information & Analysis (CHIA)
Non-Governmental Application for Case Mix Data**

This form is required by all Applicants, except Government Agencies as defined in 957 CMR 5.02. 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 if your organization may receive CHIA data. Please be sure the documents are completed fully and accurately. You may wish to consult the Evaluation Guide that CHIA will use to review your documents. Prior to receiving CHIA Data, the organization must execute the Data Use Agreement. You may wish to review that document as you complete these forms.

NOTE: *In order for your application to be processed, you must submit the required application fee. Please consult the fee schedule for the appropriate fee amount. A remittance form with instructions for submitting the application fee is available on the CHIA website.*

All attachments must be uploaded to IRBNet with your Application. All applications, documents can be found on the CHIA website in Word and/or PDF format.

I. GENERAL INFORMATION

APPLICANT INFORMATION	
Applicant Name:	Christopher J. Louis, PhD
Title:	Clinical Assistant Professor
Organization:	Boston University School of Public Health
Project Title:	Evaluation Services to Support the Community Hospital Acceleration, Revitalization and Transformation (CHART) Investment Program
IRBNet ID:	947617-1
Mailing Address:	715 Albany Street, Talbot 261W, Boston, MA 02118
Telephone Number:	617.414.1353
Email Address:	louis@bu.edu
Names of Co-Investigators:	Sally Bachman, David Rosenbloom, Kathleen Carey, Vicky Parker, Alan Sager, Rani Elwy
Email Addresses of Co-Investigators:	sbachman@bu.edu, drosenbloom@bu.edu, kcarey@bu.edu, vparker@bu.edu, asager@bu.edu, relwy@bu.edu
Original Data Request Submission Date:	9/12/16
Dates Data Request Revised:	
Project Objectives (240 character limit):	The objective of this project is to conduct a mixed-methods evaluation of the performance of Phase 2 of the CHART Investment program of the Health Policy Commission.
Project Research Questions (if applicable) Business Use Case(s):	The current proposal has 9 research questions: <ol style="list-style-type: none"> 1. Were the program activities effectively implemented by the awardee? 2. Were there subgroup-level patterns in program implementation? 3. Was the CHART program as a whole implemented effectively? 4. What outcomes were achieved by the awardee? 5. Were there subgroup-level patterns in outcomes? 6. Did the CHART program as a whole accomplished the desired outcomes? 7. Will the awardee sustain program activities past the CHART Phase 2 period?

	<p>8. Are there subgroup-level patterns in program sustainability?</p> <p>9. Has the CHART program as a whole produced lasting changes that will continue to benefit stakeholders?</p>
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II. PUBLIC INTEREST & PROJECT SUMMARY

1. Briefly explain why completing your project is in the public interest.

Background

Established through the Commonwealth’s landmark cost containment law, Chapter 224 of the Acts of 2012, the Health Policy Commission (HPC) is an independent state agency that monitors reform in the health care delivery and payment systems and develops policies to reduce overall cost growth while improving the quality of patient care. The HPC Community Hospital Acceleration, Revitalization, and Transformation Investment Program (CHART) makes phased investments for certain Massachusetts community hospitals to enhance their delivery of efficient, effective care. The goal of the program is to promote care coordination, integration, and delivery transformations; advance electronic health records adoption and information exchange among providers; increase alternative payment methods and accountable care organizations; and enhance patient safety, access to behavioral health services, and coordination between hospitals and community-based providers and organizations.

Phase 2 of the CHART Investment Program awarded over \$60 million to 27 community hospitals across the Commonwealth over a yearlong implementation planning period and a 2-year program period. Each awardee has, in collaboration with the HPC, set specific aims for maximizing appropriate hospital utilization, such as reducing readmissions, ED revisits, or any-bed returns. Each awardee is pioneering a care-delivery initiative customized for the local patient population. CHART Phase 2 initiatives are specifically intended to promote the transformation of community hospitals by more effectively aligning their services and capabilities to address the physical, behavioral, and social needs of the communities they serve. Thus, a goal of CHART Phase 2 is not only to promote quality care at awardee hospitals, but to transform their role within the community and the healthcare system.

See www.mass.gov/hpc for further information about the CHART investment program.

CHART Phase 2 Evaluation

Under Chapter 224, the HPC is required to conduct an evaluation of Phase 2 of the CHART Investment Program. The planned evaluation is a mixed-methods summative evaluation with performance feedback to hospitals. The goals of this evaluation include investigation of the implementation, impact, and sustainability of the CHART Phase 2 initiatives.

The HPC has engaged a team at the Boston University School of Public Health, led by Dr. Chris Louis, to provide the necessary expertise and resources for an independent, rigorous, and insightful evaluation. In order to document the impact of the CHART phase 2 initiatives, the evaluation will analyze hospital utilization, including inpatient readmissions, ED revisits, and any-bed returns. This quantitative analysis, based on CHIA Case Mix Data, will be used in combination with qualitative findings to generate a public Final Summative Report on the CHART Phase 2 Investment Program.

2. Has an Institutional Review Board (IRB) reviewed your project?

- Yes, a copy of the approval letter and protocol must be attached to this Application
- No, this project is not human subject research and does not require IRB review.

3. If your project has not been reviewed by an IRB, please attach a brief (1-2 page) description of your project including the methodology, objectives, and research questions. **Not applicable.**

III. DATA FILES REQUESTED [Applicants seeking 2015 data only should skip to Question 2]

1. FY 2004–2014 Data: Please indicate the Case Mix files from which you seek data, the Level(s), the year(s) of data requested, and your justification for requesting each file. Please refer to the Case Mix Data Specifications for details of the file contents.

CASE MIX FILES	Levels 1–6	Years Available 2004–2014
Inpatient Discharge	<input checked="" type="checkbox"/> Level 1 – 3 Digit Zip Code <input checked="" type="checkbox"/> Level 2 – Unique Physician Number (UPN) + 5 Digit Zip Code <input checked="" type="checkbox"/> Level 3 – Unique Health Information Number (UHIN) <input checked="" type="checkbox"/> Level 4 – UHIN and UPN <input checked="" type="checkbox"/> Level 5 – Date(s) of Admission; Discharge; Significant Procedures <input type="checkbox"/> Level 6 – Date of Birth; Medical Record Number; Billing Number PLEASE PROVIDE JUSTIFICATION BELOW FOR REQUESTING THE CHOSEN LEVEL: Up through Level 5 data (admission date, discharge date, and significant procedures) is required to meet our project's aims and objectives, and answer our research questions. Specifically, Level 5 data is needed to examine utilization patterns specific to inpatient admissions and readmissions among patients in the target populations for each CHART hospital project.	Year(s) of Data Requested: 2013 Release (10/1/2012-9/30/2013) 2014 Release (10/1/2013-9/30/2014)
Outpatient Observation	<input checked="" type="checkbox"/> Level 1 – 3 Digit Zip Code <input checked="" type="checkbox"/> Level 2 – Unique Physician Number (UPN) <input checked="" type="checkbox"/> Level 3 – Unique Health Information Number (UHIN) <input checked="" type="checkbox"/> Level 4 – UHIN and UPN <input checked="" type="checkbox"/> Level 5 – Date(s) of Admission; Discharge; Significant Procedures <input type="checkbox"/> Level 6 – Date of Birth; Medical Record Number; Billing Number PLEASE PROVIDE JUSTIFICATION BELOW FOR REQUESTING THE CHOSEN LEVEL: Up through Level 5 data (admission date, discharge date, and significant procedures) is required to meet our project's aims and objectives, and answer our research questions. Specifically, Level 5 data is needed to examine utilization patterns specific to readmission or return visits (for example, a patient is initially admitted as an inpatient but returns and is put into outpatient observation status within 30 days) among patients in the target populations for each CHART hospital project. Note: 5-digit ZIP is not listed here as in Inpatient for Level 2 and we would like that as well.	Year(s) of Data Requested: 2013 Release (10/1/2012-9/30/2013) 2014 Release (10/1/2013-9/30/2014)
Emergency Department	<input checked="" type="checkbox"/> Level 1 – 3 Digit Zip Code <input checked="" type="checkbox"/> Level 2 – Unique Physician Number (UPN) <input checked="" type="checkbox"/> Level 3 – Unique Health Information Number (UHIN) <input checked="" type="checkbox"/> Level 4 – UHIN and UPN <input checked="" type="checkbox"/> Level 5 – Date(s) of Admission; Discharge; Significant Procedures	Year(s) of Data Requested: 2013 Release (10/1/2012-9/30/2013) 2014 Release

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<p><input type="checkbox"/> Level 6 – Date of Birth; Medical Record Number; Billing Number PLEASE PROVIDE JUSTIFICATION BELOW FOR REQUESTING THE CHOSEN LEVEL:</p> <p>Up through Level 5 data (admission date, discharge date, and significant procedures) is required to meet our project's aims and objectives, and answer our research questions. Specifically, Level 5 data is needed to examine utilization patterns specific to ED return visits (for example, a patient is initially admitted as an Inpatient but returns to the Emergency Department within 30 days) and ED revisits among patients in the target populations for each CHART hospital project.</p> <p>Note: 5-digit ZIP is not listed here as in Inpatient for Level 2 and we would like that as well.</p>	<p>(10/1/2013-9/30/2014)</p>
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2. *FY 2015 Data:* Beginning with fiscal year 2015, Massachusetts Acute Care Hospital and Case Mix and Charge Data (collectively Case Mix Data) are released in Limited Data Set (LDS) files. Please refer to the Case Mix Data Specifications for details of the file contents.

Please indicate the Case Mix files from which you seek data, the year(s) of data requested, and your justification for requesting *each* file.

CASE MIX LIMITED DATA SET FILES	Year(s) Of Data Requested Current Yrs. Available <input checked="" type="checkbox"/> 2015
<input checked="" type="checkbox"/> Inpatient Discharge	<p>Please describe how your research objectives require Inpatient Discharge data:</p> <p>Inpatient discharge data is required to meet our project's aims and objectives, and answer our research questions. Specifically, these data are needed to examine utilization patterns specific to inpatient admissions and readmissions among patients in the target populations for each CHART hospital project.</p>
<input checked="" type="checkbox"/> Outpatient Observation	<p>Please describe how your research objectives require Outpatient Observation data:</p> <p>Outpatient observation data is required to meet our project's aims and objectives, and answer our research questions. Specifically, these data are needed to examine utilization patterns specific to readmission or return visits (for example, a patient is initially admitted as an inpatient but returns and is put into outpatient observation status within 30 days) among patients in the target populations for each CHART hospital project.</p>
<input checked="" type="checkbox"/> Emergency Department	<p>Please describe how your research objectives require Emergency Department data:</p> <p>Emergency Department data is required to meet our project's aims and objectives, and answer our research questions. Specifically, these data are needed to examine utilization patterns specific to ED return visits (for example, a patient is initially admitted as an inpatient but returns to the Emergency Department within 30 days) and ED revisits among patients in the target populations for each CHART hospital project.</p>

Sections IV-IX must be completed by all Applicants requesting 2015 data. Applications that only include requests for prior years of data can skip to Section X.

IV. GEOGRAPHIC DETAIL

Please choose one of the following geographic options for MA residents:

<input type="checkbox"/> 3 Digit Zip Code (Standard)	<input type="checkbox"/> 3 Digit Zip Code & City/Municipality ***	<input checked="" type="checkbox"/> 5 Digit Zip Code ***	<input type="checkbox"/> 5 Digit Zip Code & City/Municipality ***
<p>***Please provide justification for the chosen level of geographic detail if requesting something other than 3-Digit Zip Code only. Refer to specifics in your methodology:</p> <p>CHART hospitals serve patients originating from across the state of MA. 5-digit zip code data are necessary for more accurate analysis of each hospital's patient populations with respect to the key outcomes in our study (e.g., readmission rates). More specifically, we can use this information (patient's home zip code at time of visit/admission) to see the distance patients are traveling for care. 3-digit zip codes limit our ability to perform these analyses in that they provide information on a more aggregate level. This level of geographic detail will also allow us develop refined measures of hospital catchment areas.</p>			

V. DEMOGRAPHIC DETAIL

Please choose one of the following demographic options:

<input type="checkbox"/> Not Requested (Standard)	<input checked="" type="checkbox"/> Race & Ethnicity***
<p>*** If requested please, provide justification for requesting Race and Ethnicity. Refer to specifics in your methodology:</p> <p>Race and ethnicity data are necessary to control for trends in utilization that may relate to health care disparities in order to better understand the impacts of the CHART Phase 2 Investment program. We are specifically interested in how issues of African Americans and non-white Latinos compare to whites in terms of their admissions and readmission rates among the CHART hospital programs.</p>	

VI. DATE DETAIL

Please choose one option from the following options for dates:

<input type="checkbox"/> Year (YYYY)(Standard)	<input type="checkbox"/> Month (YYYYMM) ***	<input checked="" type="checkbox"/> Day (YYYYMMDD)***
<p>***Please provide justification for the chosen level of date detail if requesting Month or Day. Refer to specifics in your methodology:</p> <p>Dates of discharge and admission are necessary to determine the main quantitative improvement targets under the CHART program, namely inpatient readmission and ED revisit rates. Moreover, the program is focused, in part, on the readiness of CHART hospitals to adopt the practices consistent with ACO readiness. Thus, we must investigate outcomes (e.g., readmissions) that are consistent with evaluating where hospitals lie on that spectrum of readiness. More specifically, without the ability to calculate Length of Stay (LOS) and having the exact date of admission and discharge, we will be unable to create the time intervals needed to determine the how far apart the patient admissions were.</p>		

VII. PHYSICIAN IDENTIFICATION NUMBERS (UPN)

Please choose one of the following options for Provider Identifier(s):

<input checked="" type="checkbox"/> Not Requested (Standard)	<input type="checkbox"/> Hashed ID ***	<input checked="" type="checkbox"/> Board of Registration in Medicine # (BORIM) ***
--	--	---

CG 9.13.16

***If requested please, provide justification for requesting Hashed ID or BORIM #. Refer to specifics in your methodology: *As documented in the uploaded CHART Phase 2 Evaluation: Design Report, the project evaluation involves evaluating the coordination of high risk care teams, in order to evaluate those teams provide data is needed.*

VIII. HASHED UNIQUE HEALTH IDENTIFICATION NUMBER (UHIN)

Please choose one of the following:

<input type="checkbox"/> Not Requested (Standard)	<input checked="" type="checkbox"/> UHIN Requested ***
*** If requested please, provide justification for requesting UHIN. Refer to specifics in your methodology:	
UHIN numbers are to be used in this study to link the inpatient, observation and ED data.	

IX. HASHED MOTHER'S SOCIAL SECURITY NUMBER

Please choose one of the following:

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

X. DATA LINKAGE AND FURTHER DATA ABSTRACTION

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

1. Do you intend to link or merge CHIA Data to other datasets?

- Yes
- No linkage or merger with any other database will occur

2. If yes, please indicate below the types of database to which CHIA Data 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 level (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, which CHIA data elements will be linked; and the purpose for the linkage(s):

Individual Facility-level Data: Since the CHIA database uses codes to identify hospitals, we would need to link these codes to a Masterfile or reference table to translate the code into a hospital name. (<http://www.chiamass.gov/case-mix-data-documentation-archive/>). The most likely example of an existing database that we would use here would be the American Hospital Association Annual Survey of Hospitals). Linkage will be made to include structural characteristics of hospitals (e.g., bed size, admissions, etc.) where needed.

Individual Provider-level Data: Individual physicians are identified in the data with a code that would need to be linked to a Masterfile or reference table to translate the code into a provider. The specifics of the linkages and the crosswalk needed are to be determined at this point, but we would likely rely on publicly available information whenever possible.

Aggregated Data: Census data would be used (U.S. census data) to include demographic characteristics into our evaluation analysis. Zip code level data would most likely be used.

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.

Data linkages would be made by employing deterministic approach. For example, in linking the AHA data set to the Case Mix Data, hospital ID is a variable that would be found in multiple datasets and we would link the two data sets using that variable.

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

Data will only be linked in aggregate form. We do not have patient level information (e.g., level 6 data) that would be required to identify individual patients.

XI. PUBLICATION / DISSEMINATION / RE-RELEASE

1. Describe your plans to publish or otherwise disclose CHIA Data, or any data derived or extracted from such CHIA Data, in any paper, report, website, statistical tabulation, seminar, conference, or other setting. 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 display a cell less than 11, and no percentages or other mathematical formulas will be used if they result in the display of a cell less than 11.

The researchers involved in this evaluation intend to publish the results of the proposed project in academic peer-reviewed journals, present findings at conferences, and provide the Health Policy Commission with a number of reports that will be based on the data. The researchers will not disaggregate data below the cell size limitations (11) stipulated by MA CHIA.

2. Do you anticipate that the results of your analysis will be published and/or publically available to any interested party? Please describe how an interested party will obtain your analysis and, if applicable, the amount of the fee, that the third party must pay.

Yes, we anticipate our results to be published in peer-reviewed journals and the Health Policy Commission will post our reports publicly (e.g., available on the HPC website). We do not intend on making the details of our analysis available to any third-party for free or a fee.

3. Will you use CHIA Data for consulting purposes?

- Yes
 No

4. Will you be selling standard report products using CHIA Data?

- Yes
 No

5. Will you be selling a software product using CHIA Data?

- Yes
 No

6. Will you be reselling CHIA Data in any format?

- Yes
 No

If yes, in what format will you be reselling CHIA Data (e.g., as a standalone product, incorporated with a software product, with a subscription, etc.)?

N/A

7. If you have answered "yes" to questions 4, 5 or 6, please describe the types of products, services or studies.

N/A

8. If you have answered "yes" to questions 4, 5, or 6, what is the fee you will charge for such products, services or studies?

N/A

XII. APPLICANT QUALIFICATIONS

1. Describe your qualifications (and the qualifications of your co-Investigators) to perform the research described.

The members of our program evaluation team are expert in all components of the CHART evaluation. Our experience includes performing quantitative examinations of community, organization and patient-level issues. Members of our team include experts (some with more than 30 years of experience) in state and federal health policy, the MA provider landscape-with a particular specialization on community hospitals, payment model innovation, innovative care delivery models, hospital strategy and operations, quality improvement (e.g., hospital readmissions), behavioral and mental health, mixed-methods evaluation, advanced econometric and other analytic methods such as patient outcomes measurement, performing and analyzing key informant interviews and focus groups, and survey research design and analysis.

Our evaluation team and supporting seasoned programmers and statisticians are well-versed in using hospital discharge and medical claims data, survey data, cost and utilization data to analyze a broad range of clinical, process, and financial outcomes. The BUSPH also operates a Data Coordinating Center (DCC), which specializes in statistical and database programming, survey administration and study design.

Quantitative Experience. Our quantitative experience focuses in managing large and complex data systems, such as Medicaid and Medicare claims data, the MA APCD, and hospital claims and discharge data. Moreover, our evaluation team members have deployed methodologies commonly used in comparative analyses, including difference-in-differences, risk-adjustment, and patient measurement each of which we will be using in this evaluation. BUSPH operates an internal group of data cleaning, data management, and SAS programming experts within its Data Coordinating Center. We will leverage their knowledge of large data sets and vast programming capabilities to perform complex analyses in a timely manner. For example, members of our team leading the quantitative analysis have recently performed studies focusing on health care cost and utilization (Carey, 2016; Carey, 2015) and hospital readmissions (Carey & Lin, 2015; Carey, 2015; Carey & Lin, 2014).

2. Attach résumés or curricula vitae of the Applicant/principal investigator, and co-investigators. (These attachments will not be posted on the internet.)

XIII. USE OF AGENTS AND/OR CONTRACTORS

Please note: 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.

Third-Party Vendors. Provide the following information for all agents and contractors who will work with the CHIA Data.

Company Name:	
Contact Person:	
Title:	
Address:	
Telephone Number:	
E-mail Address:	
Organization Website:	

1. Will the agent have access to the CHIA Data at a location other than your location, your off-site server and/or your database?

- Yes, a separate Data Management Plan must be completed by each agent who will store CHIA Data
 No

2. Describe the tasks and products assigned to this agent for this project; their qualifications for completing the tasks; and the Organization's oversight of the agent, including how the Organization will ensure the security of the CHIA Data to which the agent has access.

N/A

XIV. FEE INFORMATION

Please consult the fee schedules for Case Mix Data and select from the following options:

- Single Use
 Limited Multiple Use
 Multiple Use

Are you requesting a fee waiver?

- Yes
 No

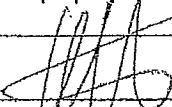
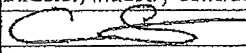
If yes, please refer to the Application Fee Remittance Form and submit a letter stating the basis for your request (if required). Please refer to the fee schedule for qualifications for receiving a fee waiver. If you are requesting a waiver based on the financial hardship provision, please provide documentation of your financial situation. Please note that non-profit status alone isn't sufficient to qualify for a fee waiver.

Non-Government Application for Case Mix Data – Published 5.6.16

By submitting this Application, the Data Applicant attests that it is aware of its data use, privacy and security obligations imposed by state and federal law *and* is compliant with such use, privacy and security standards. The Data Applicant further agrees and understands that it is solely responsible for any breaches or unauthorized access, disclosure or use of any CHIA Data provided in connection with an approved Application, including, but not limited to, any breach or unauthorized access, disclosure or use by its agents.

Applicants requesting data from CHIA will be provided with data following the execution of a Data Use Agreement that requires the Data Applicant to adhere to processes and procedures aimed at preventing unauthorized access, disclosure or use of data.

