CHIA.
center for health information and analysis

CHIA Non-Governmental Application for Massachusetts Case Mix 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 casemix.data@state.ma.us if you have additional questions about how to complete this form.

All attachments must be uploaded to IRBNet with your Application. All Application documents can be found on the CHIA website in Word and in PDF format or on IRBNet in Word format. If you submit a PDF document, please also include a Word version in order to facilitate edits that may be needed.

Applications will not be reviewed until the Application and all supporting documents are complete and the required application fee is submitted. A Fee Remittance Form with instructions for submitting the application fee is available on the CHIA website and IRBNet. If you are requesting a fee waiver, a copy of the Fee Remittance Form and any supporting documentation must be uploaded to IRBNet.

II. ORGANIZATION AND INVESTIGATOR INFORMATION

Project Title:	Long-term follow-up of atrial fibrillation after cardiac surgery
IRBNet Number:	1131664-1
Organization Requesting Data:	Brigham and Women's Hospital
Organization Website:	http://www.brighamandwomens.org/
Authorized Signatory for Organization:	Erinn Crane, J.D., LL.M.
Title:	Senior Agreement Advisor & Contracts Team Lead
E-Mail Address:	ecrane@partners.org
Address, City/Town, State, Zip Code:	399 Revolution Drive, Somerville MA 02145
Primary Investigator:	Body, Simon Christopher,M.D.
Title:	Associate Professor
E-Mail Address:	SBODY@BWH.HARVARD.EDU
Telephone Number:	617-525-8397
Names of Co-Investigators:	Raymond P. Malapero MD; Xinling Xu PhD; Jochen Muehlschlegel MD

E-Mail Addresses of Co-Investigators:	RMALAPERO@PARTNERS.ORG; xxu20@bwh.harvard.edu; JMUEHLSCHLEGEL@BWH.HARVARD.EDU;

III. FEE INFORMATION

1. Consult the Fee Schedule for Case Mix and Charge 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.

Background and Purpose:
This request is to obtain data that will allow examination of the factors that determine the occurrence, and consequences, of atrial fibrillation (AF) occurring after discharge from hospital for cardiac surgery in Massachusetts.

We, and the majority of other studies, have shown an overall rate of ~30% of patients have an episode of AF after cardiac surgery. After adjustment for risk factors for postoperative morbidity and mortality, the occurrence of AF within the hospital admission for cardiac surgery is associated with additional risk. Furthermore, we have observed that patients who are discharged from hospital while still in AF have higher mortality in the years following cardiac surgery. These observations unequivocally demonstrate the importance of AF as a treatable risk.

In order to develop a clinical pathway for the prevention and treatment of postoperative AF, we have emabarked upon two programs:

1. We are finalizing an AF risk score that could be calculated prior to cardiac surgery, that would potentially guide physician decision-making in regards to patients need for postoperative AF prophylaxis. Our publications have echoed and expanded the work of others in this regard. Broadly, AF risk in the in-hospital period can be pragmatically estimated using the patient's age, a past history of AF and the planned operation. These simple factors can be used to perform a bed-side estimate of risk that will allow the cardiac surgeon to estimate risk and perhaps plan a concurrent intraoperative procedure for AF prevention such as pulmonary vein isolation, or stroke reduction such as left atrial appendage resection.
2. The occurrence of silent or overt AF after discharge from hospital for cardiac surgery has been associated with increased risk of mortality, embolic stroke and cardiac morbidity. The work of other investigators has shown that ~20% of patients have an episode of AF (either silent or detected) in the first six weeks after discharge from hospital. However, the consequences of AF after cardiac surgery have not been well examined, principally because of the absence of accessible data. Nor are we aware of the resource use that is consequent upon postoperative AF including reporting of complications of anticoagulation for postoperative AF. These factors motivate this application.

The ***Specific Aims*** of the proposed study are to:

1. Identify the predictors of postoperative atrial fibrillation after discharge from home.
2. Identify the frequency of readmission to hospital, or other resource use such as Emergency Department or outpatient visit, for the treatment or prophylaxis of postoperative AF and consequent stroke or bleeding outcomes.
3. Identify the risks for stroke, death and other morbidity in patients after cardiac surgery and the effect of postoperative AF upon subsequent stroke or bleeding 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**: 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.

This is an amended application that has the following changes to the proposal.

