19-UFA 02563

CHIA

center for health information and analysis

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

I. INSTRUCTIONS

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

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

- Data Availability
- Fee Schedule
- Data Request Process

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

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

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

II. 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:	Can Urgent Care Centers Increase Access to Care, While Decreasing Costs? Evidence from Massachusetts.
IRBNet Number:	1377056
Organization Requesting Data (Recipient):	The Regents of the University of Michigan
Organization Website:	https://umich.edu/
Authorized Signatory for Organization:	**Maggie Swift**
Title:	Project Representative
E-Mail Address:	magnolia@umich.edu
Address, City/Town, State, Zip Code:	3003 S. State St. First Floor Wolverine Tower, Ann Arbor, MI 48109-1274
Data Custodian: **(individual responsible for organizing, storing, and archiving Data)**	**Thomas Buchmueller**
Title:	Professor
E-Mail Address:	tbuch@umich.edu
Telephone Number:	(734) 764-5933
Address, City/Town, State, Zip Code:	701 Tappan Ave, Ann Arbor, MI, 48109
Primary Investigator (Applicant): **(individual responsible for the research team using the Data)**	**Thomas Buchmueller**
Title:	Professor
E-Mail Address:	tbuch@umich.edu
Telephone Number:	(734) 764-5933
Names of Co-Investigators:	Giacomo Meille, Sarah Miller
E-Mail Addresses of Co-Investigators:	gmeille@umich.edu, mille@umich.edu

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 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.

Summary:

Per capita health expenditures are approximately twice as large in the United States compared to other similarly wealthy countries. In 2010, approximately 2.5% of these expenditures ($64 billion) were due to care for non-emergent conditions delivered in an emergency department (ED) setting (Galarraga & Pines, 2016). One promising trend is the rise of urgent care centers (UCCs). Between 2014 and 2017 the number of UCCs in the US grew by 20% (Stoimenoff & Newman, 2018) and 85% in Massachusetts (Massachusetts Health Policy Commission, 2018).

UCCs may reduce health expenditures by treating urgent conditions at a lower cost than hospital EDs. They may also expedite care for emergent conditions in the ED by reducing overcrowding. However, increases in the convenience of obtaining urgent care may increase patient demand for treatment and associated spending. Furthermore, patient health may decrease and duplicative visits may increase if the quality care at UCCs is lower than EDs.

This study will empirically evaluate these effects. It will use the Masschusetts All Payer Claims Database to examine the effects of UCC openings and closures on the probability of receiving any treatment for an urgent episode, the type of providers visited, number of total visits, and the associated cost. The proposed study will incorporate both the immediate costs of care, and costs that accrue several weeks following an urgent episode to establish the full costs of treatment. It will also assess the effect on total annual expenditures, and examine heterogeneity based on patient and provider characteristics.

The proposed study will analyze the effect of UCC openings and closures using a difference-in-differences model at the person level. The model will compare patients living within 5 miles of an UCC before and after it opens. To address concerns that areas without UCCs are systematically different than areas with UCCs, we will only utilize data from people who live within 5 miles of a UCC and identify the effect of interest based on the timing of the opening. This approach also allows us to account for any trends in use of care that occur throughout the state over time.

The effect of UCCs on health expenditures has only been minimally explored in the academic literature. While several papers estimate the percentage of ED visits that could be treated in an urgent care setting, Allen et al. (2019) and Krishna (2016) and are the only papers that we are aware of that explore the effect of UCC openings on ED visits. These papers explore this question using data from ED discharges. This allows the authors to observe the universe of emergency department visits, but utilization of other providers, such as UCCs, is not observed. Allen et al. (2019) estimates that non-emergent ED visits increase by 1.3% at the time of day that UCCs close for privately insured individuals who live in areas with multiple UCCs. Krishna (2016) estimates a reduction of 3-18% (depending on the type of condition) in the probability of ED use after an UCC opens.

This study will make several contributions relative to the existing literature. Research on UCCs has been hindered by data limitations. We will create a historical database of urgent care centers in Massachusetts by combining data from government agencies and private databases. Health and expenditure outcomes will be examined using Massachusetts' All Payer Claims Database. Relative to the current literature, which is based on data from ED discharges, the insurance claims dataset will allow us to perform longitudinal analyses of patients and directly observe utilization and expenditures at both UCCs and EDs.

Papers cited:

Allen, L., Cummings, J. R., & Hockenberry, J. (2019). *Urgent Care Centers and the Demand for Non-Emergent Emergency Department Visits* (No. w25428). National Bureau of Economic Research.

Galarraga, J. E., & Pines, J. M. (2016). Costs of ED episodes of care in the United States. *The American journal of emergency medicine*, 34(3), 357-365.