By my signature below, I attest to: (1) the accuracy of the information provided herein; (2) that the requested data is the minimum necessary to accomplish the purposes described herein; (3) the Data Applicant will meet the data privacy and security requirements describe 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) my authority to bind the organization seeking CHIA Data for the purposes described herein.

Signature: (Authorized Agent)	
Printed Name :	William P. Segarra, JD, MPH
Title:	Director, Industry Contracts & Agreements
Applicant's Signature:	
Name:	Christopher J. Louis, PhD
Title:	Clinical Assistant Professor
Original Data Request Submission Date:	9/12/16
Dates Data Request Revised:	

Attachments. Please indicate below which documents have been attached to the Application and uploaded to IRBNet:

- 1. IRB approval letter or summary of project (if applicable)
- 2. Resumes of Applicant and co-investigators
- 3. Data Management Plan (for each institution that will store CHIA Data) – BUSPH Only



EXCEPTIONAL CARE. WITHOUT EXCEPTION.



Office of the Institutional Review Board
560 Harrison Ave, Suite 300
Boston, Massachusetts 02118-2526
Tel: 617-638-7207

Title of Study: Evaluation Services to Support the Community Hospital Acceleration, Revitalization and Transformation (CHART) Investment Program (1)

IRB Number: H-35542

RE: Initial Review Submission Form

Determination: Not Human Subjects Research

Date of Action: 08/15/2016

Funding Source: Massachusetts Health Policy Commission

Award #: HPC-RFR-2016-009

August 15, 2016

Dear Christopher Louis, Ph.D., MHA,

A qualified member of the Institutional Review Board (IRB) staff has reviewed the above referenced submission and has determined that it does not constitute research involving human subjects. This determination is based on the definitions of human subject and research in the Human Research Protection Program (<http://www.bumc.bu.edu/irb/files/2015/10/PP-revisions-approved.doc>) per the following:

1. Human subject means a living individual about whom a researcher obtains data through intervention or interaction with the individual or identifiable private information about the individual, or an individual who is or becomes a subject (either a healthy human or a patient) in research, either as a recipient of the test article or as a control.
2. Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Protocol Specific Determinations

No PHI collected, accessed, used or distributed under 45 CFR 164.514.

This determination corresponds with the versions of the application and attachments in the electronic system most recently approved as of the date of this letter.

All determinations regarding this project have been made based on the information submitted by the investigator. Any modifications to the research plan that would possibly change the Not Human Subjects Research (NHSR) determination must be submitted to the IRB for review and confirmation of NHSR

status prior to initiation of the change. **PLEASE NOTE:** Minor changes to the study that do not affect the NHSR determination do not need to be submitted to the IRB.

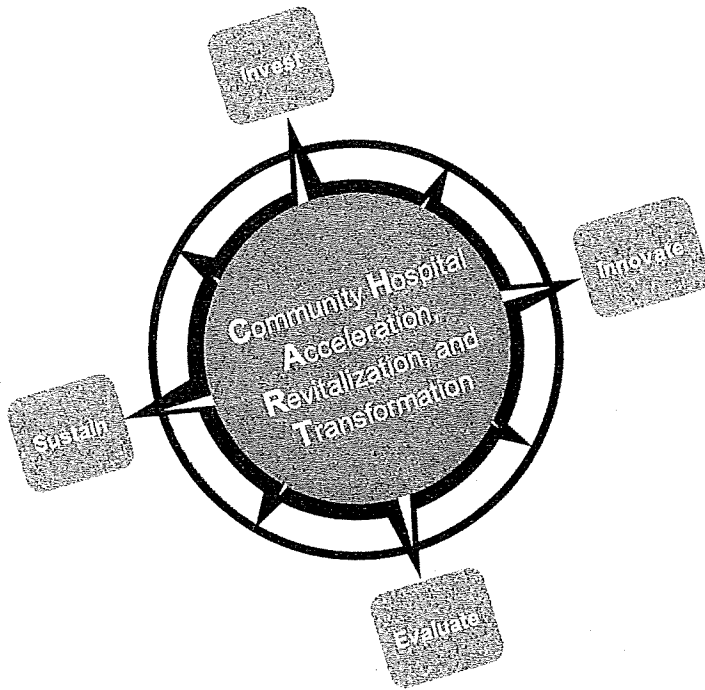
You may retain this letter in your files as documentation of this decision by the IRB. No progress reports are required for this project as long as no changes are made to the study.

It is the responsibility of the PI to ensure that any relevant HIPAA requirements have been met. It is also the responsibility of the PI to ensure that all required institutional approvals have been obtained prior to initiating any protocol related activities.

Sincerely yours,

Matthew Ogrodnik, Senior IRB Analyst

CHART Phase 2 Evaluation: Design Report



Community Hospital
Acceleration, Revitalization
and Transformation
(CHART) Investment
Program

July 31, 2016

Health Policy Commission
50 Milk Street, 8th Floor
Boston, MA 02109

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1. Evaluation Background and Conceptual Model

CHART Phase 2 Summary

Problem statement: Fragmented and inefficient care delivery contributes to excess spending on care that does not improve health. Fee-for-service payment does not provide incentives for changes in care delivery that could reduce costs and improve outcomes. Low-priced community hospitals lack the resources to improve their care delivery systems. This can inhibit these hospitals from participating effectively in accountable care, making these hospitals less financially sustainable, and ultimately depriving the evolving outcome-driven healthcare system of these lower-cost providers.

Intervention: Phase 2 of the CHART Investment Program invests in transformation of care delivery at low-priced community hospitals by supporting Health Information Technology, Hospital-Community Partnerships, and Care Delivery Redesign.

Aims: Reductions in avoidable hospital use and increased hospital capability to participate in accountable care.

Introduction

Massachusetts is a geographically small state where many patients with Medicare or private insurance travel to urban academic centers for complex medical care, despite the fact that community hospitals often provide similar quality care at lower cost.^{1,2} This pattern often leaves community hospitals disproportionately serving individuals with Medicaid or no insurance, complex health conditions, behavioral health and substance use disorders, and limited social supports. These most vulnerable, challenging, and costly patients may have poor connections to primary care and community resources, and instead rely on more costly hospital-based care.³⁻⁵ Costly and uncoordinated patterns of care are not optimal for patients and are not sustainable for Medicaid, for Medicare, for community hospitals, or for the health care system.

Accountable Care Organizations (ACOs) are expected to reduce health care cost growth by providing better coordinated and more efficient care delivery, incentivized by Alternative Payment Methods (APMs).⁶ As public and private payers increasingly employ APMs, provider organizations are forming and growing ACOs. The Community Hospital Acceleration, Revitalization and Transformation (CHART) Investment Program invests in eligible community hospitals¹ to enhance the key capabilities and capacities essential for successful participation in accountable care. These include, engaged hospital leadership; use of enabling technologies and data analytics; workforce development; care coordination; and partnering with community-based health care and social service providers. In addition to investment funding the HPC is providing extensive technical

¹ A CHART Hospital is an Acute Hospital eligible to receive an Award or Investment from the Fund or an acute inpatient campus (satellite) of an Acute Hospital as licensed by the Department of Public Health. A Qualified Acute Hospital shall not include (1) a hospital that is a Major Teaching Hospital; (2) a hospital with Relative Prices determined by the Commission to be above the Statewide Median Relative Price; or (3) a For-Profit Hospital or a hospital that is part of a For-Profit System.

MIXED-METHODS EVALUATION APPROACH

assistance (TA) to help Awardees improve these capabilities and move towards accountable, patient-centered, and fully integrated care delivery. This public-private collaboration to enhance readiness for accountable care is a new and deliberate effort in the Commonwealth.

CHART is a \$120M, multi-year investment program currently in its third year of operation. In Phase 1 of CHART, the HPC made investments for short-term, high-need projects in CHART hospitals. These projects included smaller-scale pilots, capability and capacity building investments, and strategic planning efforts. During this period, the HPC aimed to “assess the capability and capacity of participating institutions, develop engagement and foster learning among CHART-eligible hospitals, to build a foundation for system transformation.”⁷

CHART Phase 2 investments are specifically intended to promote the transformation of community hospitals by more effectively aligning their services and capabilities to address the physical, behavioral, and social needs of the communities they serve. Some of the Phase 1 pilots were expanded in CHART Phase 2, and in some cases the strategic planning or capacity investments from Phase 1 laid the groundwork for Phase 2. However, not all hospitals that participated in Phase 1 continued into Phase 2 and not all hospitals in Phase 2 also participated in Phase 1.

In CHART Phase 2, the 25 investments that span 27 community hospitals (some investments include two or more hospitals; see appendix 1 for award list) are designed to promote system transformation and ACO readiness and to contribute to the evidence base about care delivery improvement in community hospital and safety-net settings. Investments in health information technology, hospital-community partnerships, and care delivery redesign, in combination, are expected to contribute to high value healthcare and hospital transformation, as portrayed in Exhibit 1. Thus, a goal of CHART Phase 2 is not only to promote quality care at awardee hospitals, but to transform their role within the community and the healthcare system.

The HPC has identified a core set of hospital capabilities and activities that are expected to facilitate hospital movement toward accountable, patient-centered, fully-integrated care delivery. These four drivers are defined below and shown in Exhibit 1. While the HPC recognizes that these do not represent all components of ACO readiness, these are the areas that CHART targets in Phase 2.

These are shown in the conceptual framework as drivers that enable hospitals to acquire the characteristics of accountable, patient-centered care (Exhibit 1).

- **Hospital Leadership Commitment and Management Capacity.** Research has demonstrated that early involvement of internal leadership in process change and improvement increases overall staff involvement.¹⁹⁻²¹ Sufficient and appropriate allocation of resources, including staff, is critical to implementation success.¹⁸
- **Health Information Technology, Data Analytics, & Performance Monitoring.** Although organizations’ data infrastructure and analytic capacities vary significantly, studies show that health information technology—if implemented effectively—has the potential to facilitate coordination of care across providers, engage patients, and help staff manage an initiative’s target population (e.g., by documenting service access and use across departments and settings, and enrollment and disenrollment).²²⁻²⁵ In addition, data systems can be used to identify and classify target populations for programs or interventions, using established criteria. However, interoperability across health IT systems remains limited and the capacity to track and coordinate patient care across settings continues to pose a significant barrier to effective population health management.^{25, 26}

MIXED-METHODS EVALUATION APPROACH

- **Care Delivery Redesign.** Studies have demonstrated the efficacy of systematically identifying patients in need of care management and/or care transition services²⁷⁻³⁰ and engaging them in their own care and self-management.^{14, 31, 32} An increasing evidence base supports the use of care managers and community health workers as part of new accountable care models that aim to improve care coordination and serve patients in lower cost settings. Health systems are also increasingly expanding, coordinating and integrating behavioral health services using evidence-based models of coordination, collaboration, and integration of behavioral health and medical care (for an illustration of the continuum of coordination-integration models for behavioral health, see appendix 2).^{33, 34}
- **Hospital-Community Partnerships.** Engaging community stakeholders, including external service providers and referral partners, has been shown to encourage program adoption and enhance long-term sustainability.³⁵⁻³⁷ Such partnerships are particularly critical for patients transitioning from inpatient to community-based care; effective coordination and collaboration between hospital and community-based providers have been associated with reductions in readmissions.^{36, 38}

MIXED-METHODS EVALUATION APPROACH

Exhibit 1. Conceptual Framework of Hospital Transformation

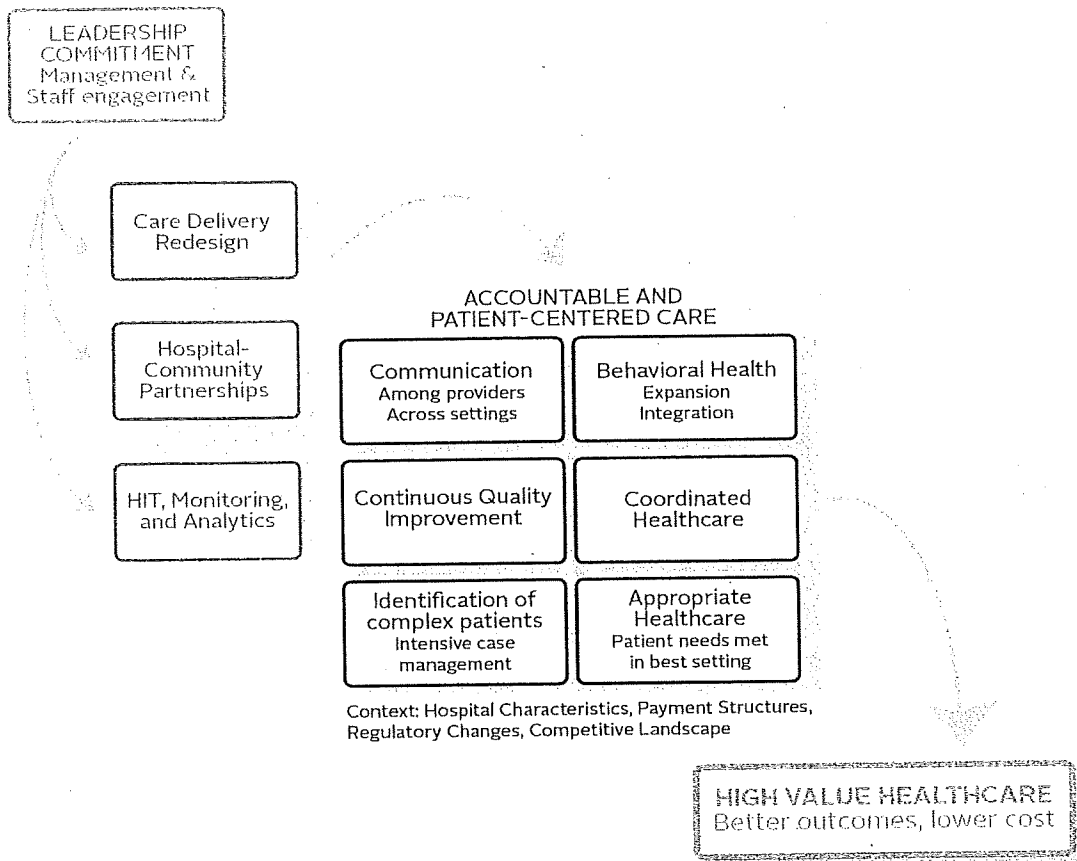


CHART Awardees and the HPC have collaboratively developed implementation plans that define how each hospital will enhance its capacities in these four core areas. In addition to improving hospital leadership and management capacity, data analytics and performance monitoring, care delivery, and community partnerships, each Awardee's implementation plan specifies concrete utilization reduction aims—outcomes against which their success will be measured. In most cases, Awardees intend to reduce avoidable hospital utilization for a specific high-risk, high-utilizer subpopulation.

The CHART Phase 2 evaluation will provide interim feedback to help the HPC and Awardees understand where progress is being made and where challenges remain. HPC staff will work with Awardees throughout the investment program to provide rapid-cycle feedback along with TA to Awardees. This feedback and TA will help drive continuous improvement in both processes and programs.

MIXED-METHODS EVALUATION APPROACH

The CHART Phase 2 evaluation will also provide summative measures of impact (change) in meeting the primary program goals. Some changes and achievements will be measured at the hospital level while others will be made at the Awardee level, among subgroups of Awardees, or aggregated and reported for the entire CHART Investment Program. The implementation plans feature specific goals that have been developed by hospital leadership in collaboration with the HPC. CHART Phase 2 hospitals are expected to advance goal A and/or goal B below, and all are also expected to accomplish goal C:⁸

- A. Reduce avoidable hospital utilization
- B. Expand and integrate high-quality, effective behavioral health care
- C. Develop capacities for accountable, patient-centered, fully-integrated care delivery

This evaluation will investigate to what extent those goals have been met. In evaluating CHART Phase 2, it is not enough to understand the barriers and challenges to implementing CHART Awardees' programs, and whether implementation is perceived by Awardees as being effective, although these are important. It is also essential to measure whether programs as implemented are effective in achieving the intended goals (A and B above), and whether the Commonwealth's investment in CHART achieves the overarching goal of moving community hospitals toward accountable, integrated, patient-centered care (Goal C).

Given the Commonwealth's \$120 million dollar investment in the CHART Investment Program, it is important to evaluate whether these hospitals' CHART-related initiatives have the potential to be sustainable, extending the value of the investment beyond the two program years, and contributing to the evidence base about care delivery improvement and transformation. An important premise of the focus on ACO-readiness is that ACO-ready hospitals will be able to participate in APMs which incentivize integrated, patient-centered care, and thus will find that the changes they have made are financially sustainable. Assessment of ACO-readiness is therefore a key component of evaluating sustainability.

1.1 Evaluation Plan and Research Questions

1.1.1 Logic Model and Evaluation Framework

CHART Phase 2 involves dedication of HPC investment funds, in-kind contributions from hospitals and their affiliated health systems, and HPC technical support. The logic model (shown in condensed form in Exhibit 2 and shown fully in Appendix 3) shows these dedicated resources or inputs, the planned activities, the expected outputs produced by those activities, the anticipated outcomes, and their alignment with program goals. The inputs and activities of HPC staff are shown in a separate row below those of the hospital. The research questions to be addressed by the evaluation are derived from the logic model.

The evaluation design employs a framework applied in evaluations of many Centers for Medicare and Medicaid Services (CMS) programs, adapted from Berry et al., 2013, which includes three broad categories of investigation.⁹

- **Implementation:** The degree to which an intervention is deployed successfully in real-world settings.
- **Impact:** The effect of an intervention on outcomes of interest.

MIXED-METHODS EVALUATION APPROACH

- **Sustainability:** Potential for beneficial programs and changes to continue past the investment period. This depends on hospital capacity to identify, test, adopt, and sustain reforms in care delivery, as well as benefits (monetary and otherwise) balanced against costs of continuation.

These three elements represent a path from the initial adoption of an innovation or program, to its effective implementation, and subsequently to its impact; successful implementation and achievement of measureable impact motivates commitment to the program and sustainability.

The bottom row of Exhibit 2 shows how these categories from Berry et al.'s framework map to the logic model. Implementation concerns whether the planned activities occurred, and whether they were performed successfully enough to produce the expected output. Impact speaks to whether the outputs led to the desired outcome. Sustainability considers whether the investment produced lasting changes, which are necessary for achievement of longer term goals. Thus, the evaluation will investigate whether implementation processes and hospital activities impacted success, whether Awardees advanced goals A,B and C above, and whether programs are sustainable.⁹

CHART Phase 2 provides a unique opportunity to examine the implementation processes—and intervening facilitators or barriers—encountered by CHART hospitals as they work to meet their goals of reducing avoidable hospitalization and expanding and integrating high quality, effective behavioral health care. Collectively, the mixed-methods analyses described below will inform the evidence base about how a government investment program can support community hospitals to develop capacities for accountable, patient-centered, fully integrated care delivery.

The CHART Awardees have been working closely with HPC staff to create unique implementation plans for the two-year investment program. These plans address investments in workforce development, use of technologies, community partnerships, and other strategies to achieve the CHART Phase 2 goals above. Each Awardee has developed specific measureable aims in consultation with the HPC, and will make new investments in program implementation and care process redesign to meet these goals. The HPC has also developed crosscutting goals for the entire CHART Investment Program. These program and Awardee-level goals are the measures of *impact*, as detailed in the logic model and Awardee implementation plans.

The left portion of the logic model in Exhibit 2, Inputs, shows the resources and TA that HPC staff offer to support Awardees. The CHART Program's TA activities and grant management processes are intended both to monitor compliance with program requirements and to facilitate collaborative learning among Awardees and the HPC. Measurement and feedback from an independent evaluator and directly from the HPC, as well as financial incentives to motivate performance, are key elements of the investment program. Analysis of implementation effectiveness will also include contextual influences – hospital characteristics, or external factors in the environment that affect Massachusetts community hospitals.

A key aspect of sustainability is hospital ACO-readiness. APMs are expected to both *require* and *support* patient-centered, integrated care delivery. Therefore, the activities funded by CHART are expected to build hospital capacity for participation in APMs, and in turn, APMs are expected to make these activities sustainable. Assessment of ACO-readiness will be a focus of the sustainability domain.

Using this framework, the CHART Phase 2 evaluation will also examine the interplay among key elements of the investments (inputs column). Specifically, the evaluation will assess whether the CHART Program's services, supports and feedback contribute to successful implementation of hospital activities; whether important activities and improvements (activities column) are implemented effectively by hospitals to enhance their internal capacities; and whether these

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improvements achieve the desired impacts (output and outcomes) and are potentially sustainable (goals).

