CHIA.
center for health information and analysis

Non-Government Application for Re-Use of Massachusetts All-Payer Claims Data Extract [Exhibit A: Data Application]

I. INSTRUCTIONS

This form is required for all Applicants, except Government Agencies as defined in 957 CMR 5.02, who wish to re-use Data received pursuant to a previously approved Data Application ("Extract"). ***If the applicant requires data not presently held by its Organization the applicant should not use this form.*** ***Re-use of All-Payer Claims Database data is limited to data released in Limited Data Set format (i.e., Release Versions 4.0 and later).***

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. A copy of the Fee Remittance Form and any supporting documentation must be uploaded to IRBNet.***

II. ALL-PAYER CLAIMS DATABASE EXTRACT TO BE RE-USED	
Project Title:	Comparing Health Insurance Types and Understanding Churn: Evidence from Longitudinal Analysis and Natural Experiments
Extract Number:	
IRBNet Number:	1452226-1
Date of Data Use Agreement	4/1/2019

III. ORGANIZATION AND INVESTIGATOR INFORMATION	
Project Title:	Optimal Risk Adjustment with Moral Hazard
IRBNet Number:	2347894-1
Organization Name:	National Bureau of Economic Research (NBER)
Organization Website:	https://www.nber.org/
Authorized Signatory for Organization	**Alterra Milone**
Title:	Director, Research and Grants Management
E-mail Address:	alterra@nber.org
Address, City/Town, State, Zip Code	National Bureau of Economic Research 1050 Massachusetts Avenue Cambridge, MA 02138
Primary Investigator:	**James Okun**
Title:	PhD Candidate
E-mail Address:	jokun@mit.edu
Telephone Number:	561-558-6448
Names of Co-Investigators:	Amy Finkelstein, PhD and Mark Shepard, PhD
E-mail Address of Co-Investigators:	afink@mit.edu and shepard.mark@gmail.com

IV. FEE INFORMATION

1. Consult the Fee Schedule for All-Payer Claims Database data and select from the following options:

☒ Researcher
☐ Other
☐ Reseller

2. Are you requesting a fee waiver?

☒ Yes
☐ No

3. Compete and submit the Fee Remittance Form. If requesting a fee waiver, submit a letter stating the basis for your request (if required). Please refer to the Fee Schedule (effective Feb 1, 2017) for fee waiver criteria. (Please note that fee must be paid in order to re-use the Data, even if no new extract of data is required upon application approval.)

V. PROJECT INFORMATION

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

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

2. Provide a summary of the specific purpose and objectives of your Project. This may include research questions and/or business use Projects.

In private insurance markets, insurers may inefficiently distort contracts to attract low-cost enrollees and avoid high-cost enrollees in a practice called “cream-skimming.” In response, regulators use risk-adjustment policies to pay insurers a diagnosis-based subsidy for each enrollee with the intent of making insurers exactly indifferent between enrolling high-cost and low-cost enrollees, muting incentives to cream-skim. However, even with perfect risk adjustment, insurers can engage in “moral hazard” by up-coding the diagnoses of their patients to increase the risk-adjusted payments they receive from the regulator, increasing their profits. Furthermore, insurers may strategically design their plans to attract the most profitable patients, who, in this case, are those patients who are easily up-coded. This second incentive exacerbates the up-coding problem with standard risk-adjustment formulae. In this project, we will study optimal risk adjustment with moral hazard in the context of Medicare Advantage (MA) and MassHealth’s MCO/ACO program. First, we will investigate how much up-coding occurs in practice. Second, we will investigate whether insurers design their plans to attract patients who are easily up-coded. Lastly, we will build a

model to shed light on the optimal risk-adjustment regime which accounts for strategic responses to risk adjustment.

This project contributes to the health economics literature on the design of private marketplaces for insurance. It is well known that competition in insurance markets can result in cream-skimming, where insurers design contracts to attract low-cost types while dumping high-cost types on competitors. This dynamic prevents competitive markets form realizing the efficient insurance contract and can in some cases result in complete unraveling (Rothschild and Stiglitz 1976). However, theoretical work shows that a regulator can design a risk-adjustment policy to fully correct this distortion and realize the efficient insurance contract (Glazer and McGuire 2000). Specifically, this policy pays a diagnosis-based subsidy to insurers to make them exactly indifferent between high-cost and low-cost patients. With this policy in-hand, competitive insurance markets can work well. The early economics literature on risk adjustment ignores the possibility that risk adjustment is imperfect in the sense that it does not fully capture risk and that many of these policies are subject to moral hazard since insurers typically report data on conditions and own provider practices that do the coding. Recent empirical work shows that risk-adjustment formulae are not perfect and leave scope for cream-skimming (Brown et al. 2014) and that insurers engage in some amount of up-coding (Kronick and Chua 2021, Geruso and Layton 2024).

