center for health information and analysis

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

I. INSTRUCTIONS

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

Before completing this Application, please review the data request information on CHIA's website:

- Data Availability
- Fee Schedule
- Data Request Process

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

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

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

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

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

II. FEE INFORMATION

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

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

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

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

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

III. ORGANIZATION & INVESTIGATOR INFORMATION

Project Title:	Long Term Outcomes of Coronary and Structural Heart Disease Interventions in a Multicenter Linked Procedural and Claims Dataset
IRBNet Number:	Click here to enter text.
Organization Requesting Data (Recipient):	Beth Israel Deaconess Medical Center, Inc
Organization Website:	**www.bidmc.org/SmithCenter**
Authorized Signatory for Organization:	**Marlena Konieczynska, PhD**
Title:	Sr. Research Contract Associate, Sponsored Programs Contracting
E-Mail Address:	mkoniecz@bidmc.harvard.edu
Telephone Number:	607-667-8238
Address, City/Town, State, Zip Code:	Beth Israel Deaconess Medical Center, 330 Brookline Ave., Boston, MA 02215
Data Custodian: **(individual responsible for organizing, storing, and archiving Data)**	Yang Song, MSc
Title:	Biostatistics Manager
E-Mail Address:	ysong5@bidmc.harvard.edu
Telephone Number:	857-210-4601
Address, City/Town, State, Zip Code:	Beth Israel Deaconess Medical Center, 330 Brookline Ave., Masco 4-Smith Center, Boston, MA 02215
Primary Investigator (Applicant): **(individual responsible for the research team using the Data)**	Robert W. Yeh, MD
Title:	Director, Richard A. and Susan F. Smith Center for Outcomes Research in Cardiology, Beth Israel Deaconess Medical Center
E-Mail Address:	ryeh@bidmc.harvard.edu
Telephone Number:	617-632-7695
Address, City/Town, State, Zip Code:	Beth Israel Deaconess Medical Center, 330 Brookline Ave., Masco 4 - Smith Center, Boston, MA 02215
Names of Co-Investigators:	Yang Song, MS; Dhaval Kolte, MD, PhD; Zaid Al-Marzooq, MBBCh
E-Mail Addresses of Co-Investigators:	Ysong5@bidmc.harvard.edu dkolte@mgh.harvard.edu zalmarzooq@bidmc.harvard.edu

IV. PROJECT INFORMATION

IMPORTANT NOTE: Organization represents that the statements made below as well as in any study or research protocol or project plan, or other documents submitted to CHIA in support of the Data Application are complete and accurate and represent the total use of the CHIA Data requested. Any and all CHIA Data released to the Organization under an approved application may ONLY be used for the express purposes identified in this section by the Organization, and for no other purposes. Use of CHIA Data for other purposes requires a separate Data Application to CHIA **or** written request to CHIA, with approval being subject to CHIA's regulatory restrictions and approval process. Unauthorized use is a material violation of your Organizations's Data Use Agreement with CHIA.

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

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

Click here to enter text.

2. Provide an abstract or brief summary of the specific purpose and objectives of your Project. This description should include the research questions and/or hypotheses the project will attempt to address, or describe the intended product or report that will be derived from the requested data and how this product will be used. Include a brief summary of the pertinent literature with citations, if applicable.

The collection of long-term outcome data for coronary and structural heart disease interventions poses a challenge to clinical sites and their patients. The collection of these data for research purposes is time consuming and expensive. As a result, these long-term data, which are critical to the evaluation of safety and effectiveness of interventional therapies and devices, often have high rates of missingness. For example, the TVT Registry, which collects patient and procedural variables related to transcatheter aortic valve replacement (TAVR) in the United States, currently requires follow-up at 1 year for the ascertainment of a number of adverse patient and valve-related endpoints, but participants note that these data are frequently difficult to obtain. Patients, who may have been referred from a remote outside facility to a tertiary medical center for the procedure, are not always being followed by the physician who performed the procedure, or even at the institution where the procedure was performed. With the rapid expansion of indications for transcatheter therapies over the past few years, and a corresponding exponential increase in the number of patients receiving these therapies, real-world evidence of safety and effectiveness of these therapies are urgently needed.

Administrative claims data such as hospital and provider billing claims for Medicare fee-for-service beneficiaries have been extensively used for comparative effectiveness research and post-market safety evaluations of medical devices. Information from these databases can be used to create comorbidity profiles of patients undergoing procedures and track long term outcomes. The use of claims data could lend a number of advantages over existing registries, including more reliably tracking outcomes after the index procedure hospitalization and having substantially lower associated costs.

Under this protocol, we aim to link patient and procedural data from the electronic medical records at Beth Israel Deaconess Medical Center (BIDMC), Lahey Hospital & Medical Center (Lahey), Massachusetts General Hospital (MGH), and Brigham and Women's Hospital (BWH) with fee-for-service claims data from the Centers for Medicare and Medicaid Services, as well as, Massachusetts data from the Center for Healthcare Information and Analysis (CHIA) – namely the Case Mix data and All-Payer Claims Database(APCD). The creation of this dataset will allow us to evaluate short- and long-term outcomes for patients undergoing procedures including TAVR, valve surgery, percutaneous coronary intervention (PCI), coronary artery bypass graft (CABG), mitral valve repair, and left atrial appendage occlusion, in a more comprehensive way than would be possible using single-site studies or registry data. Future projects involving this dataset will evaluate in-hospital, short-term, and long-term adverse event rates; investigate the outcomes of patients with aortic stenosis of varying levels of severity; and examine patient- and facility-level predictors of outcomes.