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Exhibit 2. CHART Phase 2 Condensed Logic Model (Full logic model in Appendix 3)

Inputs	Activities	Outputs	Outcomes	CHART goals	Long-term goal ²
<p>CHART Phase 2 Award supporting:</p> <ul style="list-style-type: none"> Staff for: <ul style="list-style-type: none"> Clinical care Care coordination Project leadership & management Enabling tech Strategic planning Community partnerships <p>Hospital and system in-kind contributions</p>	<p>Hospital management</p> <ul style="list-style-type: none"> Program design Leadership engagement Training & hiring staff Strategic planning <p>Care delivery</p> <ul style="list-style-type: none"> Coordination of care within hospital Expansion & integration of BH services Partnering with community providers <p>Analysis</p> <ul style="list-style-type: none"> Collect data Report data to the HPC Performance self-monitoring Implement IT for population management Review data & HPC feedback and use for continuous QI. 	<p>Process improvements</p> <p>Coordinated care delivery</p> <ul style="list-style-type: none"> Admission decision Intensive case management Multidisciplinary care Social needs addressed Appropriate BH treatment <p>Effective care across settings</p> <ul style="list-style-type: none"> Care in community Transitions Cross-setting care coordination <p>Analysis and learning</p> <ul style="list-style-type: none"> Target population captured Data analysis informs decision making Inter-hospital learning 	<p>Hospital-specific</p> <ul style="list-style-type: none"> Reduced re-admission Reduced inappropriate ED utilization <p>CHART-wide</p> <ul style="list-style-type: none"> Hospitals plan for sustainable change in care delivery Increased hospital capability for self-monitoring, data-driven continuous improvement 	<p>CHART hospitals move towards accountable, patient-centered, integrated care delivery (ACO-readiness)</p> <p>CHART hospitals increase capacity for testing and adopting reforms in care delivery</p>	<p>MA Community Hospitals participate effectively in ACOs, PCMH, AP/MS.</p>
<p>HPC staff and expert consultants</p> <p>HPC staff and outside evaluator</p>	<p>HPC guidance, technical assistance and performance monitoring</p> <p>CHART Phase 2 planned analysis and evaluation</p>	<p>Increased knowledge base about care delivery reform</p>	<p>Increased dissemination of knowledge about strategies and best practices</p>	<p>Knowledge base drives reform in care delivery and payment</p>	<p>Sustainability</p>
<i>Implementation</i>			<i>Impact</i>		
<i>Evaluation framework:</i>			<i>Sustainability</i>		

² Long-term goals will take more than two years to complete.

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1.1.2 Application of the Evaluation Framework and Levels of Analysis

The evaluation will synthesize findings from various data sources, including: secondary data, hospital-reported data, an organizational survey, a survey about CHART TA (“CHART-TA survey”), document review (e.g., implementation plans, performance reports, and strategic plans), interviews with HPC program staff, interviews with patients, and case studies of all 25 CHART Phase 2 Awards (27 hospitals). The evaluation will analyze primary and secondary data at three levels of analysis: (1) the Awardee, (2) subgroups of hospitals, and (3) the overall CHART Phase 2 program level. At all three levels, the evaluation will identify patterns or themes related to implementation effectiveness, program impact, and potential for sustainability.

Across all Awardees, the evaluation will consider whether care redesign activities such as care transitions/care coordination, high risk care teams, and behavioral health expansion/integration, were effectively implemented, contributed to the expected impacts, and are likely to be sustained. If there were recurring patterns of barriers, or consistent successes, these will be identified.

Subgroups will be used to address questions about the effect of different program strategies, hospital characteristics, and external factors. Hospitals may be grouped by region, by type of program, by competitive landscape, or other factors of interest to the HPC. Subgroups may also be used to increase power for answering quantitative questions about program impact that are difficult to answer at the level of an individual hospital.

Stepping back from the individual hospitals and subgroups to consider Phase 2 of the CHART Investment Program as a whole, the evaluation will explore whether the overall program was *implemented effectively*, had the intended *program impacts*, describes the return on the Commonwealth’s investment, and has the *potential to be sustained* by the hospitals involved, without ongoing investment by the Commonwealth. Together, these findings will grow the evidence base about community hospital transformation initiatives designed to move hospitals toward accountable, integrated care delivery. Exhibit 3 illustrates how this framework will be applied to answer the research questions at each level of analysis.

1.1.3 Research Questions for CHART Phase 2 Evaluation

The research questions are listed below by domain, with aspects to be considered in answering each question, and are shown applied to three levels of analysis in Exhibit 3.

Implementation

RQ1. Were the program activities effectively implemented by the awardee?

- Did the awardee identify and serve patients in the target population?
- Did the awardee collect and submit data as specified in the implementation plan?
- Which program activities did the awardee implement effectively?
- What internal factors contributed to successful or unsuccessful implementation?
- What external factors contributed to successful or unsuccessful implementation?

RQ2. Were there subgroup-level patterns in program implementation?

- Were there patterns in program components that were/were not successfully implemented?
- Were certain hospital characteristics associated with successful or unsuccessful implementation?

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- Were certain external factors (e.g. region, competitive environment) associated with successful or unsuccessful implementation?

RQ3. Was the CHART program as a whole implemented effectively?

- How adequate and useful was the TA provided to CHART hospitals by the HPC during the design and implementation phase?
- To what extent did the HPC's data collection and monitoring process function as intended?
- To what extent did hospitals use feedback from the HPC based on submitted data and work product to improve their program implementation or activities?

Impact

RQ4. What outcomes were achieved by the awardee?

- To what extent did the awardee reduce inappropriate hospital utilization?
- What program impacts do CHART Awardee and stakeholders perceive as meaningful?
- What internal and external factors contributed to program impact or lack thereof?
- For programs with a BH focus, did awardee expand and integrate behavioral health care?

RQ5. Were there subgroup-level patterns in outcomes?

- Were there patterns in program strategies or design associated with program impact or other outcomes?
- Were certain hospital characteristics associated with program impact or other program-wide outcomes?
- Were certain external factors (e.g. region, competitive environment) associated with program impact?

RQ6. Did the CHART program as a whole accomplished the desired outcomes?

- Did CHART hospitals as a group increase their capacity for accountable, patient-centered, fully-integrated care delivery?
- Did CHART Phase 2 contribute to the evidence base about hospital improvement and care delivery?
- Did CHART Phase 2 facilitate hospital learning and planning around care delivery transformation?
- Did the HPC obtain new evidence or insights regarding care delivery reform?

Sustainability

RQ7. Will the awardee sustain program activities past the CHART Phase 2 period?

- Which program components does the awardee expect to continue past the CHART Phase 2 period?
- What are the ongoing costs or conflicting demands for resources? What are the benefits to participants and stakeholders?
- What strategic planning processes are in place to balance costs and benefits in deciding which program components to sustain and which to terminate?
- How has the awardee moved towards a culture of continuous monitoring, feedback, and quality improvement?

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- How has the hospital improved its capacity for identifying, testing, and adopting reforms in care delivery?
- Has the awardee begun or increased participation in APMs?

RQ8. Are there subgroup-level patterns in program sustainability?

- Were there patterns in which program elements were sustained?
- Were there patterns in APM participation?
- Were certain hospital characteristics associated with program sustainability?
- Were certain external factors associated with program sustainability?
- Have CHART hospitals formed or joined learning communities that can inform their care delivery?

RQ9. Has the CHART program as a whole produced lasting changes that will continue to benefit stakeholders?

- What was the CHART Phase 2 return on investment (ROI), and what is the potential for returns to continue after the investment ends?
- Has the participation of community hospitals in APMs increased?
- How effectively did the HPC support CHART hospitals in enhancing capacity, facilitating shared learning, and advancing hospital ACO readiness?
- How effectively did the HPC disseminate findings to develop an evidence base to inform hospital improvement and care delivery?

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Exhibit 3. Application of the Evaluation Framework

Research Questions and Information Sources at each Level of Analysis			
Evaluation Framework	CHART Awardee-Level	Subgroup-Level	CHART Program-Level
Implementation	RQ1. Were the program activities effectively implemented by the awardee?	RQ2. Were there subgroup-level patterns in program implementation?	RQ3. Was the CHART program as a whole implemented effectively?
Data Sources	<ul style="list-style-type: none"> Hospital-reported metrics Document review Case studies Quarterly feedback from the HPC Context information from the HPC and CHIA 	<ul style="list-style-type: none"> Hospital-reported metrics Document review Case studies Quarterly feedback from the HPC CHART-TA survey Context information from the HPC and CHIA 	<ul style="list-style-type: none"> Hospital-reported Metrics Document review Case studies Quarterly feedback from the HPC CHART-TA survey Organizational survey I Context information from the HPC and CHIA
Impact	RQ4. What outcomes were achieved by the awardee?	RQ5. Were there subgroup-level patterns in outcomes?	RQ6. Did the CHART program as a whole accomplished the desired outcomes?
Data Sources	<ul style="list-style-type: none"> Hospital-reported metrics Case studies (impact as perceived by hospitals and stakeholders) Quarterly feedback from the HPC 	<ul style="list-style-type: none"> Hospital-reported metrics Case studies (impact as perceived by hospitals and stakeholders) Quarterly feedback from the HPC Secondary data analysis (hospital and ED utilization) 	<ul style="list-style-type: none"> Hospital-reported metrics Case studies (impact as perceived by hospitals and stakeholders) Quarterly feedback from the HPC Secondary data analysis (hospital and ED utilization)
Sustainability	RQ7. Will the awardee sustain program activities past the CHART Phase 2 period?	RQ8. Are there subgroup-level patterns in program sustainability?	RQ9. Has the CHART program as a whole produced lasting changes that will continue to benefit stakeholders?
Data Sources	<ul style="list-style-type: none"> Document review Case studies Quarterly feedback from the HPC Context information from the HPC and CHIA 	<ul style="list-style-type: none"> Case studies Secondary data analysis (ROI) Call-back interviews post-investment 	<ul style="list-style-type: none"> Case studies Secondary data analysis (ROI) Call-back interviews post-investment CHART-TA survey Organizational survey II

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The following is one example of how this framework will be applied to the Awardee level:

Effective coordination of care, especially transitions from hospital inpatient care to home and community-based services, is a component of many CHART Awardee' care delivery redesign because short turnaround returns to the hospital are often attributed to poor care transitions.³⁹

For CHART hospitals employing a transition care coordination model as part of care redesign, *implementation effectiveness* would be defined as whether the activities described in the implementation plan (e.g. redesigned workflows, coordination with other providers, medication reconciliation, patient education, and follow-up monitoring) take place for all target population patients, including those who are discharged at night or on weekends.

Because reducing readmissions is the most common award-specific goal in CHART Phase 2, the evaluation would then explore *program impact*: whether each Awardee's care delivery redesign, and their entire program as implemented, are effective in preventing returns to the hospital. Continuing the example, if the planned transition-coordination steps are taking place for all patients, the outcome measure of interest would be returns to the hospital (emergency department (ED) or inpatient) within 30 days after hospital discharge.

Near the end of the second year, the evaluation team will assess the *sustainability potential* for each Awardee's program and its major components. This will include whether there are any ongoing costs or conflicting demands on resources, and whether benefits to participants outweigh such costs. The opinion and experience of hospital executives, program staff, and other stakeholders (e.g., community partners)—along with measures of program effectiveness—will inform the evaluation team's understanding of program benefits and costs.

For example, if automated data systems are in place to identify target patients, and hospitalists have become accustomed to setting an expected discharge date, there will be little additional cost and no reason to revert to prior practice; these activities are likely to be sustained. If the hospital has been able to secure funding for transition care coordinators, their activities may also be sustained. If the program reduces returns to the hospital, that may convince hospital leadership that care coordinators are a wise investment to reduce unreimbursed readmissions and avoid penalties from Medicare or other payers.

Moreover, if the awardee has successfully implemented the transition care, and the improved care has reduced readmissions, then the hospital is in a position to benefit financially from participation in APMs that reward high value care. The evaluation will consider whether the awardee has begun or increased participation in APMs.

Effective ACO participation rests on the ability to continue and expand these changes. If awardees enhance their ability to find, test, and adopt innovations in care delivery, and/or move towards a culture of learning and evidence based care delivery, these changes will be captured in the sustainability domain as well.

One year after the CHART investment funding concludes, a brief follow-up interview with hospital leadership will ascertain whether in fact the transition coordination steps are continuing, care coordinator positions are funded, or community providers continue to work closely with the hospital. This will serve to refine the final assessment of sustainability.

2. Mixed-Methods Evaluation: Data Collection and Analysis

2.1 Overview

Mixed-methods evaluation is the most rigorous and comprehensive approach to answer the 9 research questions above. Qualitative methods will be used to assess all three domains: implementation, impact, and sustainability. Quantitative analysis of hospital-reported metrics and of secondary data from the Massachusetts Acute Hospital Case Mix Database (Case Mix Database or CMD) will be used to assess impact, and secondary data will also be used for ROI analysis in the sustainability domain. The reports generated by this evaluation will synthesize quantitative and qualitative findings. The synthesis is particularly important because the intervention is not a randomized controlled trial (RCT), so causal attribution of results is complex. Any quantitative findings, such as a reduction in hospital readmissions, could theoretically be unrelated to the actual intervention. Therefore, these results must be interpreted in light of qualitative information that supports or refutes a narrative connecting the intervention and the result.

The following sources will be used for data collection:

Quantitative

- **Secondary Data Analyses:** Analysis of secondary data from the CMD to measure key changes in hospital utilization and estimate return on investment (ROI) for the entire Phase 2 of the CHART Investment Program. Average costs of encounters for high-risk, high-utilization patients based on the All-Payer Claims Database (APCD) will be generated by the HPC and provided to the evaluator for the estimated ROI.

Qualitative

- **Case Studies:** Two waves of case studies that include site visits, interviews, and focus groups with hospital staff, and interviews or focus groups with community partners where appropriate. The first wave will be conducted in-person at all 27 hospitals, and the second wave to be conducted virtually with most hospitals, and in-person with a subset.
- **Document Review:** Document review of Awardee implementation plans, periodic reports, monthly data reports, and strategic plans. Awardee-reported quality and utilization measures, from hospital-reported data for all 25 Awardees.
- **Organizational Survey:** An organizational survey with leaders in all 27 hospitals, conducted early in the CHART implementation period and again toward the end of the program.
- **Behavioral Health Integration Survey:** A brief survey to assess changes in delivery of BH services.
- **CHART-TA Survey:** A periodic survey of all 27 hospitals with a focus on Awardee feedback about CHART TA, services, and supports.
- **Periodic Feedback from the HPC Staff:** Periodic interviews, and/or review of notes, with HPC staff and contractors about Awardee progress, barriers, and facilitators.
- **Context Information from the HPC and CHIA:** Information from the HPC and CHIA will allow the evaluators to understand external factors affecting community hospitals in Massachusetts, such as changes in the regulatory environment or competitive landscape.

These data sources are complementary. The early waves of the organizational survey and case studies will inform data collection in later waves and will aid in the analysis and interpretation of quantitative findings.⁴⁰ Case studies will identify facilitators and barriers to implementation effectiveness, impact as perceived by participants and stakeholders, and the programmatic components with sustainability potential. The case studies and organizational survey will also provide insight into implementation effectiveness and program impact by exploring how programs work "on the ground."⁴¹ Quantitative analysis of key utilization measures will determine whether there was a reduction in avoidable utilization, and will suggest additional areas of inquiry to be pursued during follow-up, in-depth case studies. The case studies, CHART-TA survey, and quarterly feedback from HPC staff will help evaluators form insights as to the potential for sustainability, and post-investment extension of gains and savings. These analyses will explore whether each Awardee's initiatives and improvements were implemented effectively, and whether together these improvements achieved the anticipated impacts on quality, utilization, and cost, and are likely to be sustained.

2.2 Quantitative: Impact: Care Delivery and Hospital Utilization

2.2.1 Self-Reported Hospital Performance Metrics

To track improvement over time, each of the 25 CHART Awardees will track and report key utilization and service delivery measures such as:

- Total quarterly ED visits
- Rate of ED revisits within 30 days of ED discharge
- Median ED Length of Stay
- Rate of ED boarding
- Total quarterly inpatient discharges
- Rate of inpatient readmissions within 30 days of inpatient discharge
- Rate of ED returns within 30 days of an inpatient or observation discharge
- Rate of return to inpatient or observation stay within 30 days of discharge from inpatient or observation stay
- Average number of contacts per patient served
- Number of units of service provided, by service types, service modality, and role type.
- Proportion of target population patients with care plan

The evaluator will assist the HPC in using this data to create a quarterly performance report for each Awardee, summarizing trends in key metrics. Self-reported performance measures will be included in the awardee memos. These outcomes can also be aggregated for hospital subgroups or

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populations of interest (e.g., high utilizers, behavioral health patients).ⁱⁱⁱ Selected subgroup or program level findings will also be incorporated into the both the baseline summative report, interim report of findings, and final summative report.

2.2.2 Level of Analysis-Secondary Data

The Case Mix Database (CMD) will be the secondary dataset for analysis of hospital utilization. There are three levels for secondary data analysis of utilization changes resulting from the CHART Phase 2 investments.

Awardee-level Analysis.^{iv} The evaluator will develop descriptive statistics for hospital-level secondary analysis. These will include risk-adjusted readmission and ED utilization rates. Additionally, Awardee-level analyses for a sub-set of investments will be used to extend the value of hospital reported data by (1) validating reported data on readmissions and ED utilization, (2) analyzing reutilization to other hospitals, (3) looking at regression to the mean for high-utilizer populations. These analyses will compare select hospitals to see how utilization may differ. The evaluator, in consultation with the HPC, may conduct additional analyses for the larger awards, or the most successfully implemented awards, or others identified by the HPC for in-depth study.

Subgroup Analysis. The evaluator will create subgroups of Awardees for analysis for two purposes. First, quantitative assessment of the CHART Investment Program impact on the primary outcomes can be done with larger populations and therefore more statistical confidence compared to assessment of individual hospitals. Second, subgroups of hospitals can be compared. One goal of the CHART Phase 2 evaluation is to learn about which strategies are most successful at accomplishing project goals, and which hospital characteristics or external factors influence success. Comparing subgroups of hospitals is a useful way to address these questions. Analysis of hospital-submitted data will be used to identify patterns and relationships that emerge from consideration of multiple hospitals. Identification of an apparent pattern can lead to formation of a hypothesis that can be tested quantitatively by analyzing secondary data for a cluster of hospitals. The selection of hospitals that belong to each subgroup will be driven by the question being asked.

Analyzing data for subgroups of hospitals is complicated by the differences among hospitals in definition of target population, in intervention design, and in targeted outcome. Each analysis will require consideration of commonalities in population and program, and identification of an outcome that is meaningful for measuring and comparing impact.

ⁱⁱⁱ The Baystate Joint program is substantially different from the rest of the CHART programs and so will be analyzed separately and not included in secondary data analysis.

^{iv} The HPC has designed a model for the graduated payment of each CHART award, based in part on a hospital's level of achievement of its aim statement. In order to ensure timely payment for services rendered and for performance, payment is determined utilizing hospital-reported monthly performance measures. The analysis of outcomes described in this evaluation report will utilize the Massachusetts Acute Hospital Case Mix Database developed by the Center for Health Information and Analysis (CHIA) to produce an independent assessment of hospital utilization that considers admissions to other hospitals as well as to CHART hospitals. This analysis will not be applied to payment determinations.

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An example of hospital subgrouping is shown in Exhibit 4. The BH subgroup (second row) could be used to investigate the impact of a primarily BH CHART program on ED revisits, while the HU subgroup (third row) would investigate the impact of a broad spectrum approach CHART program on IP readmissions. Other possible subgroups might investigate whether CHART hospitals within a large ACO system were more successful at reducing global readmissions, or whether hospitals in regions with few outpatient BH providers were less successful in reducing ED revisits.

The potential challenges column lists variations among the hospitals that complicate the subgroup analysis, illustrating the challenges in analyzing an intervention that is actually a diverse group of interventions. In order to account for variations in definition of target, the evaluator will create a definition of a theoretical target population that overlaps well with all of the hospitals' definitions and include those patients. Similarly, choice of an outcome measurement is complicated by variations in hospital strategies and target. Subgroups for some research questions may need to include hospitals that did not share the same primary aim. Still, since each hospital did have a specific utilization goal, it should be possible to define an outcome meaningful across a subgroup.

Defining the specific questions to be addressed by clustering and the strategies for the analysis will be a collaborative process between the HPC and the evaluator.

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Exhibit 4. Subgroup Example: Primary Aim

Proposed Subgroup	Award	Outcome	Potential Challenges (Quantitative)
Behavioral Health (BH) Only (ICD-9: 290-319)	Harrington Memorial Holyoke Health Alliance Haywood-Athol BIDH-Milton BIDH-Plymouth Mercy Medical (Lahey-Lowell) (Hallmark Health)	ED Revisits	<ul style="list-style-type: none"> Some exclude BH ICD-9: 290, 305.1, 317-319, 293 (most include all) BIDH-Milton ED revisits is only a "secondary" goal Ignores dual-eligible patients in BIDH-Plymouth who do not also have BH issue (BIDH is only dual-target population hospital to target ED so probably belongs here) BIDH Plymouth also targets "admission from ED" but is only one Some hospitals do not exclude transfer to IP or discharge to acute rehab (most do) Lahey-Lowell and Hallmark Health target ED HU but somewhat focused on BH with ED revisits as target outcome (Definitions may not be sufficiently congruent for a split-off cluster)
High Utilizers (HU) Only (≥4 IP Admit [OR ≥ 10 ED])	Southcoast Hospitals Lowell General Baystate Franklin UMass Marlborough Milford Regional (Anna Jacques) (Winchester) (Beverly Hospital) (Addison Gilbert) (Baystate Noble)	IP Readmit	<ul style="list-style-type: none"> All hospitals have IP HU rule but only 4 have ED visit as rule—have to balance including/excluding those patients Anna Jacques "predicts" high users—may have to exclude from analysis since it will prevent HU from being observed Winchester/Noble also targets PAC—to extent PAC population overlaps "potential" HU, may prevent patients from hitting HU status Addison/Beverly—Includes active BH treatment and palliative care. May prevent these from hitting HU status Milford cutoff is 3 IP admits not 4 Assumes "12-mo. lookback" period consistent across all hospitals
"Other" #1 (All Patients)	Berkshire Medical Signature Healthcare	IP Readmit	<ul style="list-style-type: none"> Berkshire technically only targets "local" patients but no way to define comparison group that are congruent
"Other" #2 (high-risk principal diagnosis, palliative care, active BH treatment)	Emerson Lawrence General (Addison Gilbert)	IP Readmit	<ul style="list-style-type: none"> Will have to balance three potential inclusion rules for group as not all three hospitals have all three rules Relatively few hospitals in cluster may not allow for adequate statistical power
"Other" #3 (discharge to SNF)	Winchester Baystate Noble	IP Readmit	<ul style="list-style-type: none"> Optional cluster if overlap with HU populations at these two hospitals permits Ignores Winchester discharge to HHA Relatively few hospitals in cluster may not allow for adequate statistical power
TBD	Baystate Wing	IP Readmit	<ul style="list-style-type: none"> Only targets age > 50; target population uniquely defined Single hospital will likely result in underpowered analysis: can either analyze separately with this understanding or else drop from analyses

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Program-wide Analysis. Program-wide outcomes will be assessed by pooling all the CHART hospitals together and analyzing the aggregated set, adjusting for subgrouping of patients across hospitals. This would maximize the power to detect change because it would include patients from all 27 hospitals, and would allow the evaluator to estimate changes in outcomes for the overall CHART Phase 2 program. However, due to variation in how Awardees define their target populations and outcomes, this approach would also create challenges and the potential for error in defining the analytic sample. Because this approach may mask impacts achieved by some awardees, this analysis will also be conducted separately for those Awardees identified as having implemented effectively.