Krishna, M. (2016). Asymmetric Regulations in Health Care: Urgent Care Centers and Emergency Departments. *New York University Unpublished Manuscript.*

Massachusetts Health Policy Commission. (2018, August 9). HPC DataPoints, Issue 8: Urgent Care Centers and Retail Clinics. Retrieved from https://www.mass.gov/info-details/hpc-datapoints-issue-8-urgent-care-centers-and-retail-clinics

Stoimenoff, L., & Newman, N. (2018). *Urgent Care Industry White Paper 2018 (Unabridged): The Essential Role of the Urgent Care Center in Population Health.*

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

V. PUBLIC INTEREST

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

Per capita health expenditures are approximately twice as large in the United States compared to other similarly wealthy countries. Estimates indicate that roughly one third of these expenditures are wasteful (Cutler, 2018). This has motivated a vast literature that asks how the United States can more efficiently spend on health care. Emergency department (ED) expenditures are important to consider. In 2010, ED expenditures accounted for $330 billion or 12.5% of national health expenditure; however, 30% of visits were classified as non-emergent (Galarraga & Pines, 2015). Treatment of non-emergent cases in the ED comes at a high cost. According to the Massachusetts Health Policy Commission, the average cost of treating a low acuity patient in an ED is $688. Additionally, treating non-emergent cases in the ED may reduce the quality of care received by other patients due to overcrowding (Schull et al., 2004; Miro et al., 1999).

In this context, it is important to consider alternative settings for providing care for urgent, but non-emergent medical episodes. Two alternatives have grown rapidly over the past decade. Retail clinics are walk-in clinics located in pharmacies and staffed by nurse practitioners or physician assistants. UCCs also offer walk-in services, but are usually staffed by physicians and offer treatment for more complex conditions, such as broken bones. Both of these providers treat patients at a fraction of the cost of EDs. According to the Massachusetts Health Policy Commission, the average cost of treating low acuity patient was $78 in a retail clinic and $147 in an UCC. The UCC cost was broadly in line with traditional physician offices, which had an average cost of $165 for non-acute visits.

The goal of this paper is to determine whether UCCs are able to realize cost savings to consumers and insurers, while increasing access to care. The simple comparison of the average cost of visits at UCCs and the EDs does not account for many factors that determine whether UCCs decrease total health expenditures. To begin, UCCs increase the convenience of care, which may lead people to visit providers for conditions that they previously did not treat in the healthcare system. Conditional on visiting a provider, the quality of care, patient information, and continuity of care may all affect the efficiency of UCCs (Chang et al., 2015). Little is known about the quality of care at UCCs, but the need for follow-up visits hinges on this variable. The probability of duplicative care also depends on the patient's ability to identify a provider who has the expertise and resources that are appropriate to treat their condition. Lastly, substitution between primary care providers and UCCs has the potential to negatively affect continuity of care.

The overall effect of UCCs on health expenditures has substantial implications for public policy. If UCCs are the most efficient setting for treating non-emergent conditions, then they may help providers and policymakers reduce patient costs. For example, in recent years, hospitals that are part of Accountable Care Organizations in Massachusetts have indicated that they are opening UCCs for this very reason (Kirner, 2014). Furthermore, this question is very relevant to public insurers, such as Medicaid. Many UCCs do not accept Medicaid patients because of lower reimbursement rates. If UCCs can effectively lower the cost of care for urgent medical episodes, then Medicaid may actually be able to decrease its overall costs by matching reimbursement rates of private insurers for UCCs. This paper will directly address this question by exploring heterogeneity by type of insurance.

VI. DATA 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 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. Data requests will be fulfilled using the most current Release Version. For more information about the most current APCD Release Version, 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. 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. List years of data requested (only list years available in the current Release Version): 2012-2016

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

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

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: Medical claims are necessary to examine the spending by type of provider for persons in Massachusetts.

☒ **Pharmacy Claims**
Describe how your research objectives require Pharmacy Claims data: Pharmacy data is necessary to examine whether urgent care centers are more likely to prescribe medications than emergency departments.
☐ **Dental Claims**
Describe how your research objectives require Dental Claims data:
☐ **Member Eligibility**
Describe how your research objectives require Member Eligibility data:
☐ **Provider**
Describe how your research objectives require Provider data:
☐ **Product**
Describe how your research objectives require Product data:

VII. 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.

All-Payer Claims Database data is 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 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.

Geographic Subdivisions

The geographic subdivisions listed below are available for Massachusetts residents and providers only. Select *one* of the following options.

☐ 3-Digit Zip Code (standard)	☒ 5-Digit Zip Code***
*****If requested, provide justification for requesting 5-Digit Zip Code. Refer to specifics in your methodology:** The proposed methodology compares people who live within 5 miles of an urgent care center before and after it opens. The 5-digit zip code is necessary to accurately estimate the patient distance from an UCC.	

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:** The month is necessary to accurately determine whether an UCC was open at the time that a patient's condition was treated. The day is necessary in order to analyze the spending and number of visit by a patient over the 2 weeks that follow a visit to and urgent care center or emregency department.		

National Provider Identifier (NPI)

Select *one* of the following options.

