CHIA.

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and analysis

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

I. INSTRUCTIONS

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

Before completing this Application, please review the data request information on CHIA's website:
- Data Availability
- Fee Schedule
- Data Request Process

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

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

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

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

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

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@chiamass.gov.

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:	Health Insurance Benefit Design and Health Care Markets
IRBNet Number:	2199697-1
Organization Requesting Data (Recipient):	President and Fellows of Harvard College (through Harvard Business School)
Organization Website:	www.hbs.org
Authorized Signatory for Organization:	Megan Moore
Title:	(Harvard University, Office for Sponsored Programs) ASSOCIATE DIRECTOR, PRE-AWARD SERVICES
E-Mail Address:	megan_moore@harvard.edu
Telephone Number:	617-496-7173
Address, City/Town, State, Zip Code:	1033 Massachusetts Avenue 5th Floor Cambridge, MA 02138 USA
Data Custodian: (individual responsible for organizing, storing, and archiving Data)	Leemore Dafny
Title:	Bruce V. Rauner Professor of Business Administration
E-Mail Address:	ldafny@hbs.edu
Telephone Number:	(617) 495-2416
Address, City/Town, State, Zip Code:	Morgan Hall, Soldiers Field Rd, Boston, MA 02163
Primary Investigator (Applicant): (individual responsible for the research team using the Data)	Leemore Dafny
Title:	Bruce V. Rauner Professor of Business Administration
E-Mail Address:	ldafny@hbs.edu
Telephone Number:	(617) 495-2416
Address, City/Town, State, Zip Code:	Morgan Hall, Soldiers Field Rd, Boston, MA 02163
Names of Co-Investigators:	Olivia Zhao
E-Mail Addresses of Co-Investigators:	ozhao@hbs.edu

IV.   PROJECT INFORMATION

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

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

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

☐ Inclusion in a product   ☐ Other (describe in box below)

Click here to enter text.

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

The purpose of the research is to study how health insurance benefit design affects patients (both in terms of their health and the financial burden they experience or face).

The research will consider specific benefit features related to prescription drug copays. The first specific benefit feature is called a "copay maximizer program," or "maximizers." Maximizers are an increasingly common benefit design in self-insured insurance plans.[1] While the specifics of implementation vary across plans, maximizers generally affect plan payments for high-cost specialty drugs. They often reduce patients' copays for these select drugs, but involve some hassle costs for patients, who must enroll in drug manufacturer assistance programs.[2]

The effects of maximizers on patient prescription drug adherence is unknown. While existing literature and theory would suggest that reducing copays should increase drug adherence all else equal [3], a separate literature suggests that sufficient hassle costs may instead deter individuals from filling their prescriptions.[4] The net effect of maximizers on patients, and whether any effects disproportionately affect certain types of patients, is an open empirical question.

The investigators will explore questions related to copay maximizer programs, including:

What are the characteristics of patients that take drugs typically included in maximizers?

Do maximizers affect patients' utilization of affected drugs or medical services, adherence to prescribed therapies, out-of-pocket spending, and health outcomes?

Do effects on patients vary by characteristics such as income, age, or heath conditions?

Understanding the effects of maximizers on patients can help to inform and improve future implementations of maximizers and related new types of benefit design.

We are already in possession of a claims dataset from a large self-insured employer, which implemented a copay maximizer program in January 2021. However, we lack a control group of privately insured enrollees who are not enrolled in such a program during the study period. We aspire to create the control group from privately-insured enrollees in the MA APCD, specifically those in fully insured plans which are not legally able to implement copay maximizers.

A second, related benefit design feature is a "copay accumulator." Under a copay accumulator, payments by third parties (such as pharmaceutical manufacturers) toward patients' deductibles and other cost-sharing only apply to the specific subsidized service/drug. In order to study this benefit design feature, we will attempt to identify treatment and control groups both from within the MA APCD. One challenge is that the data lack information on enrollee deductibles and whether an accumulator is in fact in place; to the extent possible, we will attempt to infer this information from claims history and/or public plan design documents for certain carriers or market segments. If successful, we can study the effects of accumulators on a similar set of outcomes (patient decisions, spending, and utilization) as outlined above for copay maximizers.

[1] DrugChannels, 2024, "Copay Accumulator and Maximizer Update: Adoption Expands as Legal Barriers Grow," https://www.drugchannels.net/2024/02/copay-accumulator-and-maximizer-update.html
[2] Brennan TA, Kesselheim AS. Accumulators and maximizers: A new front in the battle over drug costs (part 2). Health Affairs Forefront. 2022. November 18.

