

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 <u>apcd.data@state.ma.us</u> 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 <u>CHIA</u> 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 <u>Fee Remittance Form</u> 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 <u>Fee Remittance Form</u> and attach it and all required supporting documentation with your application. Refer to the <u>Fee Schedule</u> (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:	Provider Behavior after Stillbirth and Other Adverse	
	Pregnancy Outcomes	
IRBNet Number:	2119609-1	
Organization Requesting Data (Recipient):	Harvard TH Chan School of Public Health	
Organization Website:	https://www.hsph.harvard.edu/	
Authorized Signatory for Organization:	Wendy Chan	
Title:	Associate Director, Sponsored Programs	
	Administration	
E-Mail Address:	Nga@hsph.harvard.edu	
Telephone Number:	617-432-8135	
Address, City/Town, State, Zip Code:	677 Huntington Ave, Boston, MA 02115	
Data Custodian:	Scott Yockel	
(individual responsible for organizing, storing, and archiving		
Data)		
Title:	University Research Computing Officer	
E-Mail Address:	scott_yockel@harvard.edu	
Telephone Number:	817-793-6634	
Address, City/Town, State, Zip Code:	1350 Massachusetts Ave, Cambridge, MA 02138	
Primary Investigator (Applicant):	Jessica Cohen	
(individual responsible for the research team using the Data)		
Title:	Bruce A. Beal, Robert L. Beal and Alexander S. Beal	
	Associate Professor of Global Health	
E-Mail Address:	cohenj@hsph.harvard.edu	
Telephone Number:	617.432.7577	
Address, City/Town, State, Zip Code:	665 Huntington Avenue Building 1, Room 1209	
	Boston, MA 02115	
Names of Co-Investigators:	Haley Sullivan, Anna Sinaiko PhD	
E-Mail Addresses of Co-Investigators:	hsullivan@g.harvard.edu, asinaiko@hsph.harvard.edu	

IV. PROJECT INFORMATION

<u>IMPORTANT NOTE</u>: 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 <u>no</u> 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' Data Use Agreement with CHIA.

1. What will be the use of the CHIA Data requested? [Check all that apply]			
□Cost trends			
☐ Rate setting			
☐ Severity index tool (or other derived input)			
☐ Utilization review of resources			

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.

Stillbirths—loss of a fetus at or after 20 weeks of gestation—occur in 5.74 out of 1000 births in the United States.¹ The burden of stillbirth is inequitably distributed: while 4.7 out of 1,000 births in white people end in stillbirth, the rate for Black people is more than double at 10.3 per 1,000 births.¹ Despite the prevalence of stillbirths and the devastating impact they can have on families who lose a wanted pregnancy, stillbirth prevention is not well studied. Policymakers recognize the need to address gaps in stillbirth research: in 2023, the National Institute of Child Health and Human Development (NICHD) working group on stillbirth released a report that called for the "development of a research agenda to advance prevention for stillbirth."¹

Existing research on stillbirth prevention focuses on early delivery and increased fetal surveillance.¹ These strategies derive from a common cause of preventable stillbirths: fetal hypoxia. When fetal oxygen levels fall due to placental abnormalities, umbilical cord entanglement or other conditions, it can often be observed in signs such as decreased fetal movement, or changes in fetal heart rate.^{2,4} When these signs are detected via fetal surveillance, early delivery can avert potential stillbirth. One study estimates that at least 22.3% of stillbirths may be preventable through such interventions.⁴

Current guidelines for the use of early delivery and fetal surveillance in clinical practice provide varying recommendations. The American College of Obstetrics and Gynecology (ACOG) suggests different frequency of fetal monitoring for pregnant people with certain high-risk conditions (e.g., fetal growth restriction, multiple gestation, maternal hypertension, maternal diabetes, sickle cell disease, high pregnancy BMI, and previous poor pregnancy outcomes). Additionally, ACOG recommends early delivery for people with certain severe conditions (e.g., placenta previa, oligohydramnios, fetal growth restriction, uncontrolled or severe hypertension, poorly controlled gestational diabetes, and preterm PROM). ACOG acknowledges poor evidence quality surrounding these guidelines and therefore issues its recommendations with large ranges (i.e., several weeks) during which early delivery might be indicated or defers to "individualized" or nonspecific (i.e., "once or twice weekly) guidelines for frequency of fetal surveillance.