2.2.3 Analytic Approach

Two broad approaches will be employed for the secondary data analysis of utilization impacts: a pre/post approach and a difference-in-difference (DID) approach that compares changes against a comparison group not affected by the intervention.

Pre-Post Design. The most straightforward approach to estimating changes in outcomes is to compare outcomes before the start of the intervention with those after the intervention (a pre/post design). The major shortcoming of this approach is that estimated changes over time cannot be solely attributable to the CHART program, to the exclusion of other concurrent causes.⁶³ Pre-Post analysis will be used for certain awards where impact is measured on the individual Awardee-level.

Difference-in-Difference Approach. The more rigorous approach is a difference-in-difference (DID) design which tests whether pre/post changes in the CHART hospitals are greater than pre/post changes in a group of hospitals that are not involved in the CHART program. This in turn requires the construction of well-matched comparison groups, and use of regression analysis to control for observable differences between intervention and comparison populations. DID will be employed for certain subgroup analyses where a meaningful comparison group can be identified.

For either approach, the evaluator will create a baseline (pre) period extending two years prior to the start of the CHART intervention. Since the start date of each hospital's initiative varies, this two-year baseline would be anchored to the start date of each individual hospital.

Under a DID approach, the comparison group would be assigned to the same baseline period as the intervention group. If analyses are conducted at the pooled or subgroup level, and if start dates are not all the same, comparison patients could be randomly assigned to the baseline or intervention period to correspond with rolling start dates among the hospitals.

Analytic Method	Awardee	Subgroup	Program-wide
Pre-Post	Selected individual awards	Selected Subgroups	TBD
Difference-in-difference	-	Selected Subgroups	TBD

2.2.4 Comparison Groups

Massachusetts non-CHART Hospital Comparison.

The comparison group for DID will be defined using hospitals from within Massachusetts that did not receive CHART awards. The advantage of this approach is that these hospitals will be located in the Massachusetts regulatory and market environments, and creating a within-state comparison group will be less costly than creating an out-of-state comparison group, since it will not require obtaining or processing additional data.

This approach will be challenging, however, because many non-profit community hospitals in Massachusetts are CHART Awardees, leaving limited options for creating a well-matched comparison group. Although key characteristics of non-CHART hospitals may differ from CHART hospitals (e.g., academic affiliation, for-profit status, ACO penetration), these factors may be less likely to impact outcomes for the specific populations that CHART hospitals target (e.g., behavioral health patients, high utilizers) than they would for more typical patient populations. Another potential issue is that patients may use both CHART and non-CHART hospitals.

Appendix 5 lists the non-CHART hospitals in Massachusetts that could potentially serve as comparisons; the final set will require consultation with the HPC. In selecting comparison hospitals, evaluators could consider factors such as: location, size, ownership, parent "system", services offered (e.g., inpatient psychiatric unit), and the hospitals' service population. Due to the limited number of potential comparison hospitals, not all of these factors can be included as selection criteria, and it may not be possible to find ideal matches for CHART hospitals. Any important factors that cannot be included as selection criteria could be considered for use as control variables in regression analyses.

2.2.5 Defining Study Populations

The evaluator will employ an 'intent to treat' approach wherein all patients who meet the Awardee's target population definition are assumed to be 'treated' because the evaluator would not be able to verify if they were or were not. In general, the Awardees specify their target populations in ways that should be identifiable in secondary data (e.g., behavioral health ICD-9 code, discharge to SNF, discharge to hospice). In some awards, staff may use highly clinical criteria or social factors (e.g., presence/absence of a caregiver) to select which patients to intervene with; the evaluator will need to consider how best to create a CMD-identifiable patient set to mirror these populations. Patients who meet hospital target population specifications would be considered eligible for the intervention. Those defined by a given set of criteria would come from either CHART hospitals or comparison hospitals selected for their similarity to CHART hospitals.

In order to ensure comparability, it is important to consistently apply one set of criteria to create all four groups for the DID analysis (pre-intervention, post-intervention, pre-comparison, post-comparison). The evaluator will therefore use secondary data to develop a single set of criteria for each subgroup of Awardees that mirrors the Awardee registries as closely as possible, and then apply those criteria identically to create all four groups. In doing this, a balance must be struck between analytic samples that are too broad, and those that are too specific.

2.2.6 Outcomes and Explanatory Measures

Almost all CHART Phase 2 Awardees have a primary goal of reducing inpatient readmissions or ED revisits. The analysis will therefore focus on these two outcome measures, although other outcomes

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of interest to hospitals or HPC staff could also be included (e.g., preventable readmissions, length of stay). Outcomes can be tailored to best measure progress towards Awardee-level goals. For instance, improved effectiveness of behavioral health care can be measured as reduced inpatient readmissions and/or ED revisits among hospitals targeting behavioral health patients, based on the expectation that effective services will reduce inappropriate hospital utilization. All outcomes will be determined through dialogue with HPC staff, and selection will require a careful balance between the HPC's primary interests, feasibility of measuring the outcome(s) with the available data, and anticipated additional level of effort.

Although it is important to analyze changes in standard measures of utilization (e.g., rate of ED revisits within 30 days, rate of inpatient readmissions within 30 days), limiting the analysis to these measures may fail to capture the full effect of the intervention, since it would not account for visits to the ED or inpatient admissions that were avoided altogether due to the intervention.^v To account for episodes of care that were avoided completely, the evaluator will employ a cohort-based design that tracks eligible patients from the first appearance in the data indicating eligibility for the intervention. For example, at Awardee hospitals that target high utilizers (and comparison hospitals for such Awardees), once a patient reaches the Awardee-designated threshold for high utilization (e.g., 4 inpatient admissions in the last 12 months) that patient would be included in the analytic sample. Evaluators would then estimate changes in total utilization per unit of time (e.g. quarterly or for the entire length of the program) between eligible patients who received the intervention and those who did not.

All outcomes will be risk-adjusted for patient characteristics using a regression modeling approach. Anticipated control variables include patient demographics (e.g., age, gender, community income, and patient health (e.g., Charlson Comorbidity Index). To the extent possible, evaluators should also control for hospital characteristics that may affect outcomes such as size, location, system membership, local market hospital concentration, or payer mix. However, lack of variation in characteristics (e.g., all CHART hospitals are non-profit) may make it infeasible to control for certain characteristics at the hospital level.

Changes in outcomes will be reported in two formats. First, quarterly estimates will be reported in chart format covering all intervention quarters, and estimates in the charts will include 95% confidence intervals. Additionally, a single estimate pooled over time will cover the average change in outcomes over the life of the CHART Phase 2 investment. It is likely that the quarterly estimates will be underpowered, but will help to illustrate the trajectory of the intervention. Conversely, a single point estimate pooled over time is less informative than knowing how the outcomes changed over time, but will increase the power available to detect a significant difference in outcomes.

^v That is, a readmission or ED revisit requires a patient to appear in the hospital in the first place. If the intervention prevents the first admission or ED visit, then there can be no readmission or revisit.

2.3 Quantitative: Sustainability: Estimated Return on Investment (ROI)

CHART Phase 2 intends to transform care delivery to emphasize appropriate use of primary care and community based services, and to reduce inappropriate and avoidable use of emergency department and inpatient care. At the end of two years, more care is expected to be provided to the target populations in non-hospital settings, and less in hospital settings. The substitution of non-hospital care for hospital care is expected to improve population health status while reducing episodic and overall costs. The Commonwealth is making substantial investments in CHART hospitals, contributing financing as well as TA and other supports. The HPC is interested in knowing whether the return (savings) on the government's investment are greater than the dedicated costs. Return on investment or ROI, is commonly calculated as

$$\text{(Gains or savings - Cost) / Cost}$$

ROI can be calculated repeatedly to understand the trajectory and whether ROI is accelerating over time. The shift from avoidable hospital utilization to appropriate community-based care will likely gain momentum over the course of the next two years, as CHART hospitals improve their care management, patient engagement, information sharing, and community partnerships.

The sections below describe the gain (savings) component of the equation, and the investment (cost) component. Ultimately, this ratio must be interpreted in light of the qualitative insights the evaluation will be able to offer about sustainability of ROI after the program concludes. Secondary data will be used to estimate ROI of the CHART Phase 2 investment, complemented by qualitative findings regarding potential for sustaining these returns.

2.3.1 Gains/Savings

Hospital utilization can be measured using CMD data, but that data source does not include actual spending. Therefore, ROI will be estimated, using average spending associated with changes in utilization which the HPC will derive from the APCD. The evaluator will use secondary data from the CMD to measure the utilization reductions that most CHART awardees aim to achieve, and will use those measured reductions, together with imputed average costs, to estimate the savings resulting from those avoided episodes.^{vi} Measuring the true ROI would require information about utilization and costs of care in both hospital and non-hospital settings, which is not in-scope currently for this evaluation.

The calculated averages (generated by the HPC) will be specified to be consistent with the type of patients defined by the analytic sample (e.g., average encounter spending for behavioral health patients, average encounter spending for high utilizers), and could be modeled to allow for variation based on observable patient characteristics (e.g., average encounter cost for male behavioral health patients under 35 years of age). Estimated changes in spending produced in this way would not allow evaluators to determine whether the estimated change was significantly different from zero, however the magnitude of the estimates combined with other quantitative and

^{vi} The two capital projects as well as the Baystate Joint project will not be considered in the secondary data analyses or ROI.

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qualitative findings would give a strong indication of whether the program was successful in reducing spending.

2.3.2 Investment/Cost

The investment amounts for each of the 25 Awards are the most tangible cost element of CHART Phase 2, but not the only one. The HPC is also dedicating staff time to work with Awardees, providing TA, monitoring performance, and supporting mid-course corrections. The HPC carefully documents time spent on calls and TA, and FTEs dedicated to CHART Phase 2. Cost will be captured through document review of HPC records.

2.3.3 Analysis and Reporting

The ROI analysis could be performed twice: the first time in the Interim Report, to provide an early indication of ROI, and again in the Final Report. The ROI calculation can be performed separately for various phases of the intervention (e.g., four times, with six-months of data each time). The reason for repeated calculations is to show the trajectory of ROI, which may start somewhat slowly, with more costs than gains in the first year, and gain momentum until gains meet or exceed costs at the end of the second year. Understanding this trajectory will be useful for the HPC when planning future investment programs. However, ROI calculations at the 6-month level may be underpowered, and so a single ROI covering the full length of the investment will also be computed. Results presented in the final ROI report can also compare outcomes based on subgroups, to provide insight as to which approaches provided the best ROI. For example, evaluators could compare the ROI of ED-focused interventions to those of inpatient interventions, or interventions targeting behavioral health patients to those targeting high utilizers.

The final ROI report will include qualitative information about critical Awardee program components that must continue if gains are to be sustained. The ROI report will also include information gathered during call-backs conducted 1-2 years after CHART Phase 2 ends, regarding whether Awardee hospitals were able to marshal other resources to sustain these most essential program components, and will offer an evidence-based prediction as to whether the ROI calculated after two years of program funding and support is likely to be fully or partially sustained.

2.4 Qualitative: Implementation, Impact, and Sustainability

2.4.1 Hospital Case Studies

Case studies are ideal for exploring “how” and “why” complex organizational processes occur in real world settings.⁴² They are also valuable for exploring implementation processes, adherence or deviation from what was intended, and the facilitating factors and barriers to success. Case studies will be conducted with all 27 hospitals early in the first evaluation year with a follow-up wave in Year 2, and will involve site visits, interviews and focus groups with CHART Awardee program staff and frontline providers, and possibly with a small number of patients who have experienced the program at some selected hospitals. The case study approach is designed to address the qualitative aspects of each of the nine research questions (Exhibit 3). Specific case study topics will be chosen with the HPC. This will likely occur after Wave 1 interviews.

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Case study findings and qualitative data can be analyzed and reported at the individual hospital level, for the subgroups of hospitals that parallel those used for quantitative analyses, and across the entire CHART Phase 2 set of investments.

The case study approach will be the main evaluation of the two capital projects as well as for the Baystate Joint Award. These investments are different from the other care delivery investments as they involve paying for capital build outs or are used to reimburse tele-medicine consults. Additionally the HPC may wish to have case studies on specific investments, especially larger joint hospital awards.

Finally, crosscutting themes will be identified, across subgroups of hospitals and among high and low performers, to inform evaluators' assessment of implementation effectiveness and impact as perceived by participants and stakeholders. Questions about program sustainability will also be addressed in the second wave of case studies and through a final follow-up interview one year after the investment period ends.

Parallel methodologies will be used to examine each hospital, using a standard protocol tailored as necessary for each unique program. Use of the same protocol will facilitate coding, memo development, and analysis of cross-Awardee themes. In order to protect the identity of participants, case study findings can be reported across groups or subgroups of Awardees and/or at the program level.

2.4.2 Interview Guide Development and Validation

Topics to be explored with the 27 hospitals include the hospital's management capacity, data analytics and performance metrics, care delivery redesign, and hospital-community partnerships (see Exhibit 5 for examples). These hospital activities and processes, associated changes over time, and the context within which hospitals are operating, will be the focus of case studies. Contextual factors, inputs and assistance from HPC staff, the role of financial incentives, and the value of formative feedback and benchmarking will also be explored.

The initial case studies with all 27 hospitals will help to further identify subgroups of hospitals that are similar enough for reasonable and useful qualitative analyses, based on factors of interest to the HPC (e.g., highly coordinated to less-coordinated care delivery systems, behavioral health initiatives, information technology use, region, competitive landscape). Follow-up case studies will be conducted in the second evaluation year with all hospitals—virtually with most, and in-person with a strategically selected subset—to further explore important themes, identify solutions for overcoming barriers, and understand the potential for sustainability. Summative themes across subgroups of hospitals and high/low-performers will inform how and why certain aspects of the programs were successful, cost effective, and sustainable. Understanding both facilitating factors and barriers to program success are essential to improving future investments and for enhancing sustainability.

Semi-structured interview and focus group guides will be developed at the beginning of the evaluation period and used for case study data collection. The evaluation conceptual model and research questions, and initial reviews of program documents, will inform the content and structure of these guides. Guides will be designed so that all key research domains and questions are addressed, but will allow interviewers the flexibility to pursue additional relevant themes that interviewees introduce.^{43,44}

The topics to be explored during case studies are described in Exhibit 5, and additional topics are likely to arise during the course of the evaluation. The final semi-structured interview guides will

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be organized by type of interviewee (e.g., medical director, community health worker) and the guides will contain the topics to be pursued in each interview.⁴³ The interview guides included in Appendix 4 are offered as examples; they will be expanded and tailored into interview guides for different respondent types.

Exhibit 5: Case Studies Topics

Examples of Possible topics for Case Studies			
Evaluation Framework	CHART Awardee-Level	Subgroup-Level	CHART Program-Level
Implementation	RQ1. Were the program activities effectively implemented by the awardee?	RQ2. Were there subgroup-level patterns in program implementation?	RQ3. Was the CHART program as a whole implemented effectively?
<i>Topics</i>	<ul style="list-style-type: none"> • Care redesign • Workforce development • Patient tracking • Performance monitoring • Data analytics • Community partnerships • Hospital management capacity • Hospital leadership commitment • Challenges, solutions, lessons learned 	<ul style="list-style-type: none"> • Relationship of leadership engagement to implementation • Relationship of data collection and reporting to implementation 	<ul style="list-style-type: none"> • Usefulness and timeliness of CHART TA • HPC support during development of implementation plans • Strategic planning support • Financial risk/incentives • Role of ongoing performance monitoring and feedback
Impact	RQ4. What outcomes were achieved by the awardee?	RQ5. Were there subgroup-level patterns in outcomes?	<ul style="list-style-type: none"> • RQ6. Did the CHART program as a whole accomplished the desired outcomes?
<i>Topics</i>	<ul style="list-style-type: none"> • Stakeholder perceptions of program impact on hospital utilization • Perceived changes in coordination of care • Perceived changes in hospital processes, workflow • Unintended consequences • Challenges, solutions, lessons learned 	<ul style="list-style-type: none"> • Relationship of HIT investment to care coordination • Relationship of availability and capacity of community partners to cross-setting management of BH patients • Impact of inter-hospital communication and learning 	<ul style="list-style-type: none"> • Perception of benefits and support for program continuation by staff, participants, and community stakeholders • Hospital ACO readiness
Sustainability	RQ7. Will the awardee sustain program activities past the CHART Phase 2 period?	<ul style="list-style-type: none"> • RQ8. Are there subgroup-level patterns in program sustainability? 	<ul style="list-style-type: none"> • RQ9. Has the CHART program as a whole produced lasting changes that will continue to benefit stakeholders?
<i>Topics</i>	<ul style="list-style-type: none"> • Program components continued after award • Hospital perception of ongoing costs/ savings • Strategic planning • Sustainability of community partnerships 	<ul style="list-style-type: none"> • Relationship of perceived ROI to program continuance • Relationship of program impact to program continuance • Relationship of program impact to ACO readiness 	<ul style="list-style-type: none"> • Hospital ACO readiness & participation • Modernization of hospital HIT • Hospital capacity for continuous improvement care delivery

2.4.1 Interviews and Focus Groups with Program Staff and Frontline Providers

The evaluator will use purposive sampling techniques^{45, 46} to select a range of service providers to interview at each hospital and from relevant community partner organizations, who are knowledgeable about Awardee organizational structures, decision-making processes, patient engagement, care coordination, and workflow processes of importance. The interviewees selected will be tailored as needed to reflect each hospital's structure and program. Interviewees at each hospital will include the CHART executive sponsor, program manager, clinical and operational investment directors, frontline clinicians and staff implementing the program (e.g., physicians, nurses, psychologists, social workers, community health workers), the program data manager/analyst, and, where applicable, an ACO administrator and the director of health IT. Recognizing the key role of community partners as outlined in implementation plans, it will be important to identify key partner organizations and interview a member of the senior leadership team from each (e.g., the executive director, clinical director, or another senior administrator) who is most responsible for interfacing with the Awardee hospital.

2.4.2 Patient Perspective Study

Patient engagement is likely to be an important feature of the success of CHART Phase 2 initiatives. Identifying target population patients when they are admitted, and proactively engaging them in an ongoing and collaborative relationship after they leave the hospital, may be new activities for many CHART hospitals. Given the HPC's aim of moving hospitals toward accountable, patient-centered, integrated care delivery, it would be useful to understand which aspects of patient engagement are effective from the patients' perspective as well as from the perspectives of hospital and HPC staff.

Obtaining patient perspectives is an important goal, but must be conducted with respect for the patient. Patients in many target populations have particular vulnerabilities, especially regarding privacy and consent. Methods for obtaining patient perspectives will consider best practices for vulnerable populations, consulting with experts, community organizations, and advocates as appropriate.

The evaluator will engage in key informant interviews and focus groups with approximately 100 patients that have received project-specific health care services at CHART Investment program hospitals. By starting with individual interviews that are broad in scope, the evaluator will identify specific themes that patients identify as important, which the team can then use to shape the interview guides for focus groups, bringing together small groups of patients (defined by similar demographic and care experiences) to discuss their experiences related to those specific themes.

2.4.3 Organizational Survey

Overview

A goal of CHART Phase 2 is for hospitals to develop capacities for accountable, patient-centered, fully-integrated care delivery. In addition to case studies, document review, and interviews with HPC staff, primary data about "ACO readiness" will be captured through an organizational survey. The organizational survey will be conducted at two points during the evaluation—at the earliest and latest possible stages—to maximize the evaluators' capacity to observe and measure change.

Instrument Development and Validation

The organizational survey instrument will be based on an existing instrument, but customized to assess ACO readiness in CHART hospitals. The criteria for assessment will be aligned with the HPC criteria for ACO certification, though focused on those areas relevant to CHART Phase 2.

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The survey will be based on the *National Survey of Accountable Care Organizations (NSACO)*, or a similar existing survey. Developed by the Dartmouth Institute for Health Policy and Clinical Practice and first fielded in 2012 – 2013, the NSACO survey instrument collects organizational data, including staffing structures, financing models, and internal performance measurement, from over 250 “early” ACOs (i.e., those founded before July 2013).⁵¹⁻⁵⁵ Administered electronically, the survey contains approximately 100 questions. A subset of the NSACO’s questions have also been extracted and used in the development of a readiness self-assessment tool for ACOs.⁵⁶ The evaluator may contract with a qualified expert, such as the authors of the survey, to customize and validate the new instrument.