[3] Chandra, A., Flack, E., & Obermeyer, Z. (2024). The Health Costs of Cost-Sharing*. The Quarterly Journal of Economics, qjae015. https://doi.org/10.1093/qje/qjae015
Einav, L., Finkelstein, A., & Polyakova, M. (2018). Private Provision of Social Insurance: Drug-Specific Price Elasticities and Cost Sharing in Medicare Part D. American Economic Journal: Economic Policy, 10(3), 122–153. https://doi.org/10.1257/pol.20160355
Einav, L., Finkelstein, A., & Schrimpf, P. (2015). The Response of Drug Expenditure to Nonlinear Contract Design: Evidence from Medicare Part D *. The Quarterly Journal of Economics, 130(2), 841–899. https://doi.org/10.1093/qje/qjv005
[4] Handel, B. R., & Kolstad, J. T. (2015). Health Insurance for "Humans": Information Frictions, Plan Choice, and Consumer Welfare. American Economic Review, 105(8), 2449–2500. https://doi.org/10.1257/aer.20131126
Marshall, G. (2015). Hassle Costs and Price Discrimination: An Empirical Welfare Analysis. American Economic Journal: Applied Economics, 7(3), 123–146. https://doi.org/10.1257/app.20130046

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

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

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

V.   PUBLIC INTEREST

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

As copay maximizer designs become more common among commercial insurance plans, the number of patients potentially affected increases. Despite their increasing prevalence, little is known about how they might affect patients. This project will help us understand whether this new benefit design affects adherence to prescribed medications.

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. For more information about APCD Data, including available years of data and a full list of elements in the database please refer to 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</u>

data files and data elements included in the initial Release annually or as available. Please note that approved subscription requests are subject to the Data Use Agreement, will require payment of fees for additional Data for Non-Government Entities, and subject to the limitation that the Data can be used only in support of the approved Project.

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

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

2. CHIA is currently supporting requests for claims data from 2016 to 2022. Requests made outside of these years may not be supported by CHIA and will be considered on a case-by-case basis. Please specify the years of data that are being requested: **<mark>2018-2022 (2022 release)</mark>**

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:
Click here to enter text.

☒ **Pharmacy Claims**
Describe how your research objectives require Pharmacy Claims data:
We plan to study benefit design features specific to prescription drug benefits. Our first outcome variable is medication adherence, which is calculated using the history observed fills for any given patient.

☐ **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:
For our study of copay maximizers, we would like to limit our analysis sample to patients facing similar cost-sharing throughout the calendar year. One notable sub-population that can have highly variable observed cost-sharing payments over the plan term are individuals in high-deductible health plans (HDHPs). For this reason, we would like to exclude HDHP enrollees from our analysis. In order to do so, we plan on using some combination of the member deductible variables (ME049, ME050, ME112) and firm size variable (ME030), as larger firms are more likely to offer HDHPs. For our study of copay accumulators, we will ideally compare enrollees in HDHPs with and without copay accumulator, where the existence of a copay accumulator is identified or inferred through prescription drug claims history, plan characteristics, or employer characteristics. Additionally, the member eligibility is necessary to understand demographics of the patient population from CHIA we include in our analysis sample. Important demographic variables include zip code of residence, age, sex, and (when applicable) employer size.

☐ **Provider**

Describe how your research objectives require Provider data:
Click here to enter text.

☐ **Product**
Describe how your research objectives require Product data:
Click here to enter text.

VII.   DATA ENHANCEMENTS REQUESTED

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

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

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

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

a. Geographic Subdivisions

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

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

Select *one* of the following options.

☐ 3-Digit Zip Codes (standard)	☒ 5-Digit Zip Codes***
***If requested, provide justification for requesting 5-Digit Zip Code. Refer to specifics in your methodology:	
For the copay maximizer study, we aspire to create a control group that is as similar as possible to our treatment group, which consists of employees at a large self-insured employer in Massachusetts. We would like to ensure the distribution of enrollees in our CHIA sample across zipcodes is similar to that in our treatment group. Income is correlated within zipcode, and existing research has shown that income and financial strain are associated with various health care utilization measures, including medication adherence. In addition, access to healthcare providers – notably physicians prescribing high-cost medications – may vary by geography. For these reasons, the narrower 5-digit zip code is necessary for our study design.	

b. Date Resolution

Select *one* option from the following options.

☐ Year (YYYY) (Standard)	☐ Month (YYYYMM) ***	☒ Day (YYYYMMDD) *** [for selected data elements only]
*** **If requested, provide justification for requesting Month or Day. Refer to specifics in your methodology:** Our main outcome variable is medication adherence, defined using standard measures in the literature such as Proportion of Days Covered or Medication Possession Ratio. These measures require knowing the exact date of pharmacy fills.		

c. **National Provider Identifier (NPI)**

Select *one* of the following options.

☒ Encrypted National Provider Identifiers (standard)	☐ Decrypted National Provider Identifiers***
*** **If requested, provide justification for requesting decrypted National Provider Identifier(s). Refer to specifics in your methodology:** Click here to enter text.	

VIII.   MEDICAID (MASSHEALTH) DATA

1. Please indicate whether you are seeking Medicaid Data:

☐ Yes
☒ No

2. Federal law (42 USC 1396a(a)7) restricts the use of individually identifiable data of Medicaid recipients to uses that are ***directly connected to the administration of the Medicaid program***. If you are requesting MassHealth Data, please describe, in the space below, why your use of the Data meets this requirement. *Your description should focus on how the results of your project could be used by the Executive Office of Health and Human Services in connection with the administering the MassHealth program*. Requests for 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 Data.