1. Narrowing the time period to 2012-2016. This was done for cost reasons.
2. Expanding the patient base by including other Massachusetts Cardiac Surgery Programs. In the last month we have approached the 12 Massachusetts Cardiac Surgery Programs to ascertain their interest in this proposal. Nine have agreed to be included. In order to reach approval for this step, each Program is negotiating a Data Use agreement with Brigham and Women's Hospital and is obtaining individual IRB approval, either through their own IRB or by ceding review to the Partner's IRB through SmartIRB.

To perform this work, we propose the following overall *Analysis Plan:*

Study Population: We plan to investigate the Specific Aims in the ~50,000 patients who have undergone cardiac surgery at nine Massachusetts Cardiac Surgery Programs between 2012-2016.

Exclusion criteria are surgical procedures that do not include coronary artery bypass graft surgery, aortic valve surgery or mitral valve surgery; surgical procedures that include MAZE surgery, or pulmonary vein isolation, ventricular assist device, heart transplantation, congenital heart surgery, bacterial endocarditis, cardiac trauma, cardiac tumor, ventricular septal defect repair, left ventricular aneurysm repair, pulmonary thromboendarterectomy, sub-aortic stenosis resection or surgical ventricular restoration; surgical procedures on patients that have undergone MAZE surgery, AF ablation procedures, pulmonary vein isolation or left atrial appendage resection or ablation (such as Watchman devices).

Data Sources and Definitions:
We will use two data sources for this study. Data has been collected during the patients' stay from each Institution and variables are defined by Society for Thoracic Surgeons (STS) Adult Cardiac Surgery database definitions, version 2.81 or prior versions, at each Institution. These records will be amalgamated with CHIA data using the algorithm described in section VIII of this application.

From Institutional data we will extract the following patient-specific information: Demographic variables included age, gender, and race and age at death. Risk factors included height, weight, prior AF, diabetes, dyslipidemia, hypertension, tobacco use, and history of chronic lung disease amongst others. Collected laboratory tests included cardiac biomarkers, WBC count, uric acid and last creatinine level prior to surgery. Previous cardiac status included prior myocardial infarction, heart failure, and history of arrhythmia. Collected pre-operative medications were ACE inhibitors, anticoagulants, B-blockers, and calcium channel blocker use. Cardiac risk factors for AF included number of diseased vessels, left ventricular ejection fraction and valve disease status. Operative characteristics included type of surgery performed, urgency of the operation, and number of vessel anastomoses.

From the *CHIA data*, we will use ICD9/10 -CM and -PCS codes contained in the variable DiagnosisCode and dates of service and discharge, including counts of days, from the Hospital, ED and Outpatient datasets.

AF is defined for the preoperative, in-hospital and post-discharge phases of the study.
Preoperative AF or atrial flutter (AFl) is defined as any of the following:

1. Occurrence of an ICD10 subcode from I48, or equivalent mapped classifications from ICD9, for AF or AFl occurring prior to hospital admission
2. A CPT code for MAZE surgery, AF ablation procedures, pulmonary vein isolation or left atrial appendage resection or ablation.
3. A preoperative ECG that demonstrates AF or AFl prior to cardiac surgery
4. A patient admission record of AF or AFl.

In-hospital AF or AFl is defined as any of the following:

1. Occurrence of an ICD10 subcode from I48, or equivalent mapped classifications from ICD9, for AF or AFl occurring during hospital admission
2. An in-hospital ECG that demonstrates AF or AFl after cardiac surgery
3. A patient discharge record of AF or AFl.

Post-discharge AF or AFl is defined as any of the following:

1. Occurrence of an ICD10 subcode from I48, or equivalent mapped classifications from ICD9, for AF or AFl occurring occurring after primary hospital admission

Stroke is defined as occurrence of an ICD10 subcode from I63 or I69, or equivalent mapped classifications from ICD9. Mortality is defined as all-cause mortality 0ccuring after primary hospital discharge. Bleeding is defined as occurrence of a hemorrhage ICD10 code or subcode of I61, I62, K27, K29, K57 or K92, or equivalent mapped classifications from ICD9.

Analysis Plan:

For all three aims, univariate analyses will be used to establish the unadjusted correlation between perioperative variables and the end-points. Chi-square tests, T tests, and non-parametric tests will be carried out for the initial identification of important predictors. During modeling, when the number of predictors is large, variable selection procedures will be performed, e.g. stepwise variable selection based on p-values. Perioperative variables with counts <11 will be omitted in all analyses.

Aim 1: The AF status at different time points for each patient will be reviewed. More specifically, they are preoperative AF status when admitted in hospital, postoperative AF status after surgery, and AF status after discharge. Due to the high correlation among these variables, generalized linear mixed models with binomial distribution and logit link function will be used, accounting for the correlation within patients, to estimate the risk-adjusted odds ratio of having AF at different stages. Perioperative variables such as prior history of AF will be adjusted in the models.