Another survey instrument that may be used in its entirety or in part by the evaluators is the *National Survey of Physician Organizations (NSPO)*. Administered electronically, the NSPO survey instrument collects information related to management and governance of the organization, implementation of care management processes, care coordination, care delivery, chronic disease, health IT, and organizational culture.

Data Collection Approach

Respondents. The NSACO requires only a single respondent who is deemed to be the most knowledgeable about the questions of interest – generally a CEO, CFO, or ACO administrator. In keeping with this strategy, and to reduce burden associated with data collection, the evaluator will administer the organizational survey to a single respondent at each CHART hospital. A similar approach will be used if using a different survey instrument.

Survey Administration. The organizational survey should include no more than 30-40 items and take less than 15-20 minutes to complete, to minimize burden and enhance response rates. The survey would most efficiently be implemented electronically, if email addresses for respondents are available. Respondent telephone numbers will also be needed to follow-up with non-respondents and address any concerns that prevent their response.

Analysis and Reporting

Descriptive statistics will be prepared for each survey item, with both mean and median responses. Some items may be collapsed into scales or indices within domains. The small number of respondents will preclude regression-based analysis, but cross-tabulations will display any differences based on hospital size, specific CHART program goals, or other salient characteristics. The evaluator will compare survey responses from the first and second survey waves to examine changes over time, and the time elapsed between the two waves of the survey should be as long as possible to maximize the period during which changes may occur.

Survey data can be analytically linked to coded case study data, using analytic software, as part of the mixed-method analysis. Survey responses may also be linked with secondary data to complement quantitative analyses and to understand characteristics of high and low-performing sites. Key survey responses could be included in bivariate models (subject to limitations related to statistical power). Findings from the first wave of surveys could also be used to inform case study interview guide modifications and be used as criteria to stratify or select sites for follow-up in-depth case studies in the second year.

Analytic findings from the organizational survey will be included at the overall program level (not the individual hospital or subgroup level) in both the interim and final reports.

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2.4.4 Behavioral Health Integration Survey

A behavioral health integration survey will be used, for applicable awards, to assess changes in delivery of BH services. (Awards without a BH focus may also be surveyed as a comparison group.) The Integrated Practice Assessment Tool (IPAT) is proposed for this purpose because it is short, simple, and well-aligned with the HPC ACO certification criteria for BHI. Created under contract with the SAMHSA-HRSA Center for Integrated Health Solutions in 2014, this survey documents practices' facility, staffing, and care delivery structures as they relate to behavioral health integration.⁵⁹ IPAT is a decision tree that grades a medical practice as level 1 through 6 (see appendix 2). Some changes in wording may be needed to make the instrument appropriate for use in a hospital setting. This survey will be conducted twice, in parallel with the organization survey, to capture changes during the program period.

2.4.5 Qualitative Data Coding and Analysis

The evaluator will use a relational database designed to support qualitative research analysis, which can be used in the field by teams of researchers (e.g., Dedoose, NVivo). These software tools offer evaluators flexible data entry and analysis, including hierarchical coding schemes, report generation (such as dashboard metrics), and modifiable charts and graphics. Such tools can be used by a team of Evaluators through a secure online platform, with continuous access and real-time data sharing, with tight controls for access levels and version management.

After the first two case studies, researchers will develop a codebook of key themes, organized to follow the topics in the interview protocols. Two or more researchers will independently cross-code several interviews and then meet to discuss divergence, refine the codebook, and continue to cross-code and revise until coding is consistent.⁴⁴ This process improves inter-coder concordance and reduces the influence of the coder on the eventual data. Additional themes will be added to the codebook, as additional case studies are completed and new themes emerge.^{11,12}

Content analysis of documents, and interview and focus group notes, will focus on shared and contrasting themes within and across hospitals, and within subgroups of Awardees.⁴⁷ Analytic strategies for coding and classifying data will be employed such as convergence (i.e., looking for recurring regularities, patterns, and category development) and the mirror strategy of divergence (i.e., looking for inconsistencies and deviations in the data and cases).⁴⁷ Comparative tables will be developed across relevant subgroups that summarize similar and divergent themes. This process will facilitate the cross-case identification of themes related to implementation effectiveness, and variation between high- and low-performing Awardees.

2.4.6 Document Review

The HPC has worked closely with Awardees to design their implementation plans, and will continue to provide TA, review Awardee-reported metrics, and advise Awardees about adaptations that will help them stay on track and enhance program impact. For example, the HPC plans to hold bimonthly calls with Awardees, conduct webinars addressing common issues and challenges, and have other interactions with Awardees aimed at helping them succeed with their specific initiatives.

Each Awardee's implementation plan specifies how they will achieve specified aims and program goals. Plans contain concrete utilization reduction aims. Awardees intend to reduce inappropriate hospital utilization or ED use for target populations. Understanding the nature of activities and processes that Awardee's intend to implement to achieve these goals will help evaluators understand whether the program designs were successfully implemented.

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Some Awardees are likely to revise their implementation plans over time, with HPC approval, and will document these important course corrections to the HPC. Evaluators will keep abreast of Awardee changes throughout the program in collaboration with the HPC, and particularly those modifications that result from TA and rapid-cycle performance feedback. Implementation plans, change requests that Awardees make to the HPC, Awardee periodic reports, and periodic interviews with HPC staff, will be especially useful for understanding what changes were made over the course of the investment and why they were made. The evaluator will review any implementation plan changes and code the types of adaptations or revisions made. Changes in staff hiring and roles/assignments, target populations or in intended outcomes, the use of technology and selected vendors, and other key activities can then be assessed as part of the analysis of implementation effectiveness.

2.4.7 Interviews with CHART Staff

Periodic interviews will also be conducted with the CHART program officers and other key CHART staff to capture their evolving perceptions of implementation effectiveness and factors associated with program success. Questions for HPC staff will explore how the HPC supports CHART hospitals in enhancing capacity, delivery system transformation, advancing hospital ACO readiness, and other topics. Content analysis will be conducted to understand themes that cut across the CHART program and subgroups of hospitals.

2.4.8 Survey of CHART Technical Assistance (CHART-TA) and Investment Management Activities

Throughout the program period, the HPC will provide extensive TA and other investment management supports to CHART Awardees, and would like to know which TA and supports are most useful, and what additional support Awardees would find useful that could be offered by the HPC. To that end, the HPC will conduct an Awardee “CHART-TA Survey” about CHART’s TA offerings, to be repeated at strategically timed intervals throughout the investment period. The goal of the CHART-TA Survey will be to understand how effectively the HPC has supported CHART hospitals to build capacity, achieve utilization reduction goals, and advance ACO readiness. This information will be used by evaluators to understand the inputs that drive change, and will also be useful for the HPC in their future work with hospitals. The evaluator will use the results of TA surveys, together with document review of Awardees reports, and periodic interviews and focus groups with Awardees and the HPC, to better understand the impact of this iterative feedback and improvement process. The Interim report and Final Summative report will include findings regarding the role of TA in the continuous performance improvement process, including survey results where appropriate.

2.4.9 Data Collection Timing

Wave 1 Case Studies: To capture common themes across the 27 diverse CHART hospitals, case studies in Year 1 (Spring 2016) will include one-day site visits to each hospital during which interviews will be conducted with key program staff, as well as interviews or focus groups with frontline clinicians. If a hospital is working with community organizations, the case studies will include these key partners, either during the one-day site visit or through follow-up telephone interviews. The evaluation team will work with the 27 hospitals to understand their initiatives, identify key interviewees, schedule these one-day visits, and optimize evaluators’ time on-site.

Wave 2 Case Studies: Case studies in Year 2 will be conducted by phone with all hospitals, and the evaluators also will focus more intensively on a strategically-selected subset using a combination of in-person and telephone interviews and focus groups. Findings from Wave 1 of the organizational survey and Year 1 of the case studies will be used to inform the selection of hospitals for detailed

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follow-up in Wave 2. For example, if the Year 1 case study identifies a hospital whose behavioral health initiative appears to be working particularly well, Year 2 interviews with program staff and focus groups with behavioral health providers would illuminate the factors responsible for implementation success. A similar approach will be used to identify hospitals that are struggling with common implementation challenges, for in-depth investigation in Wave 2.

Year 2 follow-up case studies (whether virtual or in-person) will capture characteristics of program maturation and contextual changes. Findings from this wave will also be used to interpret findings from surveys and secondary data analyses. The second case study wave will explore the evolution of the initiatives, as well as changes in the nature of engagement with community stakeholders, target patient groups, use of technology and tools, and any other important developments. While the same interview domains should be explored in Waves 1 and 2 to ensure consistency and permit identification of changes, additional research questions can be explored in Year 2 based upon the information that emerged in the Year 1 analyses, document review, and surveys. For example, changes in the environment—contextual factors—may be important barriers or facilitators, and these may accelerate or subside over the two program years. A key focus of the second wave of case studies will be assessing the potential for sustainability and additional inputs that would improve the likelihood of sustainability.

Post-Phase 2 Follow-up: The potential for sustainability can be ascertained during the second round of in-depth case studies, but ultimately the question of sustainability will be best answered a year or two after the investment period ends. This question will be explored through a follow-up telephone interview with each of the CHART Awardees (all 27 participating hospitals) to learn about which program components continued, which changed in important ways and why, and which did not continue. For example, newly-hired staff (e.g., care managers or navigators) might not be supported after investment funding ends, but some of their responsibilities may be shifted to existing staff (e.g., social workers) to preserve some of the most important program components. The results of this follow-up call will inform the HPC as to which program components were so valuable to the hospitals that they preserved them, and which program components were either too costly or of such marginal value that they were not sustained. These calls should be structured, last 5-10 minutes, and should be completed just once.

2.5 Synthesis: Integrating Quantitative and Qualitative Findings

This evaluation will take advantage of multiple data sources and methods to answer the research questions. These methods will be complementary, and results of some assessments will inform later data collection and analysis. Information from document review and interviews with HPC staff will help evaluators focus both primary data collection and secondary data analysis. For example, if many Awardees make important changes and results improve thereafter, evaluators may decide to pool and analyze secondary data for specific time periods (e.g., Year 1 vs. Year 2). In this way, disappointing early results can be distinguished from later successes. For another example, if target populations are narrowed to enhance focus and impact, the evaluation criteria applied to secondary data to construct comparison groups will also need to be narrowed. In addition, revised implementation plans and information from routine calls will help evaluators revise their interview guides to explore why Awardees made changes and what they see as the positive impact of these changes.

Synthesis of results from different sources also will aid in interpretation of the findings. Even a well-implemented hospital program that accomplishes all of the activities in the center of the conceptual model may fail to have statistically significant impact on readmissions or ED use due to the small population size, and short time period. This would not mean that the activities were

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useless—they may improve care delivery and prepare hospitals and their community partners to participate in accountable care. In this case, qualitative findings will provide documentation of positive impact of the program.

The strength of this mixed methods evaluation design is that it separately considers several program attributes using different data sources—whether the hospitals have the necessary inputs (qualitative data, Awardee CHART-TA Survey), programs are *implemented effectively* and accomplish important aspects of readiness for accountable care (qualitative data), the organizational capacities and capabilities are enhanced (organizational survey, qualitative data), and the program as a whole has an impact on the CHART program aims (secondary data).

The analysis to answer some research questions will be formative – conducted early, and often repeatedly – to support mid-course corrections. The organizational survey, TA survey, and case studies can all make important formative contributions. The analyses to answer other research questions will be summative, providing a “bottom line” assessment of what the program accomplished, and these analyses are generally based on a measure of change (pre/post, DID).

Together, all of these components are essential for understanding whether the Phase 2 CHART investment, CHART’s intensive TA and investment management approach, and all of the activities undertaken across the two years of program implementation are successful in preparing CHART community hospitals to deliver patient-centered, fully accountable care.

3. Data Security and Human Subjects Protection

At this time there are three components of the evaluation that are anticipated to involve interaction with human subjects:

1. Organizational and behavioral health surveys will involve Awardees' program staff
2. Case studies will involve interviews with Awardees' program staff
3. Patient interviews will involve contact by the evaluator. IRB approval of communication processes and materials will be obtained and complied with.

3.1 Human Subjects Protection

The evaluator will be responsible for determining the need for, and development and implementation of a plan for, compliance with all applicable IRB review requirements, in coordination with Awardees.

3.2 Data Security Plan and Data Use Agreements

The evaluator will be responsible for development and implementation of a Data Security Plan to establish appropriate administrative, technical, and physical safeguards to protect the confidentiality of all project data, including secondary data, and to prevent unauthorized use, access or disclosure of data. The safeguards shall provide a level and scope of security that is consistent with 45 CFR § 164.530(c) and any applicable federal or state privacy law, implementing regulation or executive order.

The evaluator will be responsible for development of a standard data use agreement (DUA) template between the evaluator and Awardees for receipt of data, and tailored to meet the requirements of each Awardee hospital's requirements, as necessary.

The evaluator will be required to execute a confidentiality agreement(s) or DUA(s) for secondary data as specified by the HPC.

4. Evaluation Timeline and Deliverables

4.1 Deliverables

4.1.1 Data Collection Instruments and Interview Guides

All evaluation instruments and data collection protocols will be drafted and submitted to HPC according to the schedule listed below in Exhibit 6; these will be developed in collaboration with the HPC. Materials will include the organizational survey and HPC-TA survey instruments, interview and focus group guides to be used during the case studies and quarterly discussions with HPC Program Officers. Instruments will be submitted electronically to the HPC for their review and comment. After the HPC's suggested edits have been sufficiently addressed, a "final" set of documents will be submitted for IRB approval.

4.1.2 Baseline Summary

The Baseline Summary will provide a summary of Awardee-level baseline measures from Awardee self-reported data, and both Awardee-level (where appropriate) and program-wide utilization baselines from Case Mix Data (CMD). Awardee-level and program level baselines derived from CMD will serve as pre-intervention measurements for later impact analyses. Quantitative summaries will be synthesized with hospital implementation plans and review of Awardee periodic reports to summarize the starting point for each Awardee or cluster of Awardees.

4.1.3 Interim Report of Findings

The Interim Report of Findings will include analyses from the first wave of qualitative data collection (e.g., case studies, interviews with HPC POs, and document review), the organizational survey, as well as findings regarding the role of TA in the continuous performance improvement process, including results of the HPC-TA surveys where appropriate. Qualitative findings will be reported at the Awardee, subgroup, and/or program level as appropriate. Organizational survey analyses will be reported at the program level.

Due to lags in secondary data, quantitative analysis in this report will be limited to pre/post estimates of changes in target outcomes derived from Awardee-provided aggregate data. Estimates will be reported in graph form, displaying changes in outcomes at the quarterly level through the period covered by the interim report.

4.1.4 Thematic Reports

Themes that contribute to each hospital moving towards their goal, or not moving towards their goal, will be shared electronically with the HPC in the form of case study reports. Theme reports will be developed as stand-alone, short-form written reports, anticipated to be between five and fifteen pages in length, and include design elements like call-outs for quotes, data tables, graphs, illustrations, photos, maps, and/or other content. The evaluation team will work with the HPC to decide which themes to highlight in case studies after each round of case study interviews and focus groups.

4.1.5 Patient Perspective Report

The findings of the patient perspective study will be shared electronically with the HPC as a stand-alone report, and then will be integrated into the final summative report.

4.1.6 Case Study Awardee Memos

A synthesis of each Awardee's Wave 1 qualitative analyses and Wave 2 qualitative and quantitative analyses will be shared electronically with the HPC in the form of a brief memo (2-5 pages). These memos will identify how the Awardee is doing on a variety of domains explored in the case study interviews.

4.1.7 Final Summative Report

The Final Report will present all findings from both waves of case studies and surveys, including a summary of changes in qualitative findings and survey analyses between Waves 1 and 2. Other qualitative data collected throughout the investment program, such as the periodic interviews with HPC Program Officers and program document review, will be included in the qualitative data analysis. The Final Report will also describe findings regarding the role of TA in the continuous performance improvement process, including results of the HPC-TA surveys where appropriate. Qualitative findings will be reported at the Awardee, subgroup, and/or program level as appropriate (section 2.2). Organizational survey analyses will be reported at the program level.

The report will also include the most rigorous and up-to-date set of quantitative estimates (pre-post and difference-in-difference) derived from secondary data (CMD). For those awards selected for pre-post secondary data analysis, Awardee-level baselines derived from Case Mix data for the baseline summary will serve as pre-intervention measurements for these impact analyses. Additional subgroup populations may be defined based on interim findings, requiring additional CMD baselines. Quantitative estimates will be presented in two formats. First, quarterly-level estimates will be presented in graph format to track trends in outcomes over the course of the investment. Graphs will present both point estimates and associated 95-percent confidence intervals. It is likely that estimates at the quarterly level will be underpowered to detect significant differences, but they will provide valuable information on the trajectory of changes. In order to provide summative results for the entire span of the investment period, a single point estimate will also be reported that covers the average change from the baseline period over the entire span of the investment. These point estimates will have greater statistical power than the quarterly-level estimates, increasing the chance of detecting statistically significant changes in outcomes. The final report will also include the ROI for the CHART investment. This will include the estimated ROI for each six-month interval of the investment, as well as a final, overall ROI spanning the entire length of the investment period. The report will discuss the estimated ROI in the context of qualitative results, in order to summarize the anticipated sustainability of the changes attributable to CHART.

Qualitative and quantitative results will be synthesized to provide a comprehensive response to HPC's research questions, summarizing the extent to which individual Awardees and the HPC met their stated goals.

4.2 Timeline of Deliverables

Exhibit 6. Timeline of Deliverables

Contract Year (Calendar Year)	Year 1 (2016)			Year 2 (2017)			Year 3 (2018)				Year 4 (2019)	
	Month	July	Oct	Dec	Jan	Apr	July	Jan	Apr	July	Oct	Jan
Due Date	7/31	10/31	12/15	1/31	4/30	7/31	1/31	4/30	7/31	10/31	1/31	
Final Evaluation Design	■											
Primary Data Collection												
Interview Guides		■										
Finalized Qualitative Study Plan		■										
Site Visit Results					■					■		
Patient Perspective Study Results							■					
Surveys												
Customized TA Survey Instrument		■										
Customized Organizational Survey Instrument		■										
Aggregated Organizational Survey Results				■			■					
Customized BHI Survey Instrument		■										
Aggregated BHI Survey Results				■			■					
Customized Template for Awardee PI data		■										
Performance Monitoring												
Case Study Awardee-level Memos					■			■				
Reports including all elements¹												
Baseline Summary			□	■								
Interim Report of Findings					□	■						
Patient Perspective Summative Report							□	■				
Theme Reports									□	■		
Final Summative Report										□	■	

□ = Draft Deliverable ■ = Final Deliverable

¹Reports will include all of the following elements: Written report, presentation, cleaned datasets, quantitative and qualitative coding and analytic files. Survey and interview respondents will be de-identified.

Note: At least monthly progress meetings with HPC Staff will occur, and Quarterly Update Reports will be submitted by BUSPH to HPC.

5. Appendices

Appendix 1. CHART Phase 2 Awards

Hospital	Total Award
Addison Gilbert Hospital	\$1,269,057
Anna Jaques Hospital	\$1,200,000
Baystate Franklin Medical Center	\$1,800,000
Baystate Wing Hospital	\$1,000,000
Berkshire Medical Center	\$3,000,000
Beth Israel Deaconess Hospital - Milton	\$2,000,000
Beth Israel Deaconess Hospital - Plymouth	\$3,700,000
Beverly Hospital	\$2,500,000
Emerson Hospital	\$1,200,000
Harrington Memorial Hospital	\$3,500,000
HealthAlliance Hospital	\$3,800,000
Holyoke Medical Center	\$3,900,000
Lawrence General Hospital	\$1,482,654
Lowell General Hospital	\$1,000,000
Marlborough Hospital	\$1,200,000
Mercy Medical Center	\$1,300,000
Milford Regional Medical Center	\$1,300,000
Baystate Noble Hospital	\$1,200,000
Signature Healthcare Brockton Hospital	\$3,500,000

Winchester Hospital	\$1,000,000
Joint Hospitals	Total Award
Athol Memorial Hospital, Heywood Hospital, and HealthAlliance Hospital	\$2,900,000
Addison Gilbert Hospital, Beverly Hospital, Winchester Hospital, and Lowell-General Hospital	\$4,800,000
Southcoast Hospitals Group - Charlton Memorial Hospital, Tobey Hospital, and St. Luke's	\$8,000,000
Hallmark Health - Melrose-Wakefield Hospital and Lawrence Memorial Hospital	\$2,500,000
Baystate Franklin Medical Center, Baystate Noble Hospital, and Baystate Wing Hospital	\$900,000

Appendix 2. The Standard Framework for Levels of Integrated Care

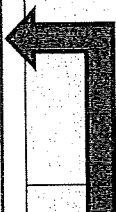
	COORDINATED Key Element: Communication		CO-LOCATED Key Element: Physical Proximity		INTEGRATED Key Element: Practice Change	
	Level 1 Minimal Collaboration	Level 2 Basic Collaboration at a Distance	Level 3 Basic Collaboration Onsite	Level 4 Close Collaboration Onsite with Some System Integration	Level 5 Close Collaboration Approaching Integrated Practice	Level 6 Full Collaboration in a Transformed/ Integrated Practice
System Components						
Physical Location	Separate facilities	Separate facilities	Same facility not necessarily same offices	Same space in the same facility	Same space in same facility (some shared space)	Same space in same facility; sharing all practice space
Systems	Separate	Separate	Separate	Somewhat shared, like scheduling or medical records	Somewhat shared, and staff actively pursue system solutions or "work-arounds"	Fully integrated and functioning as a single system, which most or all system issues resolved
Communication	Rarely, and about cases only under compelling circumstances	Periodically, about shared patients	Regularly, about shared patients, by phone or e-mail	In person, on an as needed basis	In person, on a frequent basis	Consistently, at the system, team and individual levels
Collaboration	Provider need	Specific patient issues	Need for each other's services and more reliable referral	Need for consultation and coordinated plans for difficult patients	Desire to be a member of the care team	Shared understanding of team care
Staff Interaction	May never meet in person	May meet as part of larger community	Meet occasionally to discuss cases due to close proximity	Have regular face-to-face interactions about some patients	Have regular team meetings to discuss overall patient care and specific patients	Have formal and informal meetings to support integrated model of care
Staff Roles	Have limited understanding of each other's roles	Appreciate each other's roles as resources	Feel part of a larger yet non-formal team	Have a basic understanding of roles and culture	Have an in-depth understanding of roles and culture	Have roles and cultures that blur or blend

Appendix 3. Full Logic Model

Problem statement: Fragmented and inefficient care delivery contributes to excess spending on care that does not improve health. Low-priced community hospitals lack the resources to improve their care delivery systems. This can inhibit these hospitals from participating effectively in accountable care, making the hospitals financially unsustainable and ultimately depriving the evolving outcome-driven healthcare system of these lower-cost providers.