This project will build on this literature by characterizing optimal policy with imperfect risk adjustment and upcoding. While there exists a small body of empirical work on both topics separately, no paper has combined them to estimate the welfare effects of cream-skimming, up-coding, and their interaction. Therefore, more work is needed in this literature to characterize the optimal risk-adjustment policy with moral hazard. This exercise can deliver policy recommendations that improve the outcomes of risk-adjustment policies while saving taxpayer dollars. Furthermore, no paper has leveraged policy variation in Medicare's (or MassHealth's) risk-adjustment model which provides a rare natural experiment to investigate how coding intensity responds to risk adjustment. This policy variation improves and builds upon tests of up-coding in the literature (e.g., Kronick and Chua 2021, Geruso and Layton 2024) by providing qausi-random variation in risk adjustment. Our work will provide novel insights on the extent of up-coding and cream-skimming from this variation in risk adjustment.

We also contribute to a separate economics literature on designing policies when agents endogenously respond and manipulate or game the policy to their advantage. In healthcare, various papers show that private actors manipulate payment rules to increase their profits (Ho et al. 2014, Decarolis 2015, Geruso and Layton 2024). Outside of healthcare, gaming by private actors is found in many high-stakes decisions when profits are on the line (e.g., tax avoidance). Much theoretical attention in economics has been paid to the importance of strategic responses to policies (Mirrlees 1971, Akerlof 1978, Ramsey 1927, Agarwal and Budish 2021), and new work aims to provide actionable insights regulators can use to minimize gaming by private actors while delivering the intended benefits of policy (Björkegren et al. 2024). We will leverage statistical and theoretical insights by Björkegren et al. (2024) on manipulation-robust prediction to inform how a regulator might better design risk-adjustment policies when they are subject to moral hazard.

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.

VI. PUBLIC INTEREST

1. Briefly explain why completing your Project is in the public interest. *Uses that serve the public interest under CHIA regulation 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.*

Millions of Americans receive health insurance from private marketplaces that are regulated by the government. In these markets, private insurers have frequently been accused of avoiding sick patients to increase their profits. To manage this problem, marketplace regulators have implemented risk-adjustment policies with the goal of making insurers indifferent between enrolling low-cost and high-cost patients. However, these policies are subject to moral hazard on the part of insurers: insurers can "up-code" patients to increase risk-adjusted payments from the government, and they can strategically select for patients who are cheap for their observable risk score or who are easy to up-code, increasing their profits. Our project will document the extent to which insurers up-code their patients and engage in strategic risk-selection in response to risk adjustment. This will inform key policy questions about how to appropriately design risk-adjustment policies when insurers can strategically respond to risk-adjustment formulae. Shedding light on this optimal design has the potential to mitigate perverse risk selection, increase health insurance coverage for sick patients, and save taxpayer dollars by minimizing up-coding. Existing policy proposals hypothesize that eliminating overpayments under Medicare Advantage's status quo risk-adjustment regime could save the federal government $400 billion over the next decade, yet no research to date explores the optimal design of risk-adjustment policies with moral hazard and the effects of alternative policy designs on patient welfare and government spending. Our work will fill this gap in the literature and offer insights on feasible changes to the design of risk-adjustment policies to save all of this excess spending and put it back in the pockets of taxpayers while accomplishing the goals of risk adjustment. Furthermore, as more state Medicaid programs use risk-adjustment policies, our research will help state Medicaid programs, like MassHealth, improve the design of their risk-adjustment models.

VII. DATASETS REQUESTED

The Recipient will use Data included in the Extract referenced above for use in this Project; no new Data will be released under this Application.

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

☒ **Medical Claims**

☐2011 ☐2012 ☒2013 ☒2014 ☒2015 ☒2016 ☒2017 ☒2018 ☒2019 ☒2020

Describer how your research objectives require Medical Claims data:

We will use Medical Claims data to identify diagnosis codes that are used in Medicare Advantage's HCC risk-adjustment model and MassHealth's DxCG risk-adjustment model. These data will allow us to test for up-coding and selection of patients into plans.