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

V. PUBLIC INTEREST

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

Transcatheter heart valve and coronary interventions play a major role in the management of certain pathologies amongst cardiovascular disease patients. In the United States, >70,000 TAVR procedures are now performed annually across >700 centers. The exponential increased in the volume of such procedures calls for a more accurate measurement of effectiveness and outcomes. Long-term data are needed to evaluate the safety and effectiveness of these interventions. Existing procedural registries contain a high degree of missing data, and are limited in the length of follow-up that they capture. Linking procedural data from hospitals with post-procedural outcome data from CHIA could lend a number of advantages over existing registries, including more reliably tracking outcomes and quality of care after the index procedure hospitalization and having substantially lower associated costs. Results of the proposed research will be intended for publication in academic medical journals, and will be used to improve scientific understanding of outcomes associated with interventional cardiac procedures.

VI. DATASETS REQUESTED

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

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

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

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

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

☒ **Release MA APCD CY 2018 (R 8.0)**	☒ **Release MA APCD CY 2020**
☒ 2014	☒ 2016
☒ 2015	☒ 2017
☒ 2016	☒ 2018
☒ 2017	☒ 2019
☒ 2018	☒ 2020

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

☒ **Medical Claims**
Describe how your research objectives require Medical Claims data: The medical claims data will allow us to obtain diagnoses and treatment information, and determine the associated outcomes (mortality, readmission, cost, length of stay, etc.). The multiple years of data will allow us to evaluate individual outcomes for several years after undergoing cardiovascular procedures, and to assess trends in treatments and outcomes over time.
☒ **Pharmacy Claims**
Describe how your research objectives require Pharmacy Claims data: Pharmacy claims will be used to measure outcomes associated with medications used in association with certain cardiac procedures.
☐ **Dental Claims**
Describe how your research objectives require Dental Claims data: Click here to enter text.
☒ **Member Eligibility**
Describe how your research objectives require Member Eligibility data: Our project aims to identify factors that influence patient outcomes after interventional cardiovascular procedures. We will use the member eligibility data to identify gaps in health insurance coverage and investigate whether they influence outcomes in these patient groups.
☒ **Provider**
Describe how your research objectives require Provider data: We will use provider data to assess variation and trends in outcomes, resource utilization, and treatment strategy among providers with regard to cardiovascular procedures.
☐ **Product**
Describe how your research objectives require Product data: Click here to enter text.

VII. DATA ENHANCEMENTS REQUESTED

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

All-Payer Claims Database data is released in Limited Data Sets (LDS). All Organizations receive the "Core" LDS, but may also request the data enhancements listed below for inclusion in their analyses. Requests for enhancements will be reviewed by CHIA to determine whether each represents the minimum data necessary to complete the specific Project objective.

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

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

a. Geographic Subdivisions

ZIP code and state geographic subdivisions are available for Massachusetts residents and providers only. Small population ZIP codes are combined with larger population ZIP codes. One ZIP Code per person (MEID) per year has been assigned based on the ZIP code/state reported in the member eligibility record's earliest submission year month. If the record does not have an MEID, assignment is based on distinct OrgID/Carrier Specific Unique Member ID.

Non-Massachusetts ZIP codes and sate codes except for CT, MA, ME, NH, NY, RI, and VT are suppressed.

Select *one* of the following options.

☐ 3-Digit Zip Codes (standard)	☒ 5-Digit Zip Codes*** *.
***If requested, provide justification for requesting 5-Digit Zip Code. Refer to specifics in your methodology: Using 5 digit zipcodes will allow for greater match rates.	

b. Date Resolution

Select *one* option from the following options.

☐ Year (YYYY) (Standard)	☐ Month (YYYYMM) ***	☒ Day (YYYYMMDD) *** [for selected data elements only]
*** If requested, provide justification for requesting Month or Day. Refer to specifics in your methodology: To derive time-to-event outcomes, we need complete date information including year, month, and day. So we can use the standard and conventional survival analysis methods including Kaplan-Meier Curves and Cox regressions.		

c. National Provider Identifier (NPI)

Select *one* of the following options.

☒ Encrypted National Provider Identifiers (standard)	☐ Decrypted National Provider Identifiers***

***** If requested, provide justification for requesting decrypted National Provider Identifier(s). Refer to specifics in your methodology:**

Click here to enter text.

VIII. MEDICAID (MASSHEALTH) DATA

1. Please indicate whether you are seeking Medicaid Data:

☒ Yes
☐ No

2. Federal law (42 USC 1396a(a)7) restricts the use of individually identifiable data of Medicaid recipients to uses that are ***directly connected to the administration of the Medicaid program***. If you are requesting MassHealth Data, please describe, in the space below, why your use of the Data meets this requirement. *Your description should focus on how the results of your project could be used by the Executive Office of Health and Human Services in connection with the administering the MassHealth program*. Requests for MassHealth Data will be forwarded to MassHealth for a determination as to whether the proposed use of the Data is directly connected to the administration of the MassHealth program. CHIA cannot release MassHealth Data without approval from MassHealth. This may introduce significant delays in the receipt of MassHealth Data.