Inputs	Activities	Outputs	Outcomes	CHART goals	Long-term goal
<p>CHART Phase 2 award supporting:</p> <ul style="list-style-type: none"> • Staff for: <ul style="list-style-type: none"> ○ Clinical care ○ Care coordination ○ Project leadership & management • Enabling tech • Strategic planning • Community partnerships <p>Hospital in-kind contributions</p> <ul style="list-style-type: none"> • Staff • Facilities 	<p>Hospital management</p> <ul style="list-style-type: none"> • Program design • Leadership engagement • Training & hiring staff <p>Program management</p> <ul style="list-style-type: none"> • Strategic planning • Care delivery • Workforce • Sustainability • Performance Self-Monitoring <p>Care Delivery</p> <ul style="list-style-type: none"> • Coordination of care within hospital <ul style="list-style-type: none"> ○ Develop protocols for flagging and managing HU patients ○ Develop individual care plans ○ Deploy complex care teams ○ Deploy case managers, navigators, CHWs ○ Provide medication review & optimization ○ Employ telemedicine consults ○ Follow up post-discharge with calls & visits • Expansion & Integration of BH services <ul style="list-style-type: none"> ○ Identify BH patients in ED 	<p>Process</p> <ul style="list-style-type: none"> • Hospital-wide commitment to transformation • Hospital is staffed with enough care coordination professionals (navigators, CHW, coordinators) • Hospital staff is equipped and prepared to deliver integrated care <p>Coordinated Care Delivery</p> <ul style="list-style-type: none"> • HU patient's full situation informs decision to admit • Social needs identified and addressed through connection with community resources • Complex patient receives intensive case management 	<p>Hospital Primary Goals</p> <ul style="list-style-type: none"> • Reduced admissions • Reduced ED revisits <p>Hospital Secondary goals</p> <ul style="list-style-type: none"> • Reduced Length of stay • Increased Post-discharge Follow-up • Improved Patient Safety 	<p>CHART hospitals move towards accountable, patient-centered, integrated care delivery</p> <p>CHART hospitals increase capacity for testing and adopting</p>	<p>MA Community Hospitals participate effectively in ACOs, PCMH, APMs.</p>

	<ul style="list-style-type: none"> ○ Deploy BH providers in ED ○ Train staff including ED providers in management of BH patients ○ Expand inpatient BH treatment ○ Deploy multidisciplinary care teams ○ Actively manage transition of BH patients into post-acute or community-based care ● Partnering with community providers <ul style="list-style-type: none"> ○ Outreach ○ Warm handoffs ○ IT-facilitated transitions ○ Cross-setting sharing of care plans <p>Analysis</p> <ul style="list-style-type: none"> ● Collect Data ● Report of Data to HPC ● Participate in monitoring & evaluation ● Implement of IT for Population Management ● Review data & HPC feedback, use for continuous QI. 	<ul style="list-style-type: none"> ● Complex patient receives appropriate multidisciplinary care ● BH patient receives appropriate care <p>Effective care across settings</p> <ul style="list-style-type: none"> ● Patients connected with care in community ● Pts successfully transitioned to SNF or other care ● Patient care coordinated across settings <p>Analysis and learning</p> <ul style="list-style-type: none"> ● IT infrastructure and staff knowledge is adequate for monitoring target population ● Target population clearly defined and understood ● Data used both internally and via HPC feedback to inform internal decision making & planning ● Hospitals participate in learning community and incorporate insights into internal decision making & planning 	<ul style="list-style-type: none"> ● Increased Referrals <p>CHART-wide</p> <ul style="list-style-type: none"> ● Hospitals plan for sustainable change in care delivery <ul style="list-style-type: none"> ● Increased hospital culture of self-monitoring, data-driven continuous improvement 	<p>reforms in care delivery</p>
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<p>HPC staff and expert consultants</p>	<p>HPC guidance, technical assistance and performance monitoring</p> <ul style="list-style-type: none"> • Guide program development • Support implementation planning • Create opportunities for learning for CHART hospitals • Monitor implementation • Guide data collection • Data analysis and feedback 	 <p>Increased knowledge base about care delivery reform</p>	<p>Increased dissemination of knowledge about strategies and best practices</p>	<p>HPC disseminates knowledge about strategies and best practices</p>	<p>Knowledge about strategies and best practices drives reforms in care delivery and payment</p>
<p><i>Evaluation framework</i></p>		<p><i>Implementation</i></p>		<p><i>Impact</i></p>	<p><i>Sustainability</i></p>

Appendix 4. Draft Interview Domains

The following are domains and examples of topics to be explored during case studies; each interview guide will be tailored to the individual being interviewed.

Hospital Management Capacity Enhancement and Engagement

1. Is the CHART program an extension of previous work or is it a new initiative?
2. What was the impetus for the hospital to undertake this initiative?
3. What are the key goals of the program?
4. How does this project align with the overall mission and other ongoing initiatives at the hospital?

Target Population

5. What patient populations are targeted in this program? Has the target population changed over the course of the initiative?
6. How are patients identified as being in the target population? Is it based on their “presenting” diagnosis and problem list? Are records reviewed to count previous visits? Are any IT systems used? Is all of this done while they are at the hospital or after they’ve gone home?
7. Is the initiative likely to expand to other populations during the investment period, or after the investment period?
8. What parts of the hospital are involved in identifying target patients and enrolling them in the program? ED, inpatient staff, outpatient departments? What types of staff are involved in identifying and enrolling patients in the program? Have these providers/staff worked together previously on any initiatives to improve quality and/or control costs?
9. After a patient has been enrolled, how are they identified on subsequent return visits – is there a list? Whose job is it to identify enrolled patients when they return? Does this happen 24/7/365?

Care Redesign

10. Was there any deliberate process redesign activity (e.g., LEAN) undertaken in the design phase for this CHART program? What did that involve?
11. Were other programs, tools, or curricula adopted from other sources for this CHART program?
12. What types of staff deliver program services in the hospital? Are these positions supported by the CHART investment? Any new people hired specifically for this program, or did they previously work in other capacities in the hospital?
13. What types of staff deliver program services outside the hospital, after the patient’s visit (e.g., care coordination, ongoing engagement)? Are these staff employed or are they contractors? Are these positions supported by the CHART investment? Any new people hired specifically for this program, or did they previously work in other capacities in the hospital?
14. What is the nature of the intervention: how do program staff work with patients?
 - Patient education

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- Regular check-ins by phone or in person?
 - Group or “peer support” sessions?
 - Coordination with other care providers and community services?
 - Care Team meetings about individual patients?
15. What are the steps in transitioning and enrolling patient from the hospital to other care providers and community services? Is patient data being shared among providers? If so...
- What information is sent to the next provider?
 - What information does that provider return to the program about care they provide to the patient?
 - Is this information exchange automated (using IT)?
16. Who is responsible for care transitions? Is this a dedicated position for the CHART program, or part of the routine job functions of existing staff?
17. Has the CHART program evolved over time? What components were added or changed and why? Anything tried and abandoned because it was not effective?
18. Which components do staff and managers perceive as most impactful? Are different components more/less effective with different types of patients?

Workforce Development

19. Which staffs are involved in the CHART program? Were any hired specifically for this initiative? How did managers determine which skills were needed, and which positions to dedicate to the program?
20. How were staff trained to deliver services and perform their role in the program? Is there a specific training curriculum? How was it developed?
21. How is the training delivered (classroom, via webinar, at the bedside)?
22. Has training been revised since it was first delivered? Is there periodic retraining? If there is staff turn-over, are new staff trained in the same way as the ‘original’ staff?
23. How is the CHART program integrated into the existing workflow for staff at the hospital? Changes to workflows? Changes in shifts/scheduling?
24. Are there new communication strategies, channels, or tools used by program staff? What are these new communication approaches, why were they instituted, do they work well?

Data Analytics and Performance Monitoring

25. Are IT systems (EHR, information exchange, etc.) used as part of the CHART care redesign? How is IT used to identify target populations? Manage patients over time at the hospital? Coordinate with other care providers outside the hospital?
26. Is IT used to identify when enrolled patients visit other hospitals – any sort of ‘alerts’ when this happens? Any information shared with, or received from, other hospitals about ‘frequent fliers’?
27. What data are tracked over time about individual program enrollees? About the entire enrolled program population? Are there any dashboards or run charts that managers track regularly (documentation)? How often are these reports reviewed?

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28. Do any indicators trigger specific actions? For example, if a patient is returning to the ED repeatedly, is this highlighted in data reports and are care coordinators notified to reengage with the patient?
 29. Are you measuring any quality/success indicators? If so, are these specific to the CHART program or are you tracking quality measures for another initiative or payer? In that case, are any QM results being submitted to payers to qualify for shared savings?
 30. Who is responsible for data analytics, dashboards, etc.? Is this person supported by the CHART investment? Does this person have the necessary training and skills?
 31. Do program staff receive regular feedback about how the enrolled population is going? About patients who continue to use hospital services inappropriately?
 32. (Assuming program is using IT-enabled data recording/sharing as part of CHART) Are current IT/data systems adequate to meet all of the CHART program needs? Is it possible to send/receive information from other providers' IT systems – and is this a routine part of the program? Are IT improvements/enhancements needed to better support the CHART program?

Hospital-Community Partnerships

33. Are there specific community providers who work with many of the enrolled CHART program patients? Any preferred providers patients are referred to, who are 'on board' with the program? Any community providers that would be good to include who are not yet involved? Any community providers who refused to participate?
34. How were these community providers selected and how were they brought into the CHART initiative? Are there any formal/contractual agreements with them? Are they part of a larger integrated delivery system?
35. How do CHART program staff learn about the services enrolled patients receive from community providers?
36. Do community partners receive any regular feedback about enrolled patients (e.g., returns to the ED)?
37. Are community partners involved in any team care meetings or care planning for enrolled patients? How does this take place?
38. Has the CHART program changed the relationship between the hospital and any community providers – in what ways?

Hospital Management Capacity, Enhancement, and Engagement

39. What elements of the CHART program have been implemented so far and what elements are forthcoming? Has the timeline changed over time? What caused any delays?
40. What is the management structure for the program – where does it sit in the hospital organizational chart (which department, which managers, etc.)?
41. How involved has leadership been in implementing and overseeing the CHART program? Who are the main champions for the program? Is there more that leadership could do to support the program?
42. Are senior hospital leaders involved in monitoring program progress? What information do they receive and how often?

43. Do hospital leaders participate in any of the calls, TA, or other interactions with HPC staff? Do they perceive this as useful, and a good use of their time?

Perceived Program Impact

44. Which components of the CHART program are most effective/successful:

- Identifying patients
- Enrolling patients
- Care transitions
- Patient education and engagement
- Tracking patients over time

45. What impact is the program having on use of hospital services? Have enrolled patients had fewer ED visits? Fewer hospitalizations? More outpatient visits to the hospital? How is this tracked?

46. Is this impact on track to meet program goals? If not, are any corrections planned?

47. What impact is the program having on use of non-hospital services (how is this tracked)?

48. What impact is the program having on quality of care? On patient safety? What measures are tracked regarding quality or safety?

49. What impact is the program having on patient engagement in their own care? Patient satisfaction? Are patients surveyed? Any other mechanisms to get patient feedback?

50. What impact is the program having on staff engagement? Staff satisfaction with their jobs and with the care they provide? Are staff surveyed? Any other mechanisms to get staff feedback?

51. Does the program have the necessary resources? What additional resources (staff, IT, other) would make the program more effective?

Challenges, Solutions, Lessons Learned

52. What have been the greatest challenges so far? Any challenges in the following areas:

- Staff hiring and retention
- Staff training
- Identifying eligible patients
- Enrolling patients
- Engaging with patients over time
- Patient compliance with the program – changing behavior
- Ability to monitor program progress for individual patients, or the entire enrolled population
- IT
- Leadership support
- Community partnerships

-
- Resources
 - Anything else?

53. What have been the greatest accomplishments so far? (same list)

54. If you were starting over, would you do anything differently? If another hospital were considering implementing such a program, what would be the most important guidance?

Contextual Factors

55. Are there any regulatory or other requirements that limit the care redesign that is needed for program success (e.g., EMTALA, SNF 3-day rule)?

56. Please describe any other external factors that are affecting the implementation of this initiative.

57. Did the hospital have prior experience with accountable care prior to CHART? (e.g., pay for performance, bundled payments, ACO contracts)?

58. Is the hospital (or its parent health system) in the insurance networks of most major insurers in the state (Medicare Advantage plans, Medicaid plans, commercial payers)?

59. What initiatives (e.g., Quality Improvement programs) existed prior to the implementation of the CHART program that set the stage for this program?

Unintended Consequences

60. Is CHART affecting other non-participating health care providers in your community(s)? Are referral patterns changing? Are other hospitals implementing similar programs?

61. Have patients enrolled in the program shifted to using other hospitals? Or conversely, are they now concentrating all of their services at this hospital, more than in the past?

62. Any other unplanned effects on patients, community providers, or others?

63. If ED visits and hospitalizations have declined, how does this affect the hospital's revenues? Is this loss of revenue problematic?

Sustainability

64. Which components of the program will continue after investment funding ends? Will all staff positions continue? Information sharing with community providers? Follow-up with patients after hospital discharge? Other components?

65. Which components will not be continued? (same list)

66. Where will the resources come to continue program components (future investments, hospital internal resources)?

67. How, if at all, will your experience in the CHART program help you participate in new delivery system/payment reform efforts ongoing in the State?

68. Is the hospital expecting that new ACO or managed care contracts will result from the CHART program, and help to sustain program components?

Appendix 5. Non-CHART Massachusetts Hospitals

Hospital Name	System Affiliation	Teaching Affiliation	Ownership
Mount Auburn Hospital	None	Harvard Medical School	Non-profit
Sturdy Memorial Hospital	None	None	Non-profit
CHA Cambridge Hospital	CHA	Harvard Medical School	Government
CHA Somerville Hospital	CHA	Harvard Medical School	Government
CHA Whidden Hospital	CHA	Tufts University Medical School	Government
Cape Cod Hospital	Cape Cod Healthcare	Cape Cod Hospital School of Nursing	Non-profit
Carney Hospital	Steward	Tufts University Medical School	Proprietary
Bedford VA Medical Center	VA	Multiple Associated Schools	Government
Saint Anne's Hospital	Steward	None	Proprietary
Boston Medical Center*	None	Boston University	Non-profit
St Elizabeth's Medical Center	Steward	Tufts University Medical School	Proprietary
UMass Memorial Clinton Hospital*	UMass Memorial Health Care	UMass Medical School	Non-profit
Morton Hospital	Steward	None	Proprietary
Baystate Medical Center	None	Tufts University Medical School	Non-profit
Holy Family Hospital	Steward	None	Proprietary
Beth Israel Deaconess Hospital - Needham	CareGroup	None	Non-profit
Beth Israel Deaconess Medical Center*	CareGroup	Harvard Medical School	Non-profit
Nashoba Valley Medical Center	Steward	None	Proprietary
Northampton VA Medical Center	VA	UMass Medical School	Government
South Shore Hospital	None	None	Non-profit
VA Boston Healthcare System - Jamaica Plain	VA	Multiple Associated Schools	Government
Good Samaritan Medical Center	Steward	None	Proprietary
Tufts Medical Center*	None	Tufts University Medical School	Non-profit
Norwood Hospital	Steward	None	Proprietary
Falmouth Hospital	Cape Cod Healthcare	None	Non-profit
UMass Memorial Medical Center	UMass Memorial Health Care	UMass Medical School	Non-profit
Lahey Hospital & Medical Center	None	Multiple Associated Schools	Non-profit
Metrowest Medical Center	None	None	Non-profit
St Vincent Hospital	None	None	Proprietary
Fairview Hospital	None	None	Non-profit
Brigham and Women's Hospital*	Partners Healthcare	Harvard Medical School	Non-profit
Massachusetts General Hospital*	Partners Healthcare	Harvard Medical School	Non-profit
Brigham and Women's Faulkner Hospital	Partners Healthcare	Multiple Affiliated Schools	Non-profit
Cooley Dickinson Hospital	Partners Healthcare	None	Non-profit
Martha's Vineyard Hospital	Partners Healthcare	None	Non-profit
Nantucket Cottage Hospital	Partners Healthcare	None	Proprietary
Newton-Wellesley Hospital	Partners Healthcare	Multiple Affiliated Schools	Non-profit
North Shore Medical Center	Partners Healthcare	None	Non-profit

*Large Academic Medical Centers will be excluded from possible comparison hospitals in Massachusetts.

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DATA MANAGEMENT PLAN

Any Applicants, contractors, or agents receiving CHIA data that includes Protected Health Information ("PHI" as defined under the Health Insurance Portability and Accountability Act [HIPAA] and its implementing regulations) as well as additional elements that may be used to identify an individual (the "Data") must complete and execute this Data Management Plan. The Data Management Plan(s) will be incorporated within the Data Use Agreement that must be executed prior to receipt of the Data. You may wish to refer to the Data Use Agreement as you complete this Data Management Plan. This Data Management Plan should be completed by the Chief Information Security Officer, Chief Privacy Officer, legal counsel or another officer of the organization with sufficient knowledge of the organization's data privacy and security practices and who has authority to bind the organization.

NOTE: This Data Management Plan is confidential and will not become a part of the public record.

I. GENERAL INFORMATION

Project Title: (should appear the same as on the Data Application)	Evaluation Services to Support the Community Hospital Acceleration, Revitalization and Transformation (CHART) Investment Program
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II. CERTIFICATIONS

Applicant certifies and agrees as follows:

- It is not now, and will not become at any time, without prior notification to CHIA a Covered Entity under HIPAA.
- The Data will be encrypted at rest encrypted on storage media (backup tapes, local hard drives, network storage, et al) with at least AES-256 standard or stronger.
- The Data will be encrypted in transit consistent with the approved method described in this Data Management plan at section IV.3-b.
- Anti-virus software or service is active on any server or endpoint containing the Data
- The Organization is in full compliance with the applicable privacy and security requirements of federal and state law
- CHIA Confidentiality agreements as appended to the Data Use Agreement will be executed by all individuals, including contractors, who will access CHIA data
- All non- employees who will access CHIA data will be subject to the same terms and conditions that Applicant is subject to under the terms of this Agreement
- All employees and contractors with access to the data will be trained in federal and state law regarding privacy and security of data prior to access to the data.
- The Organization has policies and procedures in place to address:
 - The sharing, transmission and distribution of data
 - The physical removal, transport and transmission of data
 - The physical possession and storage of data

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- o The destruction of data upon the completion of its use.

III. RESPONSIBLE PARTIES

Please identify the following individuals within your organization:

1. The individual responsible for organizing, storing and archiving the Data. This individual is the Custodian of the CHIA Data required under Section 20 of the Data Use Agreement.

Name:	Christopher J. Louis, PhD
Title:	Clinical Assistant Professor
Phone:	617.414.1353
Address:	715 Albany Street, Talbot 261W, Boston, MA 02118
Email:	louisc@bu.edu
Reports to (name and title):	Michael Stein, MD; Chair, Department of Health Law, Policy and Management

2. The Individual(s) responsible for the research team using the Data, including ensuring each individual (i) has a signed confidentiality agreement, (ii) accesses and uses only the minimal Data necessary to achieve the research purpose, (iii) accesses the Data only on a secured server according to Applicant's policies. This individual is also responsible for maintaining the access log required under Section 5 of the Data Use Agreement.

Name:	Christopher J. Louis, PhD
Title:	Clinical Assistant Professor
Phone:	617.414.1353
Address:	715 Albany Street, Talbot 261W, Boston, MA 02118
Email:	louisc@bu.edu
Reports to (name and title):	Michael Stein, MD; Chair, Department of Health Law, Policy and Management

3. The individual responsible for notifying CHIA of any breach of the Data Use Agreement or this Data Management Plan.

Name:	Christopher J. Louis, PhD
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Title:	Clinical Assistant Professor
Phone:	617.414.1353
Address:	715 Albany Street, Talbot 261W, Boston, MA 02118
Email:	louisc@bu.edu
Reports to (name and title):	Michael Stein, MD; Chair, Department of Health Law, Policy and Management

4. The individual responsible for ensuring the Data is destroyed upon termination of the Data Use Agreement, completing the Data Destruction Form and providing that Form to CHIA.