Aim 2: The end-points were the readmission to hospital or other resource use for the reason of postoperative AF, and the readmission to hospital or other resource use for the reason of stroke or bleeding. Multivariable logistic regression analyses will be performed to estimate risk-adjusted odds ratios for both readmissions to hospital or other resource use for posteroperative AF/AFI and stroke/bleeding.

Aim 3: To identify the risks for stroke, death and other morbidity in patients after cardiac surgery, multivariable logistic regression analyses will be performed to estimate the odds ratios of the outcomes of having different perioperative variables. Cox proportional hazard models will be used to examine the risk-adjusted hazard ratio for stroke, death, bleeding, and other morbidity after surgery as well. In the case when the proportional hazards assumption is violated, piecewise Cox proportional models, or accelerated failure models will be performed.

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.*

Atrial fibrillation is a common complication affecting patients in the post-operative period following cardiac surgery. The occurrence of AF is associated with increased morbidity and mortality. Similarly, the treatment of AF, and prevention of thrombotic stroke and mortality are also associated with morbidity and mortality.

Improved understanding of the risk factors for post-dischrge AF and its subsequent adverse events (principally stroke and death) and subsequent resource use will better allow physicians to anticipate and treat patients that are increased risk of developing AF.

We anticipate that improved risk assessment and subsequent clinical care after hospital discharge will lead to reductions in patient co-morbidity and mortality.

VI. DATASETS REQUESTED

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

☒ **Hospital Inpatient Discharge Data**
☐2004 ☐2005 ☐2006 ☐2007 ☐2008 ☐2009 ☐2010 ☐2011 ☒2012 ☒2013 ☒2014 ☒2015

Describe how your research objectives require Inpatient Discharge data:
Inpatient discharge data is critical to our analyses. Hospital length of stay as well as diagnoses during the hospital course are necessary for study, specifically if atrial fibrillation was developed in the hospital or post-hospital stay time period.

☒ **Outpatient Observation Data**
☐2004 ☐2005 ☐2006 ☐2007 ☐2008 ☐2009 ☐2010 ☐2011 ☒2012 ☒2013 ☒2014 ☒2015

Describe how your research objectives require Outpatient Observation data:
Outpatient observation data will allow post-discharge monitoring of atrial fibrillation development post cardiac surgery. Development of new onset atrial fibrillation in the first 30 and 90-day period post cardiac surgery will be analyzed.

☒ **Emergency Department Data**
☐2004 ☐2005 ☐2006 ☐2007 ☐2008 ☐2009 ☐2010 ☐2011 ☒2012 ☒2013 ☒2014 ☒2015

Describe how your research objectives require Emergency Department data:
Emergency department data will give us information relating to past medical history of the patients prior to their admission necessitating cardiac surgery. This will allow us to know if the patient had a prior history of atrial fibrillation, or if any diagnoses of atrial fibrillation during the related hospital stay are new to the patient.

2. Case Mix and Charge Data are updated each fiscal year. As certain Project objectives may require future years of data not yet available, CHIA will consider requests for additional fiscal years 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 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 years of Data and if so, which years.

☐ 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.

Case Mix and Charge Data are grouped into six "Levels" or Limited Data Sets (LDS) for release, depending on the fiscal year. Data for FY 2004 – 2014 are organized into Levels. Level 6 Data will be released to Government Applicants only. *CHIA staff will use the information provided in this section to determine the appropriate Level of Data justified for release.*

Data for FY 2015 and later are organized into LDS's. All applicants receive the "Core" LDS, but may also request 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. CHIA will use this information to determine what Level of data is needed for pre-FY 2015 data requests.

Geographic Data

The geographic sub-divisions listed below are available for CT, MA, ME, NH, RI, VT, and NY residents only for FY 2015 and after. Fiscal years 2004 – 2014 will contain the geographic sub-divisions listed below for all states. Choose *one* of the following geographic 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:** Having 5 digit zip code data will allow integration with the Partners Healthcare RPDR dataset to assess if data is for the same patient from one dataset to the other to prevent duplication and ensure that line listings are equivalent.			

Demographic Data

Choose *one* of the following demographic options:

☐ Not Requested (Standard)	☒ Race & Ethnicity***
**** If requested, provide justification for requesting Race and Ethnicity. Refer to specifics in your methodology:** In several studies, people of Asian or Indian heritage have a reduced rate of postoperative atrial fibrillation. In our analyses, race and ethnicity will be included in risk factor analysis of atrial fibrillation in cardiac patients.	