Researchers must provide the following information for MassHealth to determire how the disclosure of indentifiable MassHeath claims data is directly related to the administration of the MassHealth program:

- How does the project relate directly to the administration of the Medicaid program?

- What specific Medicaid program, policy, rule or law will be affected or changed based on the outcome of this project?

- How will MassHealth's objectives be helped or impaired by approving this project?

- Will the results of the research have the potential for:
  - reducing cost of the Medicaid program,
  - improving access for recipients, and/or
  - increasing quality of care to recipients?

- Please describe the project deliverables the researchers will provide to MassHealth

- Please describe how MassHealth can use the project deliverables in administration of the MassHealth program.

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

IX.   DATA LINKAGE

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

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

2. If yes, please indicate below the types of data to which CHIA Data will be linked. [Check all that apply]
    ☒ Individual Patient Level Data (e.g. disease registries, death data) – APPENDED but not linked
    ☐ 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.

CHIA Data will be used to create a patient-drug-time-level dataset containing outcomes derived from the prescription claims data (e.g. medication adherence) and patient characteristics like age, gender, and zip code. We will merge on income data by zip code using publicly available Census data. We will merge on drug-level variables using aggregate data from public sources e.g. CMS Part D spending data and FDA NDC Directory.

This resulting dataset will be appended to an analogous dataset already created using claims and enrollee data from a self-insured employer. Our analysis will essentially estimate differences in adherence and other drug utilization measures between the patients represented in the self-insured employer versus a control group of enrollees identified in the CHIA data, before and after implementation of a maximizier for the self-insured employer's plan. We plan to exclude all enrollees in the CHIA data enrolled in self-insured group plans, meaning there should be essentially zero overlap between individuals in the CHIA data and the self-insured employer data. *Therefore, there will be no attempt to link individuals across the two data sources.* Functionally, we will append the CHIA data to the self-insured employer data.

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.

Income data at the zip code level (e.g. median income) or publicly available drug data from CMS and FDA can be deterministically matched using the provided 5-digit zip code for the enrollee and NDC code in the pharmacy claim.

As described above, we propose simply appending the CHIA data to the self-insured employer data. There will not be any linkages between th two data sources.

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.

Census Bureau "Income by Zip code tabulation area" data collected via the American Community Survey
-Estimated median household income
-Estimated mean household income

CMS Part D Spending and Utilization
-Total spending

FDA NDC Directory
-Proprietary name
-Non-proprietary name

Variables included in the self-insured employer data that may be used for the analysis with CHIA data:
See confidential attached data dictionary for exact listing

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

There will be no attempts to link individuals across the two individual-level data sources.

As described in the submitted IRB protocol, all published results will be aggregated across individuals and medications – identifiability risk is very low.

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.

> We plan to publish findings in peer-reviewed journals and present findings at academic seminars and conferences.
>
> We will not directly or indirectly report data for any cells less than 11 enrollees. If we encounter cell sizes smaller than 11, we will group that cell with "neighboring" cells (e.g. group together two zip codes such that the number of individuals in the combined zip codes totals more than 11) so that all cells have more than 11 observations.

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.

> No plans

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?

> Geographic data will only be used to identify enrollees to include in the sample (e.g. only including enrollees in CHIA residing in certain zip codes or in the same zipcode as a matched enrollee in the treatment group) or as a control variable (e.g. zip code fixed effects). Results specific to certain geographies 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?

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.

Leemore Dafny has been an academic health economist for over 20 years, and in that time period she has written and co-authored studies using a range of claims data sources, including Medicare Claims Data (both FFS and Medicare Advantage encounter data), HCCI 1.0 Claims Data, and currently claims data from a self-insured employer. She has supervised post-docs and grad students working with these data for several years and ensured compliance with all protocols and security requirements.

Olivia Zhao is a health policy and management PhD student at Harvard Business School. She works with Leemore Dafny on this and other projects using similar individual-level claims datasets.

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

XII.   USE OF AGENTS AND/OR CONTRACTORS

By signing this Application, the Organization assumes all responsibility for the use, security and maintenance of the CHIA Data by its agents, including but not limited to contractors. The Organization must have a written agreement with the agent of contractor limiting the use of CHIA Data to the use approved under this Application as well as the privacy and security standards set forth in the Data Use

Agreement. CHIA Data may not be shared with any third party without prior written consent from CHIA, or an amendment to this Application. CHIA may audit any entity with access to CHIA Data.

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

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

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

Click here to enter text.

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

Click here to enter text.

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

☐ Yes
☐ No

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

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

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

Click here to enter text.

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

Click here to enter text.

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

☐ Yes
☐ No

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

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

XIII.   ATTESTATION

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

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

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

Signature: (Authorized Signatory for Organization)	
Printed Name:	**Megan Moore**
Title:	(Harvard University, Office for Sponsored Programs) ASSOCIATE DIRECTOR, PRE-AWARD SERVICES
Date:	June 28, 2024

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)

<mark>APPLICATIONS WILL NOT BE REVIEWED UNTIL THEY ARE COMPLETE, INCLUDING ALL ATTACHMENTS.</mark>