Name:	Christopher J. Louls, PhD
Title:	Clinical Assistant Professor
Phone:	617.414.1353
Address:	715 Albany Street, Talbot 261W, Boston, MA 02118
Email:	louisc@bu.edu
Reports to (name and title):	Michael Stein, MD; Chair, Department of Health Law, Policy and Management

IV. DATA SECURITY AND INTEGRITY

Complete this section for each location where the Data will be stored or accessed. If you plan to use an agent/contractor that has access to the Data at a location other than your location or in an off-site server and/or database, the agent/contractor must also complete this section.

1. Physical Location of the Data:

- a. Please provide the delivery address for the Data, as well as the full address, including building and floor, of each location where Data will be stored.

Organization: Data Coordinating Center, Boston University School of Public Health			
Street Address: 85 East Newton Street, M921	City: Boston	State: MA	ZIP Code: 02118
Office Telephone (Include Area Code): 617.638.5009			

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If the storage location above is managed by a third-party then answer the following:

- i. Will the Data be stored by the third party on a system in the cloud (reachable via the Internet)?
 Yes No
- ii. If you answered yes to (a): Has this Cloud Service Provider passed a FedRAMP 3PAO assessment for the specific cloud system which will host the data?
 Yes No
- iii. If you answered yes to (b): What is the name of the provider and the FedRAMP level the specific cloud system hosting the data is operating at?

2. Data Privacy Training and Awareness:

- a. Has every individual who will access the data received training on the proper handling of protected health information and/or personal data within the last year?
 Yes No

3. Encryption of Data:

- a. Will all CHIA Data at rest be encrypted on storage media (backup tapes, local hard drives, network storage, et al) with encryption at least AES-256 or stronger.
 Yes No

Data will be stored on secure, restricted use network (BUMC IT).

- b. Will CHIA Data transmitted by your organization over the Internet?
 Yes No

If you answered yes to (b): which of the following if any are used when transmitting data over the internet? If selecting *other* please describe method in space provided below.

- SSL (meets or exceeds TSL 1.1 or TSL 1.2) SFTP Other

N/A

4. Information Security:

- a. Does your organization have published information security policies which are followed and accessible to all staff accessing or handling CHIA Data?
 Yes No

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- b. Has every individual who will access the CHIA Data received cyber security awareness training in the last year?
 Yes No
- c. Has your IT organization experienced a breach of PHI or PII in the last seven (7) years?
 Yes No

If you answered yes to (c): how was the breach resolved?

Breach was handled in accordance with all applicable regulations. Policies and procedures were put in place to prevent recurrence.

5. Technical and Physical Controls:

- a. Are all the user accounts that log on to any machine (server or endpoint) that accesses the Data uniquely assigned to individual users (i.e., the user accounts are not shared)?
 Yes No
- b. Is an audit log maintained of all user log-ons to the system hosting the CHIA Data?
 Yes No
- c. What is the minimum password length and character complexity (uppercase, lowercase, numeric, and special characters) required for new passwords on the user accounts logging on to the system accessing the CHIA Data?

BU uses Kerberos:

10-15 characters

2 lower case

2 uppercase

1 numb3r or punctuation character

Cannot be word or name

Cannot contain personal identifier (e.g., username, BU ID)

- d. Describe any additional authentication technical security controls you employ to defend the system against unauthorized logon, e.g. maximum failed login attempts, lockout period, etc.:

Servers and access to networks maintained by BUMC IT include two-level authentication.

- e. Do you run a current version of a commercial off-the-shelf anti-virus or anti-malware product on the server that will host the CHIA Data?

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Yes No

f. If the CHIA Data will be on a server or network accessible storage drive, then check all the security features present in the room containing CHIA Data:

- i. Recorded video
- ii. Access log of all individuals entering the room
- iii. Secure server rack
- iv. Access control limiting access only to authorized individuals

g. What additional specific physical or technical safeguards (not mentioned in prior answers) will be used to mitigate the risk of unauthorized access to CHIA Data?

N/A

h. When was the last information security risk assessment performed in your organization? Who conducted it?

January 2015 by an independent consultant hired by BUMC IT.

i. When was the last IT audit performed in your organization? Who conducted it?

November 2015 – January 2016, BUMC IT

V. DATA RETURN OR DESTRUCTION

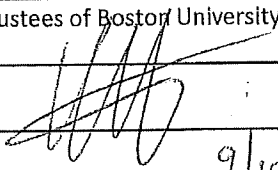
Applicants are required to attest that the CHIA Data and all copies of the CHIA Data used by the Applicant or its employees, contractors or agents will be destroyed by the Retention Date as specified in the Data Use Agreement, or upon completion of the project described in your Application, whichever occurs first. All data destruction must conform to the requirements of M.G.L. c. 93I and to the Data Use Agreement. Please specify below the technical measures you will use to meet these requirements.

Data files will be deleted from network consistent with the terms of the data use agreement. Backup files will be retained for up to one year but are inaccessible to anyone other than IT staff.

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VI. SIGNATORY

The undersigned is an authorized signatory of the organization. The organization hereby agrees to hold and/or access CHIA Data at all times in compliance with all provisions of this Data Management Plan.

Name:	William P. Segarra, JD, MPH
Title:	Director, Industry Contracts & Agreements
Organization:	Trustees of Boston University
Signature:	
Date:	9/12/2016

**EXHIBIT A
DATA APPLICATION(S)**

Exhibit A-4 - Wang

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

I. INSTRUCTIONS

This form is required for all Applicants, except Government Agencies as defined in 957 CMR 5.02. 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 apcd.data@state.ma.us if you have additional questions about how to complete this form.

All attachments must be uploaded to IRBNet with your Application. All Application documents can be found on the 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. ORGANIZATION AND INVESTIGATOR INFORMATION

Project Title:	Adoption of Non-Invasive Prenatal Testing in Diverse Populations: A Multilevel Approach
IRBNet Number:	981733-1
Organization Requesting Data:	Trustees of Boston University, School of Public Health – Community Health Sciences Department
Organization Website:	https://www.bu.edu/sph/about/departments/community-health-sciences/
Authorized Signatory for Organization:	William Segarra, JD, MPH
Title:	Director, Industry Contracts and Agreements
E-mail Address:	segarra@bu.edu
Address, City/Town, State, Zip Code:	25 Buick Street, Suite 200, Boston, MA 02215
Primary Investigator:	Catharine Wang, PhD
Title:	Associate Professor and Principal Investigator
E-mail Address:	clwang@bu.edu
Telephone Number:	617-638-5187

Names of Co-Investigators:	Dr. Amresh Hanchate, Dr. Christina Yarrington
E-mail Addresses of Co-Investigators:	Hanchate@bu.edu, tinay@bu.edu

III. FEE INFORMATION

1. Consult the Fee Schedule for All-Payer Claims Database data and select one of the following options:

- Researcher
- Other
- Reseller

2. Are you requesting a fee waiver?

- Yes
- No

3. Complete and submit the Fee Remittance Form. If requesting a fee waiver, submit a letter stating the basis for your request (if required). Please refer to the Fee Schedule (effective Feb 1, 2017) for fee waiver criteria.

IV. PROJECT INFORMATION

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

- | | | |
|---|--|--|
| <input type="checkbox"/> Epidemiological | <input type="checkbox"/> Health planning/resource allocation | <input type="checkbox"/> Cost trends |
| <input type="checkbox"/> Longitudinal Research | <input checked="" type="checkbox"/> Quality of care assessment | <input type="checkbox"/> Rate setting |
| <input type="checkbox"/> Reference tool | <input checked="" type="checkbox"/> Research studies | <input type="checkbox"/> Severity index tool |
| <input type="checkbox"/> Surveillance | <input type="checkbox"/> Student research | <input type="checkbox"/> Utilization review of resources |
| <input type="checkbox"/> Inclusion in a product | <input type="checkbox"/> Other (describe in box below) | |

2. Provide a summary of the specific purpose and objectives of your Project. This may include research questions and/or business use Projects.

The goal of the study is to examine population-level adoption of NIPT in diverse patient populations. We will use the Massachusetts All Payer Claims Database, covering inpatient and outpatient care received by virtually all residents under 65 years of age during 2011-2015.

Aim 1: Estimate annual population rate of use of NIPT among all pregnant women (# tests/100 women) and among subgroups based on maternal age, SES, race/ethnicity and insurance

Aim 2: Develop a person-level model to identify the multilevel factors – at patient, provider, hospital and geographic area levels – associated with NIPT uptake, and examine the extent to which the model accounts for disparities in NIPT uptake by SES, race/ethnicity and insurance

Aim 3: Examine the association between NIPT adoption and use of invasive diagnostic testing (CVS and amniocentesis), and variation in this association by SES, race/ethnicity and insurance

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. *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 late 2011, a cell-free DNA screening test became commercially available, which analyzes fetal chromosomal abnormalities using maternal plasma. This non-invasive prenatal testing (NIPT) has been heralded as “*revolutionizing prenatal screening and diagnosis.*” The rapid clinical adoption of NIPT highlights genomic medicine’s growth and enormous promise for patient care. The evolving research landscape stemming from genomic and precision medicine efforts, however, necessitates concomitant efforts to monitor population health impact and assure equity in access to these advances.

Currently, the population-level adoption rate of NIPT is unknown. Moreover, use of NIPT has been shown to be associated with higher education and greater patient knowledge about the test among underserved, minority patient populations. To address the gaps in empirical evidence, the goal of the present study is to examine population-level adoption of NIPT in diverse patient populations. We will use the Massachusetts All Payer Claims Database, covering inpatient and outpatient care received by virtually all residents under 65 years of age during 2010-2015. Specific study aims are listed in question 2.

VI. DATASETS REQUESTED

1. Specify below the dataset(s) and year(s) of data requested for this Project, and provide your justification for requesting *each* dataset.

Medical Claims

2011 2012 2013 2014 2015

Describe how your research objectives require Medical Claims data:

We will use medical claims to identify the study population (pregnant women), use of a range of pregnancy related services – non-invasive prenatal test (the main focus of this study), ultrasound, serum screening, amniocentesis, CVS, genetic counseling – dates of service, costs (primary and secondary payers), and provider setting (hospital, clinic).

Pharmacy Claims

2011 2012 2013 2014 2015

Describe how your research objectives require Pharmacy Claims data:

<input type="checkbox"/> Dental Claims <input type="checkbox"/> 2011 <input type="checkbox"/> 2012 <input type="checkbox"/> 2013 <input type="checkbox"/> 2014 <input type="checkbox"/> 2015 Describe how your research objectives require Dental Claims data:
<input checked="" type="checkbox"/> Member Eligibility <input checked="" type="checkbox"/> 2011 <input checked="" type="checkbox"/> 2012 <input checked="" type="checkbox"/> 2013 <input checked="" type="checkbox"/> 2014 <input checked="" type="checkbox"/> 2015 Describe how your research objectives require Member Eligibility data: We will use the Eligibility data for information on age, 5-digit patient residence zip code (this will be critical for determining race/ethnicity, median income and poverty level data at the zip code level), and insurance type.
<input checked="" type="checkbox"/> Provider <input checked="" type="checkbox"/> 2011 <input checked="" type="checkbox"/> 2012 <input checked="" type="checkbox"/> 2013 <input checked="" type="checkbox"/> 2014 <input checked="" type="checkbox"/> 2015 Describe how your research objectives require Provider data: We will use the Provider data for details on provider setting: hospital/clinic. As almost all patients are likely to have hospital use for delivery, we would like to obtain information about hospitals by merging this data with American Hospital Association survey data. Aim is to examine NIPT use differences by provider.
<input checked="" type="checkbox"/> Product <input checked="" type="checkbox"/> 2011 <input checked="" type="checkbox"/> 2012 <input checked="" type="checkbox"/> 2013 <input checked="" type="checkbox"/> 2014 <input checked="" type="checkbox"/> 2015 Describe how your research objectives require Product data: We would like to obtain information on annual deductibles and copayment limits; to examine if NIPT use varies with these indicators.

2. All-Payer Claims Database data are refreshed and updated periodically and made available in Release Versions that contain the most recent five calendar years of data. As certain Project objectives may require future years of data not yet available, CHIA will consider requests for additional Release Versions of the same data (i.e., same elements and files) without the need to submit a new application. Please note that approved requests will be subject to applicable terms in the Data Use Agreement and fees for additional data. Please indicate below whether this is a one-time request, or if the described Project will require future Release Versions of data and if so, which Versions

One-Time OR ^{CW} 2016 ^{CW} 2017 ^{CW} 2018 2019 2020

VII. DATA ELEMENTS REQUESTED

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

All-Payer Claims Database data is released in Limited Data Sets (LDS). All applicants receive the "Core" LDS, but may also request additional elements listed below for inclusion in their analyses. Requests for additional elements 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 elements you are requesting in addition to the "Core" LDS, provide your justification for requesting each element.

Geographic Data

The geographic sub-divisions listed below are available for Massachusetts residents and providers only. Choose one of the following geographic options.

<input type="checkbox"/> 3-Digit Zip Code (standard)	<input checked="" type="checkbox"/> 5-Digit Zip Code***
<p>***If requested, provide justification for requesting 5-Digit Zip Code. Refer to specifics in your methodology: The 5 digit zip code will be our chief means for obtaining race/ethnicity, and socioeconomic status characteristics (median income, poverty rate, educational achievement), which are critical variables for addressing our research questions.</p>	

Dates

Choose one option from the following options for dates.

<input type="checkbox"/> Year (YYYY) (Standard)	<input type="checkbox"/> Month (YYYYMM) ***	<input checked="" type="checkbox"/> Day (YYYYMMDD) *** [for selected data elements only]
<p>*** If requested, provide justification for requesting Month or Day. Refer to specifics in your methodology: Need to know date of patient visits to form a likely range for start of pregnancy, and evaluate the timing of NIPT use with guidelines.</p>		

National Provider Identifier (NPI)

Choose one of the following options for National Provider Identifier(s):

<input type="checkbox"/> Encrypted National Provider Identifier(s) (standard)	<input checked="" type="checkbox"/> Decrypted National Provider Identifier(s)***
<p>*** If requested, provide justification for requesting decrypted National Provider Identifier(s). Refer to specifics in your methodology: Five CPT codes have been used to bill for NIPT: 81420, 81479, 81599, 84999 and 81507. While 81420 is specific to NIPT, others, such as 84999 (a generic code for "unlisted chemistry procedure") are not and could be maternal testing for cystic fibrosis or spinal muscular atrophy carrier status. Therefore, we will also use provider name and location to identify NIPT. The number of NIPT providers has grown to eight between 2011 and 2015 (Sequenom, Quest, LabCorp, Progenity, Verinata, Counsyl, Ariosa/Roche, and Natera). As all NIPT testing is performed by the individual laboratories, who in turn submit claims for this test, this strategy will identify NIPTs comprehensively. We note that in addition to CPT and provider NPI, another critical identifier is pregnancy status; i.e., use of these tests will be examined only among women identified to be pregnant, based on criteria detailed in the proposal.</p>	

VIII. MEDICAID 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 Medicaid Data, please describe, in the space below, why your use of the Data meets this requirement. Requests for Medicaid 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 Medicaid program. CHIA cannot release Medicaid Data without approval from MassHealth. This may introduce significant delays in the receipt of Medicaid Data.

We will use commercial insurance and Medicaid-covered patients data to estimate annual population rate of use of NIPT among all pregnant women and among subgroups based on maternal age, insurance, area-level race/ethnicity and area-level socioeconomic status. We would like to compare use of NIPT among Medicaid enrollees with that among commercially covered patients.

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.

Individual Facility Level Data level:

- o To obtain additional information about the hospitals (e.g., bed capacity, # physicians by specialty, # nurse and other support staff); these data will be obtained by merging with the American Hospital Association Annual Surveys
- o American Hospital Association Annual Survey – American Hospital Association, linkage by hospital name, ID and location.

Aggregate Data:

- Using patient zip code in census data we will obtain zip code-level characteristics (median income, poverty rate, education level).
- The Area Resource File provides country-level data on healthcare resources (# hospital beds, #beds, #physicians by specialties), demographics (population by age, sex and area-level race/ethnicity), and healthcare expenditures (total spending, medicare spending).
- Census – US government data, linkage by zip code
- Area Resource File – US government data, linkage by county

4. If yes, for each proposed linkage above, please describe your method or selected algorithm (e.g., deterministic or probabilistic) for linking each dataset. If you intend to develop a unique algorithm, please describe how it will link each dataset.

Linkage will be only by hospital, zip code and county. Matching will be deterministic based on hospital name and location, and zip code and county (FIPS) codes.

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

As the linkage is only at a larger unit level (hospital, zip code and county), the merging of the aforementioned fields from linkage will not increase the risk of identification. However, to prevent identification of individual patients, one the data has been linked, all identifiers will be removed from the working database. The original database with identifiers will be removed from the network, stored on an off-line hard drive in a locked cabinet in a locked office.

X. PUBLICATION / DISSEMINATION / RE-RELEASE

1. Describe your plans to publish or otherwise disclose CHIA Data, or any data derived or extracted from CHIA Data, in any paper, report, website, statistical tabulation, seminar, conference, or other setting. 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 in the display of a cell less than 11.

- Presentation of research findings at national research meetings
- Submission for publication in high-impact peer-reviewed medical and health policy journals
- Coordination with our university's media offices to write and disseminate press releases about our findings

2. Do you anticipate that the results of your analysis will be published and/or made publically available? If yes, describe how an interested party will obtain your analysis and, if applicable, the amount of the fee, that the third party must pay.

Results will be presented at professional meetings and published and available to the public through those venues.

3. Will you use CHIA Data for consulting purposes?

- Yes
- No

4. Will you be selling standard report products using CHIA Data?

- Yes
- No

5. Will you be selling a software product using CHIA Data?

- Yes
- No

6. Will you be reselling CHIA Data in any format?

- Yes
- No

If yes, in what format will you be reselling CHIA Data (e.g., as a standalone product, incorporated with a software product, by a subscription, etc.)?

7. If you have answered "yes" to questions 4, 5 or 6, please describe the types of products, services or studies.

8. If you have answered "yes" to questions 4, 5, or 6, what is the fee you will charge for such products, services or studies?

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.

Amresh Hanchate, who is a co-PI of the NIH grant that is funding this work, is a health services researcher with considerable experience in use of claims data. Specifically, Dr. Hanchate is currently using CHIA All Payer Data for another ongoing NIH funded study on ambulance use patterns. He currently also uses claims data from Medicare and commercial payers (Marketscan), in addition to administrative data from AHRQ, CHIA and other state agencies.

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 or 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 amendmtn 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:	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.

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.

AGENT/CONTRACTOR #2
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.

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.

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)	William P. Segarra, JD, MPH	<small>Digitally signed by William P. Segarra, JD, MPH DN: cn=William P. Segarra, JD, MPH, o=Boston University, ou=Sponsored Programs, email=segarra@bu.edu, c=US Date: 2017.06.05 16:26:37 -04'00'</small>
Printed Name:	William P. Segarra	

Attachments

A completed Application must have the following documents attached to the Application:

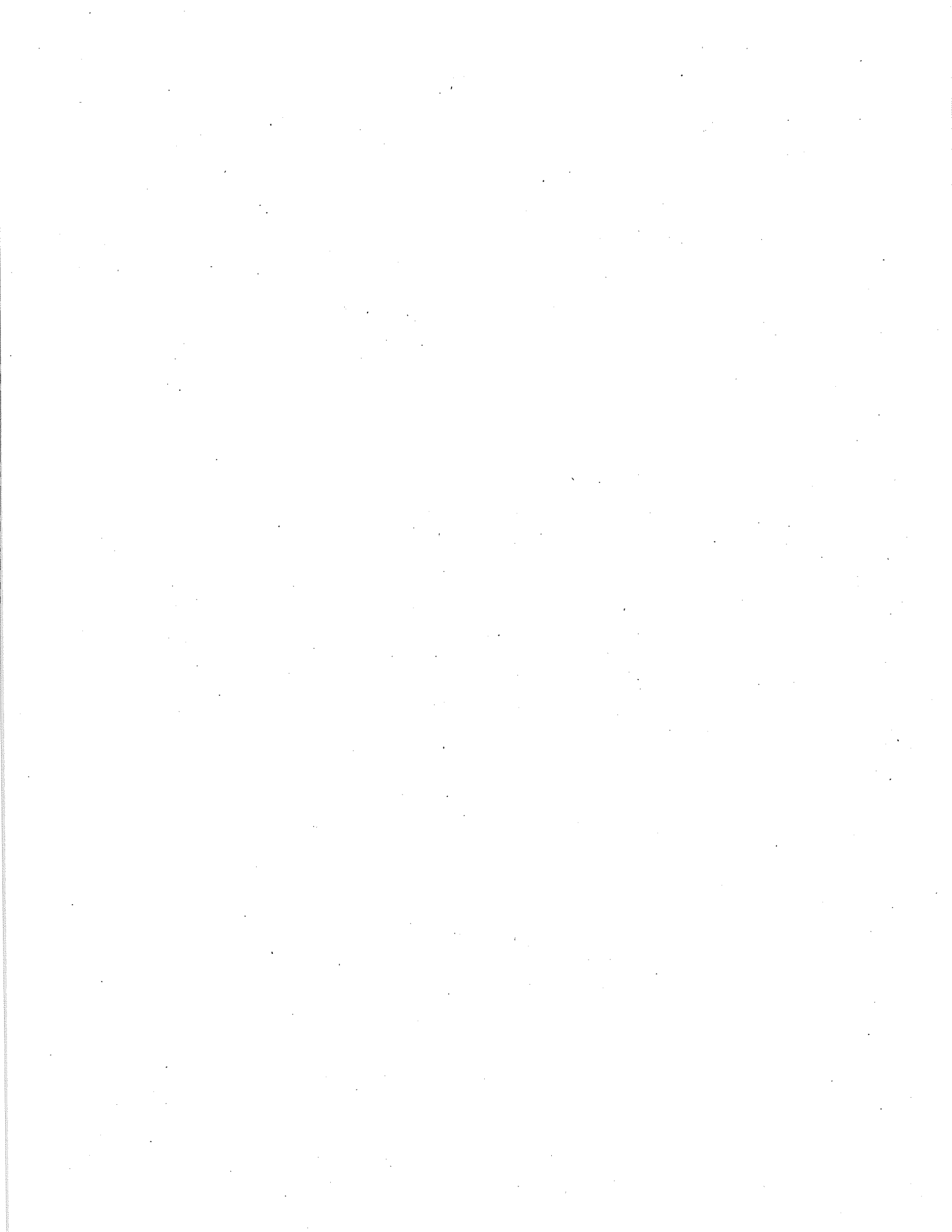
- 1. IRB approval letter and protocol (if applicable)
- 2. Research Methodology (if protocol is not attached)
- 3. CVs of Investigators
- 4. Data Management Plan (including one for each agent or contractor that will have access to or store the CHIA Data at a location other than the Organization's location, off-site server and/or database)

Applications will not be reviewed until they are complete, including all attachments.