Click here to enter text.

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

IX. DATA LINKAGE

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

1. Do you intend to link or merge CHIA Data to other data?
   - ☒ Yes
   - ☐ No linkage or merger with any other data will occur

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

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

BIDMC has created a novel dataset by linking procedural data from four hospitals (MGH, BWH, Lahey and BIDMC, locally called the Boston Heart Valve Consortium [BHVC] with data obtained from the Centers of Medicare and Medicaid services; specifically, fee-for-service data. This data only contains linkages performed for patients above the age of 65 years. It is anticipated to link the data from CHIA with the procedural dataset to include patients above the age of 18 years. This will involve the use of commercial data, as well as, Medicaid data from the All-payer claims database. In addition, hospital inpatient discharge data, outpatient emergency department visit data and outpatient observation stay data from the case mix files will be utilized for linkage.

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.

The boston heart valve consortium contains SSN's which are intended to be linked to patients in the CHIA registries through matching of SSN. This will enable a deterministic method of linkage between the current BHVC and CHIA data.

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

Variables to be included: first name, last name, social security number, date of birth, state, zip code, gender, procedure type, procedure date and hospital the procedure was performed and dates of service

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

Data sent to CHIA will initially be run through File Secure and each patient record will be given a unique identifier. Linkages involving the CHIA datasets will be performed by statisticians and a secure file will be sent back to BIDMC. Once the linkage between the two datasets has been performed, we will remove the direct identifiers from the dataset. Only those investigators with IRB approval and meeting CHIA DUA requirements will be allowed access to the combined dataset, and all analyses will be performed at the Smith Center without distribution of the raw data.

X. PUBLICATION / DISSEMINATION / RE-RELEASE

1. Do you anticipate that the results of your analysis will be published or made publically available? If so, how do you intend to disseminate the results of the study (e.g.; publication in professional journal, poster presentation, newsletter, web page, seminar, conference, statistical tabulation)? Any and all publication of CHIA Data must comply with CHIA's cell size suppression policy, as set forth in the Data Use Agreement. Please explain how you will ensure that any publications ***will not disclose a cell less than 11***, and percentages or other mathematical formulas that result in the display of a cell less than 11.

Over the coming years, the findings from this research will be presented at national/international research conferences such as the American College of Cardiology Scientific Sessions, the American Heart Association Scientific Sessions, and the Society for Cardiovascular Angiography and Interventions annual conference, and published in peer-reviewed medical journals such as *JAMA*, the *Journal of the American College of Cardiology*, and *Circulation*.

All use of data will be done in accordance with the approved CHIA DUA. All output containing individually identifiable information will be treated as confidential data. Such information will never be transferred electronically via e-mail or other protocols. This includes complying with CHIA's policy to suppress cell sizes less than 11.

2. Describe your plans to use or otherwise disclose CHIA Data, or any Data derived or extracted from such Data, in any paper, report, website, statistical tabulation, seminar, or other setting that is not disseminated to the public.

All research derived from the dataset is planned on being published.

3. What will be the lowest geographical level of analysis of data you expect to present for publication or presentation (e.g., state level, city/town level, zip code level, etc.)? Will maps be presented? If so, what methods will be used to ensure that individuals cannot be identified?

Lowest level of analysis will be at the zip code level. After linkage, data will be de-identified and no identifiable association between patient and outcome will be distributed or made publicly available.

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

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

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

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

☐ Yes
☒ No

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

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

Click here to enter text.

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

Click here to enter text.

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

Click here to enter text.

XI. APPLICANT QUALIFICATIONS

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

Investigators at the Smith Center for Outcomes Research in Cardiology at BIDMC have successfully used claims data from the Centers of Medicare and Medicaid Services, as well as, CHIA (case mix and APCD) for the publication of a variety of research projects. Success of such projects has been accompanied by the help of skilled statisticians with years of experience in analyzing Medicare claims data.

Dr. Robert Yeh is the Director of the Richard A. and Susan F. Smith Center for Outcomes Research in Cardiology at the Beth Israel Deaconess Medical Center, and Assistant Professor of Medicine at Harvard Medical School. His area of investigation focuses on evaluating cardiovascular devices and therapies in both clinical trials and observational studies, with an emphasis on understanding methods to improve the value of novel technologies as they are used in clinical practice. He serves as the Medical Director of Trial Design for the Harvard Clinical Research Institute. His clinical area of expertise is in interventional cardiology, with an emphasis in coronary chronic total occlusion intervention.

Yang Song, MS, is the Biostatistical Manager at the Smith Center for Outcomes Research. He has over 10 years of experience in using SAS program and analyzing claims data. He has previous work experience at Baim institute for clinical research in implementing complex statistical methods and mentoring clinical investifators, fellows, medical students and residents.

Dhaval Kolte, MBBS, PhD is a structural interventional cardiologist and clinical researcher at Massachusetts General Hospital. His areas of investigation are cardiovascular outcomes and quality of care. Specifically, his current research focuses on hospital-level variation in outcomes of transcatheter valve interventions and identifying modifiable practices and processes of care associated with improved patient outcomes.