These imprecise guidelines leave physicians with substantial room to vary their practice within clinical guidelines. It is unclear how providers choose when in the recommended range to deliver a fetus, or how to individualize fetal surveillance. Similarly, it is unclear if providers view fetal surveillance and early delivery as effective methods to avert stillbirth. To study these questions further, we will examine how provider behavior changes after stillbirth, and other adverse pregnancy events.

There is an extensive literature that examines how providers change clinical practice after one of their patients has a negative outcome. For example, when doctors have patients diagnosed with colon or breast cancer, their subsequent patients are more likely to get colonoscopies or mammograms.⁶ In another study, authors found that after an unexpected newborn death, subsequent babies born in the same county were more likely to be delivered by cesarean section, and receive newborn assisted ventilation.⁷ This paper extends the provider behavior

¹Fetal surveillance refers to a series of monitoring tests that can be done in an outpatient setting and include the fetal nonstress test (a measure of fetal heart rate), biophysical profile (a nonstress test, combined with an ultrasound measurement of amniotic fluid volume, and fetal movement), and the umbilical artery Doppler (which measures placental insufficiency).^{2,3}

framework to study the impact of a provider having a stillbirth on the care they provide to their future pregnant patients.

Study Aims:

- 1) Identify providers and obstetric practices in Massachusetts who oversaw care for a patient who experiences a stillbirth or perinatal death and characterize the patients, providers, and practices.
- 2) Quantify prenatal and delivery services providers and practices request for their patients before and after overseeing a stillbirth or perinatal death.
- 3) Use quasi-experimental methods to identify the causal impact of a provider experiencing a stillbirth or perinatal death on prenatal and delivery services, gestational age at delivery, delivery method, and patient outcomes that occur in future patients of that provider.
- 3. Has an Institutional Review Board (IRB) reviewed your Project?
- ☐ Yes [If yes, a copy of the approval letter and protocol <u>must</u> be included with the Application package on IRBNet.] ☐ No, this Project is not human subject research and does not require IRB review.
- 4. <u>Research Methodology</u>: 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.

In the US, 1 in 175 pregnancies ends in stillbirth each year. 8 In Massachusetts, that number is estimated to be 302 stillbirths annually, or 4.34 out of every 1000 births. 9 Racial disparities exist in stillbirth rates: while pregnancies in white people have a stillbirth rate of 1 in 211, pregnancies in Black people have a stillbirth rate of 1 in 94. 10

Despite the prevalence of stillbirths and the devastating impact they can have on families who lose a wanted pregnancy, stillbirths are not well studied and often treated as an unavoidable outcome by the medical community.

There are several implications to the results of this study. First, it is possible that many pregnant people are not getting the recommended fetal surveillance, and the salience of stillbirth pushes physicians to conform to obstetric guidelines. If this were the case, we might recommend an educational push to ensure that physicians understand the importance of fetal surveillance in high risk pregnant patients.

Second, it is possible that physicians are already following obstetric guidelines and a salient stillbirth pushes physicians into over-use of fetal surveillance, even for patients where it is not clinically indicated. If this increase in unnecessary fetal

surveillance persisted, the results of our study might suggest an area to save costs within the health care system generally and Mass Health specifically.

Finally, we might observe that there are certain patient characteristics un-related to risk that might make physicians more or less likely to recommend more fetal surveillance or early delivery. In that case, the results of our study might reveal bias or inequity in the health care system that policymakers can work to correct.