Dates

Choose *one* option from 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:**		

CHIA data will be linked to Partners Healthcare RPDR data. In order to get exact values for length of stay, admission dates, discharge dates, and date of cardiac procedures dates will be necessary for data analysis.

Practioner Identifiers (UPN)

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

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

Unique Health Information Number (UHIN)

Please choose *one* of the following:

☐ Not Requested (Standard)	☒ UHIN Requested ***
***** If requested, provide justification for requesting UHIN. Refer to specifics in your methodology:** UHIN will be neccesary for this study as CHIA data will be linked to Partners Healthcare RPDR data. This will allow a detailed and complete dataset for analyzing the vaiables linked to post-operative atrial fibrillation in cardiac patients, and for the study of additional factors such as length of ICU and hospital stay, discharge date, comorbidties, demographics, and time of diagnosis.	

Hashed Mother's Social Security Number

Please choose *one* of the following:

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

VIII. DATA LINKAGE

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

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

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

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

Data will be linked to the Partners Health System RPDR dataset of patients who have undergone cardiac surgery at Partners Institutions.

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 purposes of the linkage In this research proposal is to determine long-term outcomes and subsequent conditions for a patient from an index cardiac surgical procedure documented in Research Patient Data Registry (RPDR) of Partners Healthcare. Fully identified patient level clinical data for cardiac surgery procedures are available in RPDR. CHIA Case Mix data contains billing data for the same patients and includes additional diagnosis and procedures with information not available in the Partners RPDR dataset.

When a link is found, we will use the valid CHIA case mix unique patient identifier number (UHIN) to find subsequent diagnosises related to the index cardiac surgical procedure. For patients in both the CHIA and RPDR data sets, we can then identify an index procedure and subsequent procedures to determine outcomes related to AF outcomes.

Data Flow Process:
The steps below describe the major methods used in the linkage process.

1. Institutional Data
Create a subset from the RPDR database that contains records for patients undergoing cardiac surgery that contains the minimum set of fields needed to complete the merge with a CHIA datset.

a. Hospital: Short name identifies hospital
b. AdmitDate: Admission date to hospital
c. SurgDate: Date cardiac surgery procedure was done
d. DschDate: Discharge date from hospital
e. DOB: Patient date of birth
f. MedRecNum: Hospital patient medical record number
g. Gender: Patient gender

2. CHIA Subset Data
Create a subset of cardiac surgery patients using all three CHIA databases to maximize the chance of finding a matching cardiac surgery record in RPDR. UHINs for the cardiac surgery cases are identified in the inpatient database where at least one of 15 procedure codes or principal procedure contains an ICD9-CM code for cardiac surgery (3610-3619). The following lists the minimum set of fields needed to complete the merge.

a. MDPHHospNum: MDPH hospital number determined from all hospital IDs in the case mix data
b. AdmitDt: Admission date to hospital
c. ProcDates: Possible dates for cardiac surgical procedure (15 in inpatient, 3 in OOR data)
d. ProcedureCodes: ICD-9-CM and CPT (OOR only) codes for cardiac surgery records (only 3 ICD-9-CM in OOR data)
e. PrincipalProcDate: Date for principal procedure (OOR only)
f. PrincipalProcedure: ICD9-CM code for PCI and CABG records

g. Diagnosis Codes: Diagnosis and DRG codes for conditions
h. DischDate: Discharge date from hospital
i. RecordType20ID: CHIA Record Id Control Number
j. UHIN Unique patient identifier from CHIA
k. DOB: Patient date of birth submitted by hospital
l. MedicalRecordNum: Hospital patient medical record number
m. Gender: Patient gender

3. Link RPDR and CHIA subsets to get cardiac surgery UHINs
Perform multiple links between the RPDR subset and the CHIA Case Mix subset, keeping all records that merge successfully in a temporary data set. A successful record merge is determined by matching of three or more of the fields: Site, MedRecN, AdmitDate, DischDate, DOB, ProcDates

The temporary data set contains the minimum set of fields needed to find subsequent patient episodes of care in the CHIA databases using UHINs. The fields saved are UHIN, date of birth, gender, Mass-DAC procedure date, Mass-DAC unique patient identifier, and Mass-DAC unique record identifier.

4. Link Data to CHIA UHINs to get long-term outcomes
The merged cardiac surgery data set UHINs are merged with CHIA records where the CHIA procedure date is after the RPDR procedure date. These data are retained to determine long-term outcome. If a subsequent episode of care is found, then a new RPDR field is created that will flag the long-term outcome (e.g., stroke), 0=absent, 1=present.