Zaid Al-Marzooq, MBBCh is the chief cardiology fellow at Brigham and Women's Hospital. He is a research fellow at the Smith Center working on clinical and healthcare utilization outcomes of TAVR related stroke events. His other research interests include developing models for procedural risk stratification in structural heart interventions.

2. **Resumes/CVs**: When submitting your Application package on IRBNet, include résumés or curricula vitae of the principal investigator and co-investigators. (These attachments will not be posted on the internet.)

XII. USE OF AGENTS AND/OR CONTRACTORS

By signing this Application, the Organization assumes all responsibility for the use, security and maintenance of the CHIA Data by its agents, including but not limited to contractors. The Organization must have a written agreement with the agent of contractor limiting the use of CHIA Data to the use approved under this Application as well as the privacy and security standards set forth in the Data Use Agreement. CHIA Data may not be shared with any third party without prior written consent from CHIA, or an amendment to this Application. CHIA may audit any entity with access to CHIA Data.

Provide the following information for **all** agents and contractors who will have access to the CHIA Data. [*Add agents or contractors as needed.]*

No agents will be contracted for this project.

AGENT/CONTRACTOR #1 INFORMATION	
Company Name:	Click here to enter text.
Company Website	Click here to enter text.
Contact Person:	Click here to enter text.
Title:	Click here to enter text.
E-mail Address:	Click here to enter text.
Address, City/Town, State, Zip Code:	Click here to enter text.
Telephone Number:	Click here to enter text.
Term of Contract:	Click here to enter text.

1. Describe the tasks and products assigned to the agent or contractor for this Project and their qualifications for completing the tasks.

Click here to enter text.

2. Describe the Organization's oversight and monitoring of the activities and actions of the agent or contractor for this Project, including how the Organization will ensure the security of the CHIA Data to which the agent or contractor has access.

Click here to enter text.

3. Will the agent or contractor have access to and store the CHIA Data at a location other than the Organization's location, off-site server and/or database?

☐ Yes
☐ No

4. If yes, a separate Data Management Plan **must** be completed by the agent or contractor.

AGENT/CONTRACTOR #1 INFORMATION	
Company Name:	Click here to enter text.
Company Website	Click here to enter text.
Contact Person:	Click here to enter text.
Title:	Click here to enter text.
E-mail Address:	Click here to enter text.
Address, City/Town, State, Zip Code:	Click here to enter text.
Telephone Number:	Click here to enter text.
Term of Contract:	Click here to enter text.

1. Describe the tasks and products assigned to the agent or contractor for this Project and their qualifications for completing the tasks.

Click here to enter text.

2. Describe the Organization's oversight and monitoring of the activities and actions of the agent or contractor for this Project, including how the Organization will ensure the security of the CHIA Data to which the agent or contractor has access.

Click here to enter text.

3. Will the agent or contractor have access to or store the CHIA Data at a location other than the Organization's location, off-site server and/or database?

☐ Yes
☐ No

4. If yes, a separate Data Management Plan **must** be completed by the agent or contractor.

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

XIII. ATTESTATION

By submitting this Application, the Organization attests that it is aware of its data use, privacy and security obligations imposed by state and federal law *and* confirms that it is compliant with such use, privacy and security standards. The Organization further agrees and understands that it is solely responsible for any breaches or unauthorized access, disclosure or use of CHIA Data, including, but not limited to, any breach or unauthorized access, disclosure or use by any third party to which it grants access.

Organizations approved to receive CHIA Data will be provided with Data following the payment of applicable fees and upon the execution of a Data Use Agreement requiring the Organization to adhere to processes and procedures designed to prevent unauthorized access, disclosure or use of data.

By my signature below, I attest: (1) to the accuracy of the information provided herein; (2) this research is not funded by a source requiring the release of raw data to that source; (3) that the requested Data is the minimum necessary to accomplish the purposes described herein; (4) that the Organization will meet the data privacy and security requirements described in this Application and supporting documents, and will ensure that any third party with access to the Data meets the data use, privacy and security requirements; and (5) to my authority to bind the Organization.

Signature: (Authorized Signatory for Organization)	Drag signature image here or delete and physically sign
Printed Name:	Marlena D. Konieczynska, PhD
Title:	Sr. Research Contract Associate
Date:	

Attachments:
A completed Application must have the following documents attached to the Application or uploaded separately to IRBNet:
☒ 1. IRB approval letter and protocol (if applicable), or research methodology (if protocol is not attached)
☒ 2. Data Management Plan (including one for each agent or contractor that will have access to or store the CHIA Data at a location other than the Organization's location, off-site server and/or database);
☒ 3. CVs of Investigators (upload to IRBNet)

APPLICATIONS WILL NOT BE REVIEWED UNTIL THEY ARE COMPLETE, INCLUDING ALL ATTACHMENTS.