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 <u>same data files and data elements</u> 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 subscription.	this is a one-time request, or if the described Project will require a	
	⊠ One-Time Request OR	☐ Subscription	
2.	Select Release Version and years of data requested (Release Versions and years not listed may not b available).		
	ANNUAL RELEASE 2020	ANNUAL RELEASE 2021	
	⊠ 2016	□ 2017	
	⊠ 2017	□ 2018	
	⊠ 2018	□ 2019	
	⊠ 2019	\square 2020	
	⊠ 2020	\square 2021	

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:

We need medical claims to identify patients who have stillbirths or perinatal deaths, and patients who have deliveries. We also need to be able to measure the services these patients receive during pregnancy (e.g., fetal

monitoring, ultrasounds) and their method of delivery. Medical claims will also help us identify patients at higher risk of stillbirth due to comorbid conditions, or conditions of pregnancy (e.g., premature rupture of membranes, or pre-eclampsia).
☐ Pharmacy Claims
Describe how your research objectives require Pharmacy Claims data:
Click here to enter text.
☐ 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:
Member eligibility data is necessary for us to understand the demographics of the people in our sample (zipcode of residence, age, etc.). Additionally, we need to understand when members were enrolled in what type of health care plan. (For example, we may perform a subgroup analysis on only patients whose pregnancy was covered by Medicaid). Member eligibility data will also allow us to observe if patients transition between insurance during pregnancy and follow them through that change in coverage.
⊠ Provider
Describe how your research objectives require Provider data:
We require provider data because a central part of our project is characterizing provider behavior. We need to know the provider's NPPES taxonomy (i.e., OB/GYN vs maternal fetal medicine specialist). We also need to know if the provider is an individual (the primary target of our analyses) or an entity.
□ 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 <u>release</u> 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 <u>each</u> 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 <u>one</u> 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:		
Stillbirth and maternal health are heavily influenced by	y social determinants of health. While measures of	
education or income are not included in claims data, w	re can use aggregate measures linked to patient ZIP	
codes to account for these factors. To appropriately pe	rform the linkage, we will need 5 digit ZIP codes.	

b. Date Resolution

Select <u>one</u> 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:			
In order to perform the quasi-experimental analysis of the impact of stillbirth on provider behavior, we need			
exact dates of the stillbirth. With exact dates, we are able to sort patients into those who deliver before the			
provider has a patient with a stillbirth and those who deliver after. Additionally, our study will look at			
gestational age at delivery as an outcome. In order to define the duration of the pregnancy in claims data, we			
need to know the exact delivery date (so that we can then approximate the start of pregnancy, using claims			
data measures of gestational age three	oughout the pregnancy).		

c. National Provider Identifier (NPI)

Select <u>one</u> 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:		

We will use the decrypted NPI to link to databases with additional provider information such as the National Plan and Provider Enumeration System (NPPES). Because our study focuses on provider behavior, understanding additional information about providers is important for understanding what variables might drive differences in behavior.

VIII. MEDICAID (MASSHEALTH) DATA

⊠ Yes

Data.

1. Please indicate whether you are seeking Medicaid Data:

□ 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 identifiable
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

In 2021, Medicaid covered 29% of births in Massachusetts. ¹³ Stillbirths are more common in Black pregnant people (among whom 2/3 of births are covered by Medicaid nationwide). ¹² Our project looks at how providers make clinical decisions after having a patient who experiences a stillbirth. Some of the changes a provider might make could improve the health of the pregnant person, or fetus (potentially even averting a future stillbirth). At the same time, providers might over-prescribe certain types of care in a non-targeted, or reactive way (i.e., over ordering frequent fetal surveillance at the end of pregnancy). Over-use of care would impact the budget of MassHealth.

MassHealth has an interest in promoting maternal health—a goal that our study also shares. If we discover that certain provider behavior (e.g., following clinical guidelines with respect to fetal surveillance for high risk pregnancies) reduces likelihood of stillbirth, or other clinical outcomes that precede stillbirth, our work could educate other providers on how to improve quality of care to at-risk patients.