TRACKING TABLE (to be completed by CHIA staff only)	
Complete Application Received	
Application Fee Received	
Data Privacy Committee Review	
Data Release Committee Review	
Linkages Approved (as described)	
Approved for additional Release Versions	
Executive Director Approval	
Data Fee Received	
Date of First Audit	
Extract Number	

Attachment #1 – IRB Approval Letter & Protocol or Research Methodology

Attachment #2 – Data Management Plan(s)



Research Methodology

Our primary data source will be the Massachusetts All-Payer Claims Database (APCD), which contains comprehensive healthcare utilization data for all residents. Developed by the Center for Health Information and Analysis, a private-public state entity, this database is the product of a special legislation providing the state broad authority to collect healthcare utilization data from private and public healthcare payers, including third-party administrators.²⁶ The Database covers 99.1% of the population with Medicaid, Medicare, and 15 major commercial insurers. This data is currently available for 2011-2015. The data identifies Massachusetts residents uniquely enabling development of a longitudinal record of health care utilization, even if individuals switch insurers. The Database contains dates of services received, type of service (doctor consult, laboratory test, or scan), provider name, provider type (individual provider, clinic, hospital, laboratory test provider), and provider address. Results of laboratory tests or other diagnostics are not included. It also contains patient demographics, insurance type (Medicaid) and zip code residence location. As the data does not include individual indicators of race/ethnicity, income or education, we will follow prior research and characterize race/ethnicity and socioeconomic status based on the Census-based zip code level indicators. Dr. Hanchate has extensive experience with data from the Center for Health Information and Analysis. We will also obtain hospital level data from the American Hospital Association Annual Survey,⁴⁸ and zip code and county level data from the Area Health Resource File and Census Bureau data.⁴⁵

Our study population will consist of all pregnant women during 2011-2015; we will use data for 2011 (pre-NIPT period) to identify changes in the use of other prenatal screening and diagnostic tests following the introduction of NIPT in late 2011. We will examine testing for chromosomal abnormality separately for those aged 35 years and older (at delivery), and those younger than 35. Pregnancy, complications and prenatal care utilization will be identified using International Classification of Diseases (ICD-9-CM) and Current Procedural Terminology (CPT) codes.⁴⁹⁻⁵² Pregnancy will be identified based on a prenatal visit with an obstetrician wherein diagnosis of pregnancy is indicated (ICD9 codes V22, V23, 630-648). We will exclude women who undergo medical abortion (CPT code S0199) as this is necessarily done prior to 9 weeks, as well as women with a diagnosis of blighted ovum (ICD9 631 or 631.8), molar pregnancy (ICD9 630), ectopic pregnancy (ICD9 633.9 or CPT 59150, 59101, 59120, 59121) or missed abortion (ICD9 632) as diagnosis of any of these conditions would exempt her from NIPT.

We propose a retrospective secondary analysis of claims data covering all prenatal care for virtually all pregnant women in Massachusetts during 2011-2015. While NIPT use will be examined for the 2012-2015 period, we will use data from pre-NIPT period (2011) to better isolate the impact of NIPT introduction on use of other prenatal screening and diagnostic tests. We will estimate the annual population rates of use of NIPT for all and by subgroups of risk, race/ethnicity and SES and develop a multilevel model of individual use of NIPT to evaluate the relative importance of patient, provider, hospital/clinic and geographic area level factors. Our approach will draw from previous work from Canada on population-level aneuploidy screening rates prior to the commercial availability of NIPT.⁵³ Our primary outcome measures are use of NIPT and other prenatal tests. Specifically, we will estimate population rates of use, defined as # tests/100 women (Table 4). These rates will be estimated for pregnant women aged 35 and older (high risk) and for all women (to indicate broader use among the low risk group). We will use outpatient care claim codes to identify their use.

Five CPT codes have been used to bill for NIPT: 81420, 81479, 81599, 84999 and 81507. While 81420 is specific to NIPT, others are not. For instance, 84999 is a generic code for "unlisted chemistry procedure" and could be maternal testing for cystic fibrosis or spinal muscular atrophy carrier status. Therefore, we

will also use provider name and location to identify NIPT. The number of NIPT providers has grown to eight between 2011 and 2015 (Sequenom, Quest, LabCorp, Progenity, Verinata, Counsyl, Ariosa/Roche, and Natera).^{54,55} As all NIPT testing is performed by the individual laboratories, who in turn submit claims for this test, this strategy will identify NIPTs comprehensively. We expect that use of the specific CPT code will be standardized over time across different payers. To assess the overall validity of our approach to identifying NIPT tests, we will compare annual NIPT volume using study data with corresponding volume figures from a sample of Massachusetts hospitals. Also, we will compare payer-level annual NIPT volume from the study data with corresponding figures from the main insurance payers in Massachusetts.

Current ACOG guidelines recommend NIPT use among pregnant women aged 35 or older and those considered at high risk for chromosomal abnormalities based on prior history or other screening.³² We will use ICD9 codes to identify the population at risk comprising of those with elderly primigravida or multigravida (AMA, ICD9 659), balanced autosomal translocation in a normal individual (758.4), abnormal finding on antenatal screening (796.5), fetal (suspected) aneuploidy (655.1) and abnormality of fetus (suspected) (655.9). In reporting rates of NIPT for this high risk population, we will also be cognizant of the potential limitation of the administrative data in comprehensively identifying the high risk population. Since many insurance payers make global payments for a pregnancy case (V22 or V23), there may be inconsistency across providers in whether all risk codes are comprehensively reported. Therefore, we will also examine NIPT use among women aged 35 or older, as they are expected to account for a large majority of NIPT users.

Increase in use of NIPT may affect use of conventional prenatal care and genetic services. Genetic counseling relating to chromosomal abnormalities will be identified by outpatient claims with CPT code 96040 and an ICD9 diagnosis code of V26.31 or V26.32 or V26.33. For those with NIPT test, we will use the outpatient visit dates to measure the proportion who receive genetic counseling before and after NIPT. Diagnostic tests will also be identified using CPT codes: 59015 for CVS and 59000 for amniocentesis; although percutaneous umbilical cord blood sampling (PUBS) is a third option (CPT code 59012) we expect its use to be very low. CPT codes will also be used to identify ultrasound (nuchal translucency; 76813), standard maternal serum screening (CPT 81508-81511) and second trimester serum screening (82195, 84702 and 82677). We will estimate all utilization rates, both in observed and adjusted terms, for all pregnant women in the study population, and for various subgroups based on risk for chromosomal abnormalities, race/ethnicity, SES, and geography.



EXCEPTIONAL CARE. WITHOUT EXCEPTION.



Office of the Institutional Review Board
560 Harrison Ave, Suite 300
Boston, Massachusetts 02118-2526
Tel: 617-638-7207

Title of Study: Adoption of Non-Invasive Prenatal Testing (NIPT) in a Diverse Population: A Multilevel Approach

IRB Number: H-34832

RE: Initial Review Submission Form

Determination: Not Human Subjects Research

Date of Action: 08/15/2016

Funding Source: Massachusetts All Payers Claims Database

August 15, 2016

Dear Catharine Wang, PhD, MSc,

A qualified member of the Institutional Review Board (IRB) staff has reviewed the above referenced submission and has determined that it does not constitute research involving human subjects. This determination is based on the definitions of human subject and research in the Human Research Protection Program (<http://www.bumc.bu.edu/irb/files/2015/10/PP-revisions-approved.doc>) per the following:

1. Human subject means a living individual about whom a researcher obtains data through intervention or interaction with the individual or identifiable private information about the individual, or an individual who is or becomes a subject (either a healthy human or a patient) in research, either as a recipient of the test article or as a control.
2. Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Protocol Specific Determinations

No PHI collected, accessed, used or distributed under 45 CFR 164.514

This determination corresponds with the versions of the application and attachments in the electronic system most recently approved as of the date of this letter. All determinations regarding this project have been made based on the information submitted by the investigator. Any modifications to the research plan that would possibly change the Not Human Subjects Research (NHSR) determination must be submitted to the IRB for review and confirmation of NHSR status prior to initiation of the change. **PLEASE NOTE:** Minor changes to the study that do not affect the NHSR determination do not need to be submitted to the IRB.

You may retain this letter in your files as documentation of this decision by the IRB. No progress reports are required for this project as long as no changes are made to the study.

It is the responsibility of the PI to ensure that any relevant HIPAA requirements have been met. It is also the responsibility of the PI to ensure that all required institutional approvals have been obtained prior to initiating any protocol related activities.

Sincerely yours,

Robert Terrano
IRB Analyst



**Data Management Plan for Use of CHIA Data
[Attachment to Data Application]**

I. INSTRUCTIONS

Any Recipients, contractors, or agents receiving CHIA Data ("Data") must complete and execute this Data Management Plan. Certain CHIA Data includes Protected Health Information ("PHI" as defined under the Health Insurance Portability and Accountability Act [HIPAA] and its implementing regulations) and all CHIA Data contains elements that may be used to identify an individual. The Data Management Plan(s) will be incorporated within the Data Use Agreement that must be executed prior to receipt of the Data. You may wish to refer to the Data Use Agreement as you complete this Data Management Plan. This Data Management Plan should be completed by the Chief Information Security Officer, Chief Privacy Officer, legal counsel or another officer with sufficient knowledge of the Agency or Organization's data privacy and security practices and who has authority to bind the Agency or Organization.

NOTE: This Data Management Plan is confidential and will not become a part of the public record.

II. GENERAL INFORMATION

Project Title: (should appear the same as on the Data Application)	Adoption of Non-Invasive Prenatal Testing in Diverse Populations: A Multilevel Approach
Recipient Organization: (should appear the same as on the Data Application)	Trustees of Boston University School of Public Health - Community Health Sciences Department

III. CERTIFICATIONS

The undersigned certifies and agrees as follows:

- The Data will be encrypted at rest on storage media (backup tapes, local hard drives, network storage, et al) with at least AES-256 standard or stronger.
- The Data will be encrypted in transit consistent with the approved method(s) described in this Data Management plan at section V.3-b.
- Anti-virus software or service is active on any server or endpoint containing the Data.
- If a Covered Entity or Business Associate under HIPAA, the Agency or Organization is in full compliance with the privacy and security requirements of HIPAA; trains all staff who access PHI on the requirements of HIPAA; and has Business Associate Agreements with all non-employees who access PHI.
- The Agency or Organization has policies and procedures in place to address:
 - The sharing, transmission and distribution of PHI
 - The physical removal, transport and transmission of PHI
 - The physical possession and storage of PHI
 - The destruction of PHI upon the completion of its use
 - Confidentiality agreements with all individuals, including contractors, who will access PHI
 - Agreements governing the use and disclosure of PHI with all non-employees who will access PHI

IV. RESPONSIBLE PARTIES

Please identify the following individuals within your Agency or Organization:

1. The individual responsible for organizing, storing and archiving the Data. This individual is the Custodian of the CHIA Data required under Article XI of the Data Use Agreement.

Name:	Catharine Wang, PhD
Agency/Organization:	Boston University School of Public Health - Community Health Sciences Department
Title:	Principal Investigator, Associate Professor
Phone:	617-638-5187
Address:	801 Massachusetts Ave Crosstown Center, Boston, MA 02118
Email:	clwang@bu.edu
Reports to (name and title):	Richard Saltz, Chair, Community Health Sciences Department

2. The individual(s) responsible for the research team using the Data, including ensuring each individual (i) has a signed confidentiality agreement, (ii) accesses and uses only the minimal Data necessary to achieve the research purpose, (iii) accesses the Data only on a secured server according to Applicant's policies. This individual is also responsible for maintaining the access log required under Article II, Section 5 of the Data Use Agreement.

Name:	Amresh Hanchate, PhD
Agency/Organization:	Boston University School of Medicine - Department of Medicine
Title:	Associate Professor, Health Economist
Phone:	(617) 638-8889
Address:	801 Massachusetts Ave Crosstown Center Boston MA 02118
Email:	Hanchate@bu.edu
Reports to (name and title):	Jeffrey Samet, Professor & Vice Chair for Public Health

3. The individual responsible for notifying CHIA of any breach of the Data Use Agreement or this Data Management Plan.

Name:	Eric Jacobsen
Organization:	Boston University, Information Security
Title:	Director, Information Security
Phone:	(617) 353-8284

Address:	111 Cummington Mall, Boston MA 02215
Email:	jacobsen@bu.edu
Reports to (name and title):	Tracy Schroeder, Vice President Information Services & Technology

4. The Individual responsible for ensuring the Data is destroyed upon termination of the Data Use Agreement, completing the Data Destruction Form and providing that Form to CHIA.

Name:	Amresh Hanchate, PhD
Organization:	Boston University School of Medicine - Department of Medicine
Title:	Associate Professor, Health Economist
Phone:	(617) 638-8889
Address:	801 Massachusetts Ave Crosstown Center Boston MA 02118
Email:	Hanchate@bu.edu
Reports to (name and title):	Jeffrey Samet, Professor & Vice Chair for Public Health

V. DATA SECURITY AND INTEGRITY

Agents or contractors that will have access to or store the CHIA Data at a location other than the Recipient's location, or in an off-site server and/or database, must complete a separate Data Management Plan.

1. Physical Location of the Data:

- a. Please provide the delivery address for the Data, as well as the full address, including building and floor, of each location where Data will be delivered and stored.

Delivery:

Organization: Boston University School of Medicine			
Street Address: 801 Massachusetts Ave Crosstown Center	City: Boston	State: MA	ZIP Code: 02215
Office Telephone (Include Area Code): (617) 638-8889			

Storage:

Organization: Boston University Medical Campus – Information Technology (BUMC-IT)			
Street Address: 700 Albany St and Crosstown Center	City: Boston	State: MA	ZIP Code: 02215
Office Telephone (Include Area Code): (617) 638-5914			

b. Will the Data be stored by the third party on a system in the cloud (reachable via the Internet)?

Yes No

i. If you answered yes to (b): Has this Cloud Service Provider passed a FedRAMP 3PAO assessment for the specific cloud system which will host the data?

Yes No

ii. If you answered yes to (b): What is the name of the provider and the FedRAMP level the specific cloud system hosting the data is operating at?

2. Data Privacy Training and Awareness:

a. Has every individual who will access the Data received training on the proper handling of protected health information and/or personal data within the last year?

Yes No

3. Encryption of Data:

a. Will all CHIA Data at rest be encrypted on storage media (backup tapes, local hard drives, network storage, et al) with encryption at least AES-256 or stronger.

Yes No

b. Will CHIA Data be transmitted by your Agency or Organization over the Internet?

Yes No

If you answered yes to (b): which of the following if any are used when transmitting data over the internet? If selecting *other* please describe the method in space provided below.

SSL (meets or exceeds TLS 1.1 or TLS 1.2) SFTP other

4. Information Security:

a. Does your Agency or Organization have published information security policies which are followed and accessible to all staff accessing or handling CHIA Data?

Yes No

b. Has every individual who will access the CHIA Data received cyber security awareness training in the last year?

Yes No

- c. Has your Agency or Organization experienced a breach of PHI or Personally Identifiable Information in the last seven (7) years?

Yes No

- i. If you answered yes to (c): how was the breach resolved and what steps were taken to prevent a recurrence?

Policies can be found here:
<http://www.bu.edu/policies/information-security-home>
 Training is provided by:
<https://www.citiprogram.org/>
 In cases of a PII breach, our organization follows practices as outlined in our breach policy:
<http://www.bu.edu/policies/information-security-home/hpaa-data-security-incident-breach-policy/>

5. Technical and Physical Controls:

- a. Are all the user accounts that log on to any machine (server or endpoint) that accesses the Data uniquely assigned to individual users (i.e., the user accounts are not shared)?

Yes No

- b. Is an audit log maintained of all user log-ons to the system hosting the CHIA Data?

Yes No

- c. What is the minimum password length and character complexity (uppercase, lowercase, numeric, and special characters) required for new passwords on the user accounts logging on to the system accessing the CHIA Data?

The file system utilizes access control lists based on usernames and group membership to control who can access what data. Access to the CHIA data set will be limited to members of the research team. On central file servers, access will be verified through the use of our DLP software, which will enable us to log who accesses CHIA data.
 Account and Password policy and requirements are documented here:
<http://www.bu.edu/policies/information-security-home/data-protection-standards/access-management-and-authentication-requirements/>
 Systems must comply with Minimum Security Standards for Restricted Use data as documented here:
<http://www.bu.edu/policies/information-security-home/data-protection-standards/minimum-security-standards/>
 Account Maintenance and Security Policies are documented here:
<http://www.bu.edu/policies/information-security-home/account-maintenance-security/>

- d. Describe any additional authentication technical security controls you employ to defend the system against unauthorized logon, e.g. maximum failed login attempts, lockout period, etc.:

- e. Do you run a current version of a commercial off-the-shelf anti-virus or anti-malware product on the server that will host the CHIA Data?

Yes No

- f. If the CHIA Data will be on a server or network accessible storage drive, then check all the security features present in the room containing CHIA Data:
- i. Recorded video
 - ii. Access log of all individuals entering the room
 - iii. Secure server rack
 - iv. Access control limiting access only to authorized individuals
- g. What additional specific physical or technical safeguards (not mentioned in prior answers) will be used to *mitigate* the risk of unauthorized access to CHIA Data?

This system is comprised of a Storage Area Network (SAN) which services block-level storage to a Windows Server front-end that provides the directory and share level access and permissions. The primary components of this system reside in the BUMC IT server room at 700 Albany St and Crosstown Center. These server rooms require badged access for entry, have video surveillance to monitor activity once inside the room, and are both guarded at building entrance during normal and extended business hours. Access to University data centers is limited to approved staff and is reviewed on a periodic basis. These data centers operate with redundant cooling and power. Server and storage hardware have their own internal redundant components.

CHIA data stored on BUMC-IT central file servers will be in an encrypted container created using BitLocker. All systems utilize NTFS/share-based permissions for access control and leverages the University Active Directory for authentication. Access to data stored on central file server will be verified through the use of our DLP software, which will enable us to log who accesses CHIA data. Details are available at:

<http://www.bu.edu/policies/information-security-home/access-management-and-authentication-requirements/>

Data stored on the central file servers would be backed up as encrypted file and would still be encrypted when restored from backup.

- h. When was the last information security risk assessment performed in your Agency or Organization? Who conducted it?

In January 2015, a review was performed of the file server where the data will be stored. The review was conducted by BUMC-IT and BU Information Security.

- i. When was the last IT audit performed in your Agency or Organization? Who conducted it?

Internal Audit last reviewed BUMC-IT in April of 2010.

VI. DATA RETURN OR DESTRUCTION

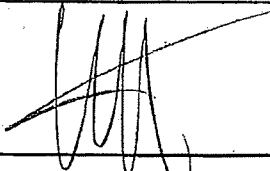
The Recipient attests that the CHIA Data and all copies of the CHIA Data used by the Applicant or its employees, contractors, or agents will be destroyed upon Project Completion or termination of the Data Use Agreement. All data destruction must conform to the requirements of M.G.L. c. 93J and to the Data Use Agreement. Please specify below the technical measures you will use to meet these requirements.

When the study has concluded, the applicant will bring physical media received containing original CHIA data to BUMC IT for data destruction. BUMC IT will certify the destruction of active identified data stored on central resources under their control. This will be done by using a tool, such as 'sdelete', to scrub the data as it exists on disk. Data stored in snapshots will expire over time and cannot be actively deleted. BUMC IT may assist in the destruction of identified data on other media, workstations or laptops.

VI. ATTESTATION

By submitting this Data Management Plan, the Agency or 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 Agency or 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 its agents.

By signature below, I attest: (1) to the accuracy of the information provided herein; (2) that the Agency or Organization agrees to hold and/or access CHIA Data at all times in compliance with all provisions of this Data Management Plan and the Data Use Agreement; and (3) to my authority to bind the Agency or Organization undersigned is an authorized signatory of the organization.

Signature: (Authorized Signatory for Agency/Organization)	
Printed Name:	William P. Segarra, JD, MPH
Title:	Director, Industry Contracts & Agreements
Organization:	Trustees of Boston University
Date:	3/6/2017