Application for Massachusetts Case Mix and Charge Data (Non-Government) [Exhibit A – Data Application]

VIII. INSTRUCTIONS

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

Before completing this Application, please review the data request information on CHIA's website:

- Data Availability
- Fee Schedule
- Data Request Process

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

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

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

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

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

IX. FEE INFORMATION

1. Consult the most current Fee Schedule for Case Mix and Charge Data.

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

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

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

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

X. ORGANIZATION & INVESTIGATOR INFORMATION

Project Title:	Long Term Outcomes of Coronary and Structural Heart Disease Interventions in a Multicenter Linked Procedural and Claims Dataset
IRBNet Number:	Click here to enter text.
Organization Requesting Data (Recipient):	Beth Israel Deaconess Medical Center, Inc
Organization Website:	**www.bidmc.org/SmithCenter**
Authorized Signatory for Organization:	**Marlena D. Konieczynska, PhD**
Title:	Sr. Research Contract Associate, Sponsored Programs Contracting
E-Mail Address:	mkoniecz@bidmc.harvard.edu
Telephone Number:	617-667-8238
Address, City/Town, State, Zip Code:	Beth Israel Deaconess Medical Center, 330 Brookline Ave., Boston, MA 02215
Data Custodian: **(individual responsible for organizing, storing, and archiving Data)**	Yang Song, MSc
Title:	Biostatistics Manager
E-Mail Address:	ysong5@bidmc.harvard.edu
Telephone Number:	857-210-4601
Address, City/Town, State, Zip Code:	Beth Israel Deaconess Medical Center, 330 Brookline Ave., Masco 4 - Smith Center, Boston, MA 02215
Primary Investigator (Applicant): **(individual responsible for the research team using the Data)**	Robert W. Yeh, MD
Title:	Director, Richard A. and Susan F. Smith Center for Outcomes Research in Cardiology, Beth Israel Deaconess Medical Center
E-Mail Address:	ryeh@bidmc.harvard.edu
Telephone Number:	617-852-3016
Address, City/Town, State, Zip Code:	Beth Israel Deaconess Medical Center, 330 Brookline Ave., Masco 4 - Smith Center, Boston, MA 02215
Names of Co-Investigators:	Yang Song, MD; Dhaval Kolte MD; Zaid Al-Marzooq, MBBCh
E-Mail Addresses of Co-Investigators:	Ysong5@bidmc.harvard.edu dkolte@mgh.harvard.edu zalmarzooq@bidmc.harvard.edu

XI. PROJECT INFORMATION

IMPORTANT NOTE: Organization represents that the statements made below as well as in any study or research protocol or project plan, or other documents submitted to CHIA in support of the Data Application are complete and accurate and represent the total use of the CHIA Data requested (the "Project"). Any and all CHIA Data released to the Organization under an approved application may ONLY be used for the express purposes identified in this section by the Organization, and for no other purposes. Use of CHIA Data for other purposes requires a separate Data Application to CHIA, with approval being subject to CHIA's regulatory restrictions and approval process. Unauthorized use is a material violation of your Organization's Data Use Agreement with CHIA.

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

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

Click here to enter text.

2. Provide an abstract or brief summary of the specific purpose and objectives of your Project. This description should include the research questions and/or hypotheses the Project will attempt to address, or describe the intended product or report that will be derived from the requested Data and how this product will be used. Include a brief summary of the pertinent literature with citations, if applicable.

The collection of long-term outcome data for coronary and structural heart disease interventions poses a challenge to clinical sites and their patients. The collection of these data for research purposes is time consuming and expensive. As a result, these long-term data, which are critical to the evaluation of safety and effectiveness of interventional therapies and devices, often have high rates of missingness. For example, the TVT Registry, which collects patient and procedural variables related to transcatheter aortic valve replacement (TAVR) in the United States, currently requires follow-up at 1 year for the ascertainment of a number of adverse patient and valve-related endpoints, but participants note that these data are frequently difficult to obtain. Patients, who may have been referred from a remote outside facility to a tertiary medical center for the procedure, are not always being followed by the physician who performed the procedure, or even at the institution where the procedure was performed. With the rapid expansion of indications for transcatheter therapies over the past few years, and a corresponding exponential increase in the number of patients receiving these therapies, real-world evidence of safety and effectiveness of these therapies are urgently needed.

Administrative claims data such as hospital and provider billing claims for Medicare fee-for-service beneficiaries have been extensively used for comparative effectiveness research and post-market safety evaluations of medical devices. Information from these databases can be used to create comorbidity profiles of patients undergoing procedures and track long term outcomes. The use of claims data could lend a number of advantages over existing registries, including more reliably tracking outcomes after the index procedure hospitalization and having substantially lower associated costs.

Under this protocol, we aim to link patient and procedural data from the electronic medical records at Beth Israel Deaconess Medical Center (BIDMC), Lahey Hospital & Medical Center (Lahey), Massachusetts General Hospital (MGH), and Brigham and Women's Hospital (BWH) with fee-for-service claims data from the Centers for Medicare and Medicaid Services, as well as, Massachusetts data from the Center for Healthcare Information and Analysis (CHIA) – namely the Case Mix data and All-Payer Claims Database(APCD). The creation of this dataset will allow us to evaluate short- and long-term outcomes for patients undergoing procedures including TAVR, valve surgery, percutaneous coronary intervention (PCI), coronary artery bypass graft (CABG), mitral valve repair, and left atrial appendage occlusion, in a more comprehensive way than would be possible using single-site studies or registry data. Future projects involving this dataset will evaluate in-hospital, short-term, and long-term adverse event rates; investigate the outcomes of patients with aortic stenosis of varying levels of severity; and examine patient- and facility-level predictors of outcomes.

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**: Applications must include either the IRB protocol or a written description of the Project methodology (typically 1-2 pages), which states the Project objectives and/or identifies 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.