☐ Encrypted National Provider Identifier(s) (standard)	☒ Decrypted National Provider Identifier(s)***
***** If requested, provide justification for requesting decrypted National Provider Identifier(s). Refer to specifics in your methodology:** The decrypted NPI is necessary to categorize providers as urgent care centers, emergency departments, primary care providers, or other types of providers. It is also necessary to categorize the affiliation of the urgent care center (physician owned, hospital affiliated, community health center affiliated).	

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.

Many UCCs do not accept Medicaid patients because of lower reimbursement rates. If UCCs can effectively lower the cost of care for urgent medical episodes, then Medicaid may be able to decrease its overall costs by matching reimbursement rates of private insurers for UCCs. This paper will directly address this question by exploring whether the likelihood of treating patients and associated changes in expenditures differ according to the reimbursement rate and type of insurance. It will specifically test whether there are differential effects for Medicaid. It will also estimate the net effect on total costs of treatment when a patient visits an UCC.

As explained above, UCCs may reduce health expenditures by treating urgent conditions at a lower cost than hospital EDs. They may also expedite care for emergent conditions in the ED by reducing overcrowding. However, increases in the convenience of obtaining urgent care may increase patient demand for treatment and associated spending. Furthermore, patient health may decrease and duplicative visits may increase if the quality care at UCCs is lower than EDs. The net effect on patient expenditures is an empirical question and it will differ based on the characteristics of the patient's insurance plan.

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.

Provider data will be linked to the AMA Physician Masterfile and National Plan and Provider Enumeration System to control for the quality of providers. Facility data will be linked to a database created by the researchers, which contains the facility address, categorizes the type of facility, the date that the facility opened and closed (if relevant), and the number of complaints that have been filed by patients. These data are necessary to calculate the distance between patients and the types of facilities that they may visit over time. They also control for quality. Census data will be linked to allow the researchers to control for zip-code level characteristics that change over time.

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.

Provider and facility data will be linked using the National Provider Identifier. Census data will be linked using the patient's zip code.

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.

AMA Physician Masterfile/National Plan and Provider Enumeration System: Licensure Medicare/Medicaid and other federal sanctions, practice specialty, major professional activity, provider taxonomy

Researcher database: Facility address, type of facility (emergency department, urgent care center, primary care, or other), date that the facility opened and closed, and the number of complaints that have been filed by patients

Census data: median income, insurance, demographics, employment.

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

Individual patient level data will not be linked. Only data that is necessary to the research design will be linked. The researchers will not attempt to identify any patients.

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.

Results will be submitted for publication at an academic journal in the area of health economics. The analyses of interest rely on statistical properties that are only relevant for large samples. Therefore, no analyses will be undertaken for cells that contain less than 11 people. Additionally, academic journals will be made aware of this requirement, which is standard for government data sources, such as the Census.

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.

Results of statistical analyses will be periodically shared at seminars at the University of Michigan and health economics conferences.

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?

Analyses will be conducted for patient-level outcomes. The determination of which patients to include in an analysis will be made at a 5-digit zip code level. Maps pertaining to patient data will not be presented.

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?

9. If you have answered "yes" to questions 5, 6, 7 or 8, please describe the types of products, software, services, or tools.

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?

XII. 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.

Professor Buchumueller and Professor Miller have direct experience using insurance claims data in their research. Both professors have used Medicare claims data in prior projects. Professor Buchmueller has a recent publication based on Medicare data: "The Effect of Prescription Drug Monitoring Programs on Opioid Utilization in Medicare", which was coauthored with Colleen Carey . Professor Miller has two working papers that utilize Medicare claims data: "Drug Firms' Payments and Physicians' Prescribing Behavior in Medicare" with Colleen Carey and Ethan Lieber, and "The Impact of Insurance Expansions on the Already Insured: The Affordable Care Act and Medicare" with Colleen Carey and Laura Wherry.

Giacomo Meille has experience with large datasets that contain health information and are very similar to claims data. His working paper "How Well Do Doctors Know Their Patients? Evidence from a Mandatory Access Prescription Drug Monitoring Program" is based on transaction records of prescription medications at the patient level, which are collected by the Kentucky and Indiana Prescription Drug Monitoring Programs.

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.)

XIII. USE OF AGENTS AND/OR CONTRACTORS

By signing this Application, the Agency assumes all responsibility for the use, security and maintenance of the CHIA Data by its agents, including but not limited to contractors. The Agency must have a written agreement with the agent 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:	
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, 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.

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

IVX. ATTESTATION

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

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

By my signature below, I attest: (1) to the accuracy of the information provided herein; (2) that the requested Data is the minimum necessary to accomplish the purposes described herein; (3) that the Organization will meet the data privacy and security requirements described in this Application and supporting documents, and will ensure that any third party with access to the Data meets the data use, privacy and security requirements; and (4) to my authority to bind the Organization.

Signature: (Authorized Signatory for Organization)	FOR
Printed Name:	**Maggie Swift**
Title:	Project Representative

Patrick Woods, JD
Managing Project Representative
UM Research & Sponsored Projects

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.