☒ **Pharmacy Claims** ☐2011 ☐2012 ☒2013 ☒2014 ☒2015 ☒2016 ☒2017 ☒2018 ☒2019 ☒2020
Describer how your research objectives require Pharmacy Claims data: We will use Pharmacy Claims as an alternative measure of patient costs and utilization which are not affected by insurer up-coding.
☒ **Dental Claims** ☐2011 ☐2012 ☒2013 ☒2014 ☒2015 ☒2016 ☒2017 ☒2018 ☒2019 ☒2020
Describer how your research objectives require Dental Claims data: We will use Dental Claims data to identify diagnosis codes that are relevant for risk-adjustment and to measure patient costs to understand how patients choose plans on the basis of cost and how insurers might include dental benefits to cream-skim.
☒ **Member Eligibility** ☐2011 ☐2012 ☒2013 ☒2014 ☒2015 ☒2016 ☒2017 ☒2018 ☒2019 ☒2020
Describer how your research objectives require Member Eligibility data: We will use Member Eligibility data to estimate demand for plans as a function of income, disability, other eligibility criteria, and other consumer characteristics which are relevant for demand.
☒ **Provider** ☐2011 ☐2012 ☒2013 ☒2014 ☒2015 ☒2016 ☒2017 ☒2018 ☒2019 ☒2020
Describer how your research objectives require Provider data: The Provider data will be used to characterize the costs and utilization of various enrollees, including the quantity, quality, and type of providers seen by enrollees in different plans. This is critical for measuring selection of patients into plans based on profitability.
☒ **Product** ☐2011 ☐2012 ☒2013 ☒2014 ☒2015 ☒2016 ☒2017 ☒2018 ☒2019 ☒2020
Describer how your research objectives require Product data: We will use the Product data to classify plans by their characteristics, including their cost-sharing schedules. These characteristics are critical for measuring how plan design responds to risk-adjustment. Furthermore, these data are critical for measuring which plan characteristics different patients respond to. We will also use the product data to match plans with publicly available data from CMS on Medicare Advantage plan characteristics and average risk-adjustment payments.

2. If there are datasets that are included in the Extract that ***are not*** required for this Project indicate below.

☐ Medical Claims ☐ Pharmacy Claims ☐ Dental Claims ☐ Member Eligibility
☐ Provider ☐ Product

3. If there are datasets included in the Extract that are not required for this Project, describe below how those datasets will be segregated and protected from use in this Project.

VIII. DATA ELEMENTS REQUESTED

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

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

1. Specify below which elements you are requesting in addition to the "Core" LDS and provide your justification for requesting each element.

Geographic Data

The geographic sub-divisions listed below are available for Massachusetts residents and providers only. Choose *one* of the following geographic options. [*Extracts with 5 digit zip code, have been filter to remove all claims that include a substance abuse diagnosis or treatment.]*

☐ 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: Travel distance is an important factor in patient utilization. We are interested in patient demand for plans and utilization conditional on plan, and therefore geographic location is an important factor in modeling a patient's choice of plan and provider. We will need 5-digit zip codes to accurately model patient choice on these dimensions.	

Dates

Choose *one* option from the following options for dates:

☐ 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: We need day-level data to follow enrollees over time. This is important for measuring the effect of changes to risk-adjustment models on diagnoses and utilization which is how we plan to measure up-coding. To do this we need to know the exact dates of diagnoses and utilization and match them with the exact dates of announced and implemented model changes. Furthermore, we also plan to measure how utilization and diagnoses respond when enrollees switch between insurers that are subject to different risk-adjustment policies, therefore we also need the exact dates of service to understand how utilization and diagnoses respond to plan switching. We also plan to use various metrics that depend on the precise timing of utilization (e.g., 30-day re-admission dates) to measure quality of care and other dimensions of care that patients might have preferences over and that plans might use in their design decisions to cream-skim. These reasons necessitate day-level data.		

National Provider Identifier (NPI)

Choose *one* of the following options for National Provider Identifier(s):

☐ 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: To accurately characterize the characteristics of different Medicare Advantage plans, we would like to measure the	

characteristics of plan networks. Merging in other data on physicians is relevant for this. To do this we want access to decrypted NPIs to merge on data from the National Plan and Provider Enumeration System (NPPES) NPI registry and the American Hospital Association (AHA) Annual Survey Database.