XII. PUBLIC INTEREST

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

Transcatheter heart valve and coronary interventions play a major role in the management of certain pathologies amongst cardiovascular disease patients. In the United States, >70,000 TAVR procedures are now performed annually across >700 centers. The exponential increased in the volume of such procedures calls for a more accurate measurement of effectiveness and outcomes. Long-term data are needed to evaluate the safety and effectiveness of these interventions. Existing procedural registries contain a high degree of missing data, and are limited in the length of follow-up that they capture. Linking procedural data from hospitals with post-procedural outcome data from CHIA could lend a number of advantages over existing registries, including more reliably tracking outcomes and quality of care after the index procedure hospitalization and having substantially lower associated costs. Results of the proposed research will be intended for publication in academic medical journals, and will be used to improve scientific understanding of outcomes associated with interventional cardiac procedures.

.

XIII. DATASETS REQUESTED

The Massachusetts Case Mix and Charge Data ("Case Mix") are comprised of Hospital Inpatient Discharge, Emergency Department and Outpatient Hospital Observation Stay Data collected from Massachusetts' acute care hospitals, and satellite emergency facilities. Case Mix Data are updated each fiscal year (October 1 – September 30) and made available to approved data users. For more information about Case Mix Data, including a full list of available elements in the datasets please refer to release layouts, data dictionaries and similar documentation included on CHIA's website.

Data requests are typically fulfilled on a one time basis, however; certain Projects may require years of data not yet available. Applicants who anticipate a need for future years of data may request to be considered for a subscription. Approved subscriptions will receive, upon request, the same data files and data elements included in the initial release annually or as available. Please note that approved subscription request will be subject to the Data Use Agreement, will require payment of fees for additional Data, and subject to the limitation that the Data can be used only in support of the approved Project.

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

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

2. Specify below the dataset(s) and year(s) of data requested for this Project, and your justification for requesting *each* dataset. Data prior to 2004 is not available.

☒ Hospital Inpatient Discharge Data ☐2004 ☐2005 ☐2006 ☐2007 ☐2008 ☐2009 ☐2010 ☐2011 ☐2012 ☐2013 ☐2014 ☒2015 ☒2016 ☒2017 ☒2018 ☒2019 ☒2020 ☒2021
Describe how your research objectives require Inpatient Discharge data: The inpatient discharge data will allow us to obtain treatment information after procedures, and determine the associated outcomes (mortality, readmission, cost, length of stay, etc.). The multiple years of data will allow us to evaluate individual outcomes for several years after undergoing cardiovascular procedures, and to assess trends in treatments and outcomes over time.
☒ Outpatient Hospital Observation Stay Data ☐2004 ☐2005 ☐2006 ☐2007 ☐2008 ☐2009 ☐2010 ☐2011 ☐2012 ☐2013 ☐2014 ☒2015 ☒2016 ☒2017 ☒2018 ☒2019 ☒2020 ☒2021
Describe how your research objectives require Outpatient Hospital Observation Stay data: Following interventional cardiovascular procedures, patients often require follow-ups at the outpatient departments. This data will improve the identification of patient outcomes following specified vascular procedures.
☒ Emergency Department Data ☐2004 ☐2005 ☐2006 ☐2007 ☐2008 ☐2009 ☐2010 ☐2011 ☐2012 ☐2013 ☐2014 ☒2015 ☒2016 ☒2017 ☒2018 ☒2019 ☒2020 ☒2021
Describe how your research objectives require Emergency Department data: Patients with cardiovascular issues often seek care in emergency departments. Data about outcomes of cardiovascular procedures can be tracked through the follow-up of patients presenting to the emergency departments for the development of complications days to years following procedures. This data would be of significant value to the production of this dataset.

XIV. DATA ENHANCEMENTS REQUESTED

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

Case Mix Data are released in Limited Data Sets (LDS). All applicants receive the "Core" LDS, but may also request the data enhancements listed below for inclusion in their analyses. Requests for enhancements will be reviewed by CHIA to determine whether each represents the minimum data necessary to complete the specific Project objective.

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

Please note that CHIA Case Mix Data contain reports produced using proprietary computer software created, owned, and licensed by the 3M Company. All Copyrights in and to the 3M APR™ Software, and to the 3M

1. Specify below which enhancements you are requesting in addition to the "Core" LDS.

Geographic Subdivisions

State code, five-digit ZIP code, and 3-digit ZIP code are available for patients residing in CT, MA, ME, NH, RI, VT, and NY. City or Town of residence is available for residents of MA only. States outside of this region will be coded as XX ("Other").

Select *one* of the following options:

☐ 3-Digit Zip Code (Standard)	☐ 3-Digit Zip Code & City/Town ***	☒ 5-Digit Zip Code ***	☐ 5-Digit Zip Code & City/Town ***
*****If requested, provide justification for requesting 5-Digit Zip Code or City/Town. Refer to specifics in your methodology:** Using 5 digit zipcodes will allow for greater match rates.			

Demographic Data

Selcect *one* of the following options:

☒ Not Requested (Standard)	☐ Race & Ethnicity***
**** If requested, provide justification for requesting Race and Ethnicity. Refer to specifics in your methodology:** Click here to enter text.	