Some state Medicaid programs put limits on the number of ultrasounds that can be received during pregnancy. MassHealth does not have this policy. If providers intensify ultrasounds in high-risk patients after having a patient with a stillbirth, this project might provide evidence to support that MassHealth is correct in not limiting necessary care.

Deliverables from our study will include a peer-reviewed publication and presenting our results at seminars and conferences. We aim to publish policy-relevant suggestions that the Executive Office of Health and Human Services can learn from. As described above, we might identify areas of cost savings for the state, or areas in which we can improve the quality of maternal care in Massachusetts.

3. Organizations approved to receive Medicaid Data will be required to execute a <u>Medicaid Aknowlegment of Conditions</u> 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
\square 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.

We will link the CHIA data to the American Community Survey. We will link at the 5-digit ZIP code level and use the linkage for obtaining area-level estimates of income, racial and ethnic makeup, and education levels for patients.

We will use provider NPI to link to individual data from the National Plan and Provider Enumeration System (HRSA NPPES). This paper is interested in provider level behavior; therefore, understanding provider level variables, such as location of practice, type of practice, specialty, years since training, and gender will help us characterize providers and understand what factors, if any, influence their behavior.

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.

We will use 5 digit ZIP code to do the matching to the ACS. ZIP codes do change over time, and it is possible that we will not have a perfect match rate. In that case, we will simply not include ACS data for those patients that do not match.

For the NPPES, we will match on decrypted provider NPI.

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

From the American Community Survey (at 5 digit ZIP code level):

Race

Ethnicity

Educational attainment

Income

From Provider Level Data (decrypted NPI):

Entity / Sole Proprietor Status

Provider Name (including organization name, if NPI is for an entity)

Provider Business Mailing Address

Provider Business Practice Location

Provider License Number State

Provider Taxonomy (Primary and other)

Group Taxonomy (Primary and other)

Gender

Year of NPI enumeration

NPI deactivation/reactivation date and reason

Employer Identification Number (EIN) (for the purpose of identifying practices)

Parent Organization Identifiers (if available)

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

In linking patient ZIP code to ZIP code data from the American Community Survey, we are simply looking at the demographics of people who live in the ZIP code. It is possible that if a ZIP code had very few people, we might have more information about a patient (e.g., if 80% of people in a very small ZIP code are white and a

patient is from that ZIP code, we might be fairly certain they are white). However, to protect patients in small ZIP codes, we will never report cell sizes less than 11.

Similarly, by linking to information about individual providers, we are not trying to identify the patients who they see. To protect patients, we will never report cell sizes less than 11. If any particular bucket is too small, we will bin results. For example if we look at a result by provider patient volume, and there is a bin with a very small number of patients, we will bin that volume level with the adjacent one.

X. PUBLICATION / DISSEMINATION / RE-RELEASE

1. Do you anticipate that the results of your analysis will be published or made publicly 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.

We hope to publish the results of our study in professional Health Policy or medical journals. Additionally, this paper will be a part of Haley Sullivan's PhD dissertation. It may also be shared at a conference in poster or presentation form. We will also likely present it at the Harvard Health Policy PhD Seminar.

In all of these documents and presentations, we will not include any cell with a size less than 11. We anticipate that cell sizes will be quite large, as many people in MA give birth every year. While stillbirth is a less common outcome, around 300 babies are stillborn each year in MA² (far above the cell size limit). When discussing providers with patients that have stillbirths, we will only report average numbers (e.g., across 100 providers, the average number of stillbirths per provider was 3; in this case, we are dividing 300 stillbirths by 100 providers to get an average of 3).

If any particular bucket is too small, we will bin our results. For example, if we look at a result by provider patient volume, and there is a bin with a very small number of patients (less than 11), we will bin that volume level with the adjacent level (or levels), until the bin that we are reporting is large enough (has 11+ patients).