2. If there are data elements that are included in the Extract that ***are not*** required for this Project indicate below.

☐ 5-Digit Zip Code ☐ Month (YYYYMM) ☐ Day (YYYYMMDD) ☐ Decrypted National Provider Identifier(s)

3. If there are data elements included in the Extract that are not required for this Project, describe below how the data elements will be segregated and protected from use in this Project.

IX. MEDICAID DATA

1. Is Medicaid Data included in the Extract?

☒ Yes
☐ No

2. Indicate whether you are seeking to use Medicaid Data for this Project:

☒ Yes
☐ No

3. 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 Medicaid Data, please describe, in the space below, why your use of the data meets this requirement. Requests for Medicaid 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 Medicaid program. This may introduce significant delays in the receipt of Medicaid Data. ***Recipient may not use the Medicaid data for the new Project until Recipient is notified of MassHealth approval.***

Our project relates to the administration of the Medicaid program because MassHealth and other Medicaid programs use risk-adjustment policies to make capitated payments to MCOs/ACOs. Our research will offer actionable policy insights on how these payments should be designed to account for up-coding and strategic risk-selection by insurers. This project will influence the use of capitated risk-adjusted payments to MCOs/ACOs. MassHealth's objectives will be helped by this project because we will offer insights on the efficacy of MassHealth's status quo risk-adjustment policy and whether there exist feasible changes to its design that can achieve the same (or better) outcomes at lower (or equal) cost to the program. This research has the potential to reduce the cost of the Medicaid program. It also has the potential to improve access to recipients to the extent that MCOs/ACOs engage in cream-skimming. We will write a paper as a result of this research. We will also give presentations to describe our findings. We are happy to share the presentations and paper with MassHealth. We would also be happy to provide an internal presentation to MassHealth on how the results of our research might be integrated into the program to reduce costs and improve patient access.

MassHealth can use these project deliverables to inform how it designs its risk-adjustment policy. We will provide insights on which kinds of conditions are up-coded and ways in which the MassHealth program could design its policy to account for and reduce up-coding, reducing program costs.

4. If the Extract contains Medicaid Data and you are not seeking to use Medicaid Data for this Project, or this Application is not approved by MassHealth, describe below how Medicaid Data will be segregated and protected from use in this Project.

X. DATA LINKAGE AND FURTHER DATA ABSTRACTION

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.

1. Provider level data: Using decrypted NPIs we will link providers with the National Plan and Provider Enumeration System (NPPES) NPI registry. This is necessary to characterize enrollee utilization under different plans.
2. Facility level data: We will link hospitals to the American Hospital Association Annual Survey Database for hospital characteristics. This is needed to better characterize the networks of plans which is important for

estimating patient demand. The variable used for linkage will be the National Provider Identifier (NPI). For observations where the NPI is incomplete or invalid we will use the Entity Name to match hospitals.

3. Aggregate data: We will merge in publicly available demographic and income data from the ACS and Census to allow consumer preferences for plans to vary by observable characteristics.
4. Other: We will link Medicare Advantage plans with publicly available data on plans from CMS. Specifically, we will use data on plan benefits (https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-advantagepart-d-contract-and-enrollment-data/benefits-data) and average risk-adjustment payments made by CMS to plans (https://www.cms.gov/medicare/health-drug-plans/plan-payment-data). This kind of merge using plan names has been successfully done by other researchers who have used the MA APCD (see e.g., Prager 2020 and Geruso and Layton 2024).

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.

1. Merge based on NPI
2. Merge based on NPI and/or entity name
3. Merge based on zip code and/or county
4. Merge based on plan names

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

We will not merge anything at the patient level so our use of other data will not compromise the identity of individual patients. We will take the utmost care to protect the identities of the individual patients in these data.

XI. PUBLICATION / DISSEMINATION / RE-RELEASE

1. Describe your plans to publish or otherwise disclose CHIA Data, or any data derived or extracted from CHIA Data, in any paper, report, website, statistical tabulation, seminar, conference, or other setting. Any and all publication of CHIA Data must comply with CHIA's cell size suppression policy, as set forth in the Data Use Agreement. Please explain how you will ensure that any publications will not disclose a cell less than 11, and percentages or other mathematical formulas that will result in the display of a cell less than 11.