Date Resolution

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

☐ Year (YYYY)(Standard)	☐ Month (YYYYMM) ***	☒ Day (YYYYMMDD)***
*****If requested, provide justification for requesting Month or Day. Refer to specifics in your methodology:** To derive time-to-event outcomes, we need complete date information including year, month, and day. So we can use the standard and conventional survival analysis methods including Kaplan-Meier Curves and Cox regressions.		

Practioner Identifiers (UPN)

Select *one* of the following options.

☒ Not Requested (Standard)	☐ Hashed ID ***	☐ Board of Registration in Medicine Number(BORIM) ***

*****If requested, provide justification for requesting Hashed ID or BORIM Number. Refer to specifics in your methodology:** Click here to enter text.

Unique Health Information Number (UHIN)

Select *one* of the following options.

☒ Not Requested (Standard)	☐ UHIN Requested ***
***** If requested, provide justification for requesting UHIN. Refer to specifics in your methodology:** Click here to enter text.	

Hashed Mother's Social Security Number

Select *one* of the following options:

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

XIV. 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.

BIDMC has created a novel dataset by linking procedural data from four hospitals (MGH, BWH, Lahey and BIDMC locally called the Boston Heart Valve Consortium (BHVC) with data obtained from the Centers of Medicare and Medicaid services; specifically, fee-for-service data. This data only contains linkages performed for patients above the age of 65 years. It is anticipated to link the data from CHIA with the current dataset to

additionally include all patients above the age of 18 years. This will involve the use of commercial data, as well as, Medicaid data from the All payer claims database. In addition, hospital inpatient discharge data, outpatient emergency department visit data and outpatient observation stay data from the case mix files will be utilized for linkage.

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.

The boston heart valve consortium contains SSN's which are intended to be linked to patients in the CHIA registries through matching of SSN. This will enable a deterministic method of linkage between the current BHVC and CHIA data

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

Variables to be included: first name, last name, social security number, date of birth, state, zip code, gender, procedure type, procedure date and hospital the procedure was performed and dates of service

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

Data sent to CHIA will initially be run through File Secure and each patient record will be given a unique identifier. Linkages involving the CHIA datasets will be performed by statisticians and a secure file will be sent back to BIDMC. Once the linkage between the two datasets has been performed, we will remove the direct identifiers from the dataset. Only those investigators with IRB approval and meeting CHIA DUA requirements will be allowed access to the combined dataset, and all analyses will be performed at the Smith Center without distribution of the raw data.

XV. PUBLICATION / DISSEMINATION / RE-RELEASE

1. Do you anticipate that the results of your analysis will be published or made publically available? If so, how do you intend to disseminate the results of the study (e.g., publication in professional journal, poster presentation, newsletter, web page, seminar, conference, statistical tabulation)? Any and all publication of CHIA Data must comply with CHIA's cell size suppression policy, as set forth in the Data Use Agreement. Please explain how you will ensure that any publications ***will not disclose a cell less than 11***, and percentages or other mathematical formulas that result in the display of a cell less than 11.

Over the coming years, the findings from this research will be presented at national/international research conferences such as the American College of Cardiology Scientific Sessions, the American Heart Association Scientific Sessions, and the Society for Cardiovascular Angiography and Interventions annual conference, and

published in peer-reviewed medical journals such as *JAMA*, the *Journal of the American College of Cardiology*, and *Circulation*.

All use of data will be done in accordance with the approved CHIA DUA. All output containing individually identifiable information will be treated as confidential data. Such information will never be transferred electronically via e-mail or other protocols. This includes complying with CHIA's policy to suppress cell sizes less than 11.

2. Describe your plans to use or otherwise disclose CHIA Data, or any Data derived or extracted from such Data, in any paper, report, website, statistical tabulation, seminar, or other setting that is not disseminated to the public.

All research derived from the dataset is planned on being published.

3. What will be the lowest geographical level of analysis of data you expect to present for publication or presentation (e.g., state level, city/town level, zip code level, etc.)? Will maps be presented? If so, what methods will be used to ensure that individuals cannot be identified?

Lowest level of analysis will be at the zip code level. After linkage, data will be de-identified and no identifiable association between patient and outcome will be distributed or made publically available

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

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

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

7. Will you be using CHIA Data as in input to develop a product (i.e., severity index took, risk adjustment tool, reference tool, etc.)
- ☐ Yes
- ☒ No

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

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

Click here to enter text.

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

Click here to enter text.

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

Click here to enter text.

XVI. APPLICANT QUALIFICATIONS

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

Investigators at the Smith Center for Outcomes Research in Cardiology at BIDMC have successfully used claims data from the Centers of Medicare and Medicaid Services, as well as, CHIA(case mix and APCD) for the publication of a variety of research projects. Success of such projects has been accompanied by the help of skilled statisticians with years of experience in analyzing medicare claims data.

Dr. Robert Yeh is the Director of the Richard and Susan Smith Center for Outcomes Research in Cardiology at the Beth Israel Deaconess Medical Center, and Assistant Professor of Medicine at Harvard Medical School. His area of investigation focuses on evaluating cardiovascular devices and therapies in both clinical trials and observational studies, with an emphasis on understanding methods to improve the value of novel technologies as they are used in clinical practice. He serves as the Medical Director of Trial Design for the Harvard Clinical Research Institute. His clinical area of expertise is in interventional cardiology, with an emphasis in coronary chronic total occlusion intervention.