5. Update RPDR analysis dataset
Use the results data set to update the RPDR analysis set

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

Data will be stored on encrypted hard drives and backed up to secure Partners-maintained storage within the Partners firewall. Secure transfer methods will be used. Final results will be reported in aggregate with no individually identifying data.

Linkage is done on a stand-alone PC which is not used by the analysts. The linkage process uses only temporary data sets that are immediately removed once the program has completed. The final analytic data set does not contain any patient names, addresses, or social security numbers. It also does not contain any CHIA case mix data fields.

IX. 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 result in the display of a cell less than 11.

Data will be presented in aggregate at a national Society of Cardiology meeting and will be published in manuscript form in a peer-reviwed journal. Data will include aggregate demographics, Odds Ratios, and results of data analysis. Data analysis is currently looking at 12,000+ in our current dataset. Cell size will not be less than 11 in any cells.

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.

The goal is to publish the results of this study in a nationally-recognized, peer-reviewed journal. The manuscript will be available through a subscription to the journal or library access. All methods and analyses will be published in the journal article.

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.)?

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

X. INVESTIGATOR QUALIFICATIONS

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

Dr. Simon Body is Associate Proferssor of Anesthesia at Harvard University, Brigham and Women's Hospital. He currently serves as the Director of Anesthesia Clinical Research. He has served on numerous editorial boards including the Journal of Cardiothoracic and Vascular Anesthesia and Anesthesia and Analgesia. He is/has been funded by two NIH and an AHA grant, examining the genetic causes of atrial fibrillation and bicuspid aortic valve disease. He is an investigator well-versed in utilizing large hospital datasets including RPDR data from the Partners Health System and data from the Society of Thoracic Surgeons Adult Cardiac Surgery database. Dr Body has published over 140 papers.

Dr. Raymond Malapero MD, MPH is a Cardiothoracic Anesthesiology Fellow at Harvard University, Brigham and Women's Hospital. He completed his MD and MPH at Rutgers University, in which his fieldwork concentrated on large dataset research. He has presented at 6 society meetings, and has 7 manuscripts in peer-reviewed journals, with an additional three in submission. He graduated from his Anesthesiology Residency at Brigham and Women's Hospital with a Distinction in Research.

Dr. Jochen D. Muehlschlegel is an Associate Professor of Anesthesia at Harvard Medical School, Brigham and Women's Hospital. He currently serves as the Director of Cardiac Anesthesia Research and is an Associate Editorial Board member for Anesthesiology. His research, examining the genetic causes of ischemia in the human heart, is funded by the National Institute of Health and the American Heart Association. Dr. Muehlschlegel is well-versed in utilizing large hospital datasets and has published over 70 original peer-reviewed manuscripts.

Dr. Xinling Xu PhD is a biostatistician in the Department of Anesthesiology, Perioperative and Pain Medicine at Brigham and Women's Hospital. She completed her MA in statistics at the University of Minnesota, and PhD at University of South Carolina. She works closely with clinicians and epidemiologists on various projects, including the analyses of serveral administrative data. She has 5 manuscripts in peer-reviewed journals, with a few others in submission.

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.)

XI. 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 work with the CHIA Data. [*Add agents or contractors as needed.]*

AGENT/CONTRACTOR #1 INFORMATION	
Company Name:	N/A
Company Website:	
Contact Person:	
Title:	

E-mail Address:	
Address, City/Town, State, Zip Code	
Telephone Number:	
Term of Contract:	

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

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

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

☐ Yes
☐ No

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

AGENT/CONTRACTOR #2 INFORMATION	
Company Name:	
Company Website:	
Contact Person:	
Title:	
E-mail Address:	
Address, City/Town, Zip Code	
Telephone Number:	
Term of Contract:	

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

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

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

☐ Yes

☐ No

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

XII. 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)	Erinn Crane Digitally signed by Erinn Crane DN: cn=Erinn Crane, o=Senior Agreement Advisor & Contracts Team Lead, ou=Research Management, Partners HealthCare, email=ecrane@partners.org, c=US Date: 2018.02.21 12:46:23 -05'00'
Printed Name :	Erinn Crane, J.D., LL.M. Senior Agreement Advisor & Contracts Team Lead

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 years of data	
Executive Director Approval	
Data Fee Received	

Date of First Audit	
IT Extract #	

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

Attachment #2 – Data Management Plan(s)

Attachment #3 – CVs of Investigators