We will not disclose any CHIA data. We only seek to share our work which includes aggregated statistics from the data via peer-reviewed economics journals, working papers, and conferences. All statistics shared in our publications and presentations will be based on at least 11 observations. To do this we will aggregate all statistics to groups that have more than 11 patients. We will have checks in the code that ensure that all statistics follow this rule.

2. Do you anticipate that the results of your analysis will be published and/or made publically available? If yes, describe how an interested party will obtain your analysis and, if applicable, the amount of the fee, that the third party must pay.

We plan to share our work via peer-reviewed economics journals, working papers, and conferences. The results presented in our work will include summary statistics and analyses completed using the data, but we will aggregate all statistics to groups that have more than 11 patients so it will not be possible to identify any patients from our published work. We will not sell our analysis to third parties. Our results will only be available in economics journals, working papers, and conference presentations. Interested parties will be able to view aggregated statistics and details of our analysis (e.g., the statistical methods we use), but won't have access to any data.

3. Will you use CHIA Data for consulting purposes?

☐ Yes
☒ No

4. Will you be selling standard report products using CHIA Data?

☐ Yes
☒ No

5. Will you be selling a software product using CHIA Data?

☐ Yes
☒ No

6. Will you be reselling CHIA Data in any format?

☐ Yes
☒ No

If yes, in what format will you be reselling CHIA Data (e.g., as a standalone product, incorporated with a software product, by a subscription, etc.)?

7. If you have answered "yes" to questions 4, 5 or 6, please describe the types of products, services or studies.

8. If you have answered "yes" to questions 4, 5, or 6, what is the fee you will charge for such products, services or studies?

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.

James Okun is a PhD candidate in economics at the Massachusetts Institute of Technology. He holds a B.S. in Applied Mathematics-Economics and a B.A. in Computer Science from Brown University. He has extensive experience using claims data and other identifiable health care data from CMS under the supervision of his advisor, Amy Finkelstein. In particular, James used claims data from CMS to study nursing home quality for one of Amy's projects (see Producing Health: Measuring Value Added of Nursing Homes Forthcoming, Econometrica). In ongoing work, James is also using claims data with Amy to study racial disparities in nursing home quality. Amy will supervise James's progress as he works with data from CHIA.

Amy Finkelstein is the John & Jennie S. MacDonald Professor of Economics at the Massachusetts Institute of Technology. She received her PhD in Economics from MIT in 2001, an M.Phil in Economics from Oxford in 1997 where she studied as a Marshall Scholar, and an A.B. in Government summa cum laude from Harvard in 1995. Amy has extensive experience working with identifiable health care data, including claims data. In work with Mark Shepard and Nathan Hendren, Amy used claims data from CommCare to estimate the value of Medicaid (see Subsidizing Health Insurance for Low Income Adults: Evidence from Massachusetts American Economic Review, April 2019 109(4): 1530-67). In other papers, Amy has used claims data from Medicare. Some recent examples include studying a payment reform for hip and knee replacement (see Voluntary Regulation: Evidence from Medicare Payment Reform Quarterly Journal of Economics, 2022 137(1): 565-618) and estimating the effect of place in explaining geographic variation in mortality (see Place-Based Drivers of Mortality: Evidence from Migration American Economic Review, 2021 111(8): 2697-2735).

Mark Shepard is an associate professor at Harvard Kennedy School of Government and a faculty research fellow at the National Bureau of Economic Research (NBER). He holds a Ph.D. in Economics from Harvard University and a B.A. in Applied Math from Harvard University. His research studies health care markets, with topics at the intersection of health, industrial organization, and public economics. Much of his work focuses on competition and policy design in health insurance markets, particularly in public programs like the Massachusetts/ACA health insurance exchanges and Medicaid managed care. Mark has experience analyzing claims data for several projects including: work with claims data from the Commonwealth Care program (from 2006-2013) MCOs for his dissertation research, used via a DUA with the Massachusetts Health Connector. Mark also has a DUA with CHIA that we seek to re-use in this project.

2. **Resumes/CVs**: If not submitted with a prior approved Application, 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

Please note: 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.

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.

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 and a Data Management Plan for this agent or contractor is not part of the Data Use Agreement, 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 Applicant