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]

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

2. Provide 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 stufy 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:

☐ **Dental Claims**
☐2011 ☐2012 ☐2013 ☐2014 ☐2015

Describe how your research objectives require Dental Claims data:

☒ **Member Eligibility**
☒2011 ☒2012 ☒2013 ☒2014 ☒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.

☒ **Provider**
☒2011 ☒2012 ☒2013 ☒2014 ☒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.

☒ **Product**
☒2011 ☒2012 ☒2013 ☒2014 ☒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** ☐ 2016 ☐ 2017 ☐ 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.

☐ 3-Digit Zip Code (standard)	☒ 5-Digit Zip Code***
***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.	

Dates

Choose *one* option from the following options for dates.

☐ Year (YYYY) (Standard)	☐ Month (YYYYMM) ***	☒ Day (YYYYMMDD) *** [for selected data elements only]
*** If requested, provide justification for requesting Month or Day. Refer to specifics in your methodology: 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.		

National Provider Identifier (NPI)

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

☐ Encrypted National Provider Identifier(s) (standard)	☒ Decrypted National Provider Identifier(s)***
*** 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.	

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:

- 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
- 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 Agecny must have a written agreement with the agent of contractor limiting the use of CHIA Data to the use approved under this Application as well as the privacy and security standards set forth in the Data Use Agreement. CHIA Data may not be shared with any third party without prior written consent from CHIA, or an amendemtn 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 whicih 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 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'
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)