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² https://countthekicks.org/statistics/ma/

Data, in any paper, report, website, statistical tabulation, seminar, or other setting that is not disseminated to the public.
We plan to publish the results of the study in a Health Policy or Medical journal. While many journals are now open-access, some are not and may place the manuscript behind a paywall.
We may also present the study at the Harvard Maternal Health working group – a group co-run by Prof. Jessica Cohen for the purposes of receiving feedback from other maternal health researchers in the Harvard community.
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?
The lowest geographic level of analysis will likely be ZIP code. If we are not able to achieve at least 11 people per cell, we will either drop small cells, or aggregate up to city or county level analysis. If maps are included, it will be to show the geographic distribution of providers who care for a patient who has a stillbirth. Each defined area of the map will have a cell size of at least 11.
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.

Dr. Jessica Cohen is an Associate Professor of Global Health in the Department of Global Health and Population and the Harvard T.H. Chan School of Public Health. Dr. Cohen is a trained economist who has substantial experience working with administrative data using econometric tools. She has conducted research in maternal and newborn health and have published several papers on the quality of childbirth care in both the U.S. and non-U.S. settings. Dr. Cohen's most recent project in this area focuses on the effect of payment policies on postpartum access to long acting reversible contraception and maternal health in the U.S.

Haley Sullivan is a PhD candidate in the Health Policy program at Harvard University, in the methods for policy research track. Haley's dissertation research is focused on examining access to specialized care during pregnancy and understanding how provider behavior changes after adverse obstetric outcomes. She has worked previously with large administrative claims databases as an RA for Dr. Anna Sinaiko and Dr. Jessica Cohen and has been trained in econometric methods. She has used Health Care Cost Institute (HCCI) commercial claims data to perform an analysis on ~2 million pregnancies in the US from 2016-2021. Haley is funded by an NSF GRFP.

Anna D. Sinaiko, Ph.D. is an Assistant Professor of Health Economics and Policy in the Department of Health Policy and Management at the Harvard School of Public Health. Dr. Sinaiko received her Ph. D. from Harvard University in 2010. She has expertise in health economics and health policy. The unifying theme of her research is an effort to understand consumer decision-making in health care settings, and the implications of consumer and other stakeholder behavior for policy that aims to improve the quality and efficiency of the U.S. health care system. Her research brings improved understanding of the dynamics, strategies, and outcomes associated with consumer health plan choice, of consumer use of information on health care quality and cost, of implications of the structure of consumer cost-sharing and provider payment, and of physician-patient discussions of cost and quality. Specific empirical projects include an examination of consumer response to tiered physician networks, of consumer response to a web-based price transparency tool, and of consumer choice of health insurance plans. Dr. Sinaiko's work has been published in the Journal of Health Economics, Health Affairs, and numerous other peer-reviewed journals.

Dr. Cohen is the chair of Haley Sullivan's dissertation committee. Dr. Sinaiko is on Haley Sullivan's dissertation committee.

2. <u>Resumes/CVs</u>: 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 <u>all</u> 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	Click here to enter text.	
Code:		
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?

Exhibit A: CHIA Non-Government A	All-Payer Claims Data Application	May 2023
☐ Yes ☐ No 4. If yes, a separate Data Managemen	nt Plan must be completed by the agent or contractor	·.
AGENT/CONTRACTOR #1 IN	FORMATION	
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.	
completing the tasks.	ssigned to the agent or contractor for this Project and	their qualifications for
Click here to enter text.		
	ight and monitoring of the activities and actions of the rganization will ensure the security of the CHIA Data	_
Click here to enter text.		
3. Will the agent or contractor have a location, off-site server and/or databases.	access to or store the CHIA Data at a location other thase?	nan the Organization's
□ Yes		

4. If yes, a separate Data Management Plan <u>must</u> be completed by the agent or contractor.

 \square No

[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:	Wendy Chan
Title:	Associate Director, Sponsored Programs Administration
Date:	Click here to enter text.

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);

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



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