Yang Song, MS, is a statistician at the Smith Center for Outcomes Research. He has over 10 years of experience in using SAS program and analyzing claims data. He has previous work experience at Baim institute for clinical research in implementing complex statistical methods and mentoring clinical investifators, fellows, medical students and residents.

Dhaval Kolte, MBBS, PhD is a structural interventional cardiologist and clinical researcher at Massachusetts General Hospital. His areas of investigation are cardiovascular outcomes and quality of care. Specifically, his current research focuses on hospital-level variation in outcomes of transcatheter valve interventions and identifying modifiable practices and processes of care associated with improved patient outcomes.

Zaid Al-Marzooq, MBBCh is the chief cardiology fellow at Brigham and Women's Hospital. He is a research fellow at the Smith Center working on clinical and healthcare utilization outcomes of TAVR related stroke events. His other research interests include developing models for procedural risk stratification in structural heart interventions.

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.)

XVII. USE OF AGENTS AND/OR CONTRACTORS

By signing this Application, the Organization assumes all responsibility for the use, security and maintenance of the CHIA Data by its agents, including but not limited to contractors. The Organization must have a written agreement with the agent of contractor limiting the use of CHIA Data to the use approved under this Application as well as the privacy and security standards set forth in the Data Use Agreement. CHIA Data may not be shared with any third party without prior written consent from CHIA, or an amendment to this Application. CHIA may audit any entity with access to CHIA Data.

Provide the following information for **all** agents and contractors who will have access to the CHIA Data. [*Add agents or contractors as needed.]*

AGENT/CONTRACTOR #1 INFORMATION	
Company Name:	Click here to enter text.
Company Website	Click here to enter text.
Contact Person:	Click here to enter text.
Title:	Click here to enter text.
E-mail Address:	Click here to enter text.
Address, City/Town, State, Zip Code:	Click here to enter text.
Telephone Number:	Click here to enter text.
Term of Contract:	Click here to enter text.

1. Describe the tasks and products assigned to the agent or contractor for this Project and their qualifications for completing the tasks.

Click here to enter text.

2. Describe the Organization's oversight and monitoring of the activities and actions of the agent or contractor for this Project, including how the Organization will ensure the security of the CHIA Data to which the agent or contractor has access.

Click here to enter text.

3. Will the agent or contractor have access to and store the CHIA Data at a location other than the Organization's location, off-site server and/or database?

☐ Yes
☐ No

4. If yes, a separate Data Management Plan **must** be completed by the agent or contractor.

AGENT/CONTRACTOR #2 INFORMATION	
Company Name:	Click here to enter text.
Company Website	Click here to enter text.
Contact Person:	Click here to enter text.
Title:	Click here to enter text.
E-mail Address:	Click here to enter text.
Address, City/Town, State, Zip Code:	Click here to enter text.
Telephone Number:	Click here to enter text.
Term of Contract:	Click here to enter text.

1. Describe the tasks and products assigned to the agent or contractor for this Project and their qualifications for completing the tasks.

Click here to enter text.

2. Describe the Organization's oversight and monitoring of the activities and actions of the agent or contractor for this Project, including how the Organization will ensure the security of the CHIA Data to which the agent or contractor has access.

Click here to enter text.

3. Will the agent or contractor have access to and store the CHIA Data at a location other than the Organization's location, off-site server and/or database?

☐ Yes
☐ No

4. If yes, a separate Data Management Plan **must** be completed by the agent or contractor.

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

XVIII. ATTESTATION

By submitting this Application, the Organization attests that it is aware of its data use, privacy and security obligations imposed by state and federal law *and* confirms that it is compliant with such use, privacy and security standards. The Organization further agrees and understands that it is solely responsible for any breaches or unauthorized access, disclosure or use of CHIA Data, including, but not limited to, any breach or unauthorized access, disclosure or use by any third party to which it grants access.

Organizations approved to receive CHIA Data will be provided with Data following the payment of applicable fees and upon the execution of a Data Use Agreement requiring the Organization to adhere to processes and procedures designed to prevent unauthorized access, disclosure or use of data.

By my signature below, I attest: (1) to the accuracy of the information provided herein; (2) this research is not funded by a source requiring the release of raw data to that source; (3) that the requested Data is the minimum necessary to accomplish the purposes described herein; (4) that the Organization will meet the data privacy and security requirements described in this Application and supporting documents, and will ensure that any third party with access to the Data meets the data use, privacy and security requirements; and (5) to my authority to bind the Organization.

Signature: (Authorized Signatory for Organization)	Drag signature image here or delete and physically sign
Printed Name:	Marlena D. Konieczynska, PhD
Title:	Sr. Research Contract Associate
Date:	

Attachments:
A completed Application must have the following documents attached to the Application or uploaded separately to IRBNet:
☒ 1. IRB approval letter and protocol (if applicable), or research methodology (if protocol is not attached)
☒ 2. Data Management Plan (including one for each agent or contractor that will have access to or store the CHIA Data at a location other than the Organization's location, off-site server and/or database);
☒ 3. CVs of Investigators (upload to IRBNet)

APPLICATIONS WILL NOT BE REVIEWED UNTIL THEY ARE COMPLETE, INCLUDING ALL ATTACHMENTS.