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:** | Competition and Insurance Benefit Design |
| IRBNet Number: | 1454452-1 |
| **Organization Requesting Data (Recipient):** | University of Minnesota, Department of Economics |
| Organization Website: | **cla.umn.edu/economics** |
| **Authorized Signatory for Organization:** | Wendy Williamson |
| Title: | Graduate Program Coordinator |
| E-Mail Address: | wendy@umn.edu |
| Address, City/Town, State, Zip Code: | 4-101 Hanson Hall<br>1925 Fourth Street South<br>Minneapolis, MN 55455 |
| **Data Custodian:**<br>**(individual responsible for organizing, storing, and archiving Data)** | Tom Kell |
| Title: | HST Server Operations Manager |
| E-Mail Address: | kell@umn.edu |
| Telephone Number: | 612-626-6219 |
| Address, City/Town, State, Zip Code: | 426 S Church Street STE 568, Minneapolis, MN 55455 |
| **Primary Investigator (Applicant):**<br>**(individual responsible for the research team using the Data)** | Tom Holmes |
| Title: | Curtis L. Carlson Professor of Economics |
| E-Mail Address: | holmes@umn.edu |
| Telephone Number: | 708-308-3723 |
| Names of Co-Investigators: | Conor Ryan |
| E-Mail Addresses of Co-Investigators: | Ryan0463@umn.edu |

## IV. PROJECT INFORMATION

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

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

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.

Background

The health and medical spending of a patient can depend on particular treatment choices. For instance, patients can adhere to drug regimens in order to manage chronic illness, receive preventive screenings, and maintain frequent

visits to a primary care doctor. These treatment decisions also depend on the characteristics of a patient's insurance plan, if any. A particular plan may require more or less out-of-pocket spending, physician referral, or prior authorization for a particular service.

In a competitive market for health insurance, firms set these characteristics, as well as price, in order to maximize their profit. However, little is known about whether the competitive incentives for insurance benefit design translate to improved treatment decisions. In this project, I focus on whether competition leads to benefit designs that encourage more use of primary and preventive care services, which have the potential to improve overall health and lower long-run medical spending.

The setting for this research is Medicare Advantage (MA), a subsidized private insurance alternative to the federally-run traditional Medicare program. Importantly, one motivation for offering such an alternative is to allow private firms to innovate in the insurance products they offer, delivering an improved benefit to eligible American seniors.

Preliminary findings suggest that firms in more competitive MA markets have lower out-of-pocket spending requirements but are more likely to require prior-authorization for primary and preventive care services. In this research, I will seek to identify the competitive incentives that explain this observation and understand the ways that these incentives for insurance firms translate into individual treatment decisions.

Project Aim

In this project, I explore how competition in MA affects the use of primary and preventive care through the insurance design decisions of the firms. I will accomplish this in three parts. First, I will identify how competition affects an insurance firm's incentive to use out-of-pocket spending or prior-authorization requirements for primary and preventive care services. Second, I will estimate how competitive markets affect the use of primary and preventive care services through these benefit design decisions. Third, I will examine how the resulting changes in primary and preventive care use affect long-run medical costs. Finally, I will use the results of my study to estimate how past mergers between insurance companies have affected treatment decisions and long-run medical costs among seniors.

Related Literature

This research will combine two areas of the health economics literature. First, it will contribute to a literature on plan choice and competition in Medicare Advantage by studying the effects of competition on product characteristics in fine detail (Miller, Petrin Town, Chernew 2019; Cabral, Geruso, Mahoney 2018; Curto, Einav, Levin, Battacharya 2018). Second, it will contribute to a literature that studies the effects of insurance benefit design on treatment choices by connecting how the incentives of competing insurance firms influence treatment choices through design decisions (Baiker, Mullainathan, Schwartzstein 2015; Manning, et al 1987).

Products

The objective of this project is to produce results to be disseminated via publication in a peer-reviewed academic journal and seminar presentations. These results will be informative to policy makers making decisions about health insurance market regulation.

3. Has an Institutional Review Board (IRB) reviewed your Project?

☐ Yes [*If yes, a copy of the approval letter and protocol must be included with the Application package on IRBNet.*]
☒ No, this Project is not human subject research and does not require IRB review.

4. **Research Methodology**: Applicants must provide either the IRB protocol or a written description of the Project methodology (typically 1-2 pages), which should state the Project objectives and/or identify relevant research questions.

This document must be included with the Application package on IRBNet and must provide sufficient detail to allow CHIA to understand how the Data will be used to meet objectives or address research questions.

## V. PUBLIC INTEREST

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

This research seeks to provide evidence on an important question: how does insurance competition affect health care outcomes?

This research is important to the public interest for two reasons. First, it informs policy makers on how the dynamics of competition translate into benefit design decisions. Competitive insurance markets are a key aspect of US health care policy, playing a central role in Medicare, Medicaid, and the Affordable Care Act. While there is substantial research on the effect of competition on insurance prices, there is comparatively little known on how competition affects insurance characteristics and the treatment choices made by the insured. This research will help inform policy makers on the benefits and limitations of competition with regard to primary and preventive care.

Second, this research has implications on the ability for competition among insurance firms to help "bend the cost curve." The United States spends more on health care, per-capita, than any other industrialized nation without any discernable gain in health care outcomes. If competition leads to more use of primary and preventice care services, it suggests that competitive insurance markets have the possibility to improve the overall health of the population and reduce long-run spending on health care services.

## 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): 2013, 2014, 2015, 2016, 2017

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:**

One central question of my research is to determine how insurance benefit design affects the use of primary and preventive care. I require the Medical Claims data in order to observe the differences in primary and preventive care use among individuals enrolled in insurance plans with different benefit designs. In particular, I will look at the effect of switching between plans and changes in plan charactersitcs over time on the primary and preventive care use among Medicare Advantage enrollees. I will use the Medical Claims file to identify primary and preventive care services, match the category of these services to particular insurance benefit categories, and develop measures for the annual frequency of visits and annual spending in each category.

**☐ Pharmacy Claims**

**Describe how your research objectives require Pharmacy Claims data:**

**☐ Dental Claims**

**Describe how your research objectives require Dental Claims data:**

**☒ Member Eligibility**

**Describe how your research objectives require Member Eligibility data:**

In my research, I am interested in how insurance plan benefit design affects treatment decisions. In order to best isolate the effects of insurance benefits, I require the Member Eligibility data in order to control for demographic differences in treatment decisions, as well as defining the relevant population of Medicare-eligible patients. The demographic variables I intend to use include age, gender, and 3-digit zipcode.

I will also use the Member Eligiblity data to determine the start and end dates of when patients are enrolled in particular products, and link medical claims to the associated insurance products of the patients.

**☐ Provider**

**Describe how your research objectives require Provider data:**

**☒ Product**

**Describe how your research objectives require Product data:**

My research centers around insurance plan benefits. In order to link external plan benefit information to the Medical Claims data, I require the product identifiers contained in the 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:**

My research methodology requires that I be able to link residents to the counties in which they live. Counties are typically larger geographic divisions than 3-digit zip codes, but do not coincide perfectly with 3-digit zip code delineation. I am requesting the 5-digit zip code to allow for more complete matching of zip codes to counties. The 5-digit zip code will be used exclusively to merge in aggregate product-level characteristics, and will not be used in any way to obtain more information on individuals.

### 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:**

My research methodology relies on observing the treatment decisions immediately before and immediately after an individual experiences changes in insurance plan benefits, either because the individual switched insurance plans or because the insurance plan altered its characteristics. In order to adequately perform this analysis, it is necessary to be able to compare the treatment decisions made during the several months prior and following a change in plan benefits. Observing the month of a treatment decision will allow for the adequate comparisons, whereas observing only the year of a treatment decision would be insufficient.

### 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:** | |

## 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.

## 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): Medicare Advantage Plan-level Data

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.

I intend to link the Product data to two publicly available data sets on Medicare Advantage plans maintained by the Center for Mediare and Medicaid Services (CMS). The first is Monthly Enrollment by Contract and County. This data is released monthly, I plan to use the data from each month between 2013 and 2017 to link information on the market shares of each insurance plan and market-level statistics such as market size and market concentration. The second is the Plan Benefits Package data, which is released annually between 2013 and 2017. I will use this data to link information on the primary and preventive care benefits of each insurance plan.

I will link both of these datasets to the product identifier (PR001) in the Product data and the county in which the members live, which I will impute from the zip code.

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 product identifiers in the Product File are encrypted (PR001). In order to match products in the CHIA data to aggregate data on Medicare Advantage plans published by the Center for Medicare and Medicaid Services (CMS), I will probabilistically match the products based on several observed product characteristics: country level enrollment, the product line of business (PR004), the insurance plan market (PR005), and the product benefit type (PR006). I will use a "nearest neighbor" matching algorithm that matches the encrypted products IDs to the most similar products in the publicly available data. I will compute the monthly, county-level enrollment for each product in the CHIA data and then assign a probability a product in the CHIA data should be matched to a product in the CMS data according the difference between the enrollment profiles of each product. I will match the CHIA products to their most likely counterpart in the CMS data, i.e. their nearest neighbor.

The CMS enrollment data is censored to include only plans that enroll at least 11 beneficiaries in a particular county. Therefore, this matching process will not apply to any products that contain fewer than 11 individuals in the CHIA data. Since this match is not deterministic, I will not be able to fully identify which products individuals in the CHIA data are enrolled in and I will not report the names of the products which I probabilistically match.

In order to match the county (to determine county-level enrollment), I will use a zipcode to county mapping provided by the Missouri Census Data Center (MCDC). In some cases, these mappings will not be deterministic (i.e., a zipcode overlaps two counties). In these cases, I will use a probabilistic matching algorithm, where the match probability is based on the portion of the population of the zipcode that lives in each county with which it overlaps. This data is also available from the MCDC. If I am not able to obtain 5-digit zip codes, this same methodology would apply to 3-digit zip codes.

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.

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

## 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.

I plan to disseminate the results of the study through publication in a peer-reviewed academic journal. The results that I intend to public primarily include effect sizes, such as "A one standard deviation increase in the level of competition leads to an X% in primary and preventive care utilization." These results will be displayed for the entire population of individuals enrolled in Medicare Advantage plans, or subgroups which are substantially larger than 11 individuals. An example of a subgroup would be Men between the ages of 65 and 70. I will guarantee that I will not include results for any subgroup contains fewer than 11 individuals.

I will also publish descriptive statistics of the data that help readers understand the underlying setting. These descriptive statistics will describe primary and preventive care use patterns and demographics of the entire population of individuals enrolled in Medicare Advantage plans. I will not include any Medicare Advantage products in my analysis that enroll fewer than 11 individuals in Massachusetts.

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.

I also intend to give seminar presentations about this research. These presentations are typically to an audience of between 5 and 30 scholars and students, and will consist of similar results to those that will eventually be published in a peer-reviewed academic journal.

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 level of geographic analysis that I expect to include in my results is county level. In any results that are specific to a particular county, I intend to use the entie population of individuals enrolled in Medicare Advantage (MA). If there is such a country with fewer that 11 individuals enrolled in MA, I will omit results for that county.

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.

The Principal Investigator, Dr. Thomas Holmes, is the Curtis L. Carlson Professor of Economics at the Unviersity of Minnesota. Dr. Holmes has extensive experience in the economic research methods that will be employed in this project, but little relevant

experience using claims data. This research will primarily be carried out as a part of the dissertation research of the Co-Investigator, Conor Ryan.

Conor Ryan is a 4th year PhD student in economics at the University Minnesota. His claims data experience comes from working for two semesters as a a teaching assistant to Dr. Steve Parente for "Health Care Analytics." This class is a masters-level course to teach students the basics of claims data analytics using SAS and R. He assisted in creating a synthetic all-payer claims database derived from real claims data from multiple public and private sources. He edited SAS scripts and developed R scripts to serve as teaching templates for the students to learn how to identify particular services and diagnoses, calculate basic summary statistics for particular sub-populations, and run basic regressions. Through teaching the course and working with Dr. Parente, he learned many of the details of how claims data are created and how to use the data in order to better serve the students.

Conor Ryan also has experience with medical data for research purposes. In a working paper on competition in health insurance markets, titled "Market Structure in the Presence of Adverse Selection," he applies the HHS Hierarchical Condition Category risk adjustment model to the Medical Expenditure Panel Survey Medical Conditions Files. This data resemble claims data in structure, except all conditions and procedures are self-reported, diagnoses are trucnacted to 3 digit ICD 9 codes, and there is no information about payment. This paper won the first place prize in the Minnesota Economics Third Year Paper contest.

Throughout the course of this project, Conor will continue to be mentored Dr. Parente, and by Dr. Pinar Karaca Mandic, who is on his dissertation committee. Dr. Karaca Mandic is the current director of the Medical Industry Leadership Institute at the Carlson School of Management and has extensive experience in using claims data for research.

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.)

## 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 **all** 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.

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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.

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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.

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|---|
| |

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:<br>(Authorized Signatory for Organization) | Wendy Williamson |
| **Printed Name:** | **Wendy Williamson** |
| Title: | Graduate Program Coordinator |

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.**

**[INSERT IRB approval letter and protocol, or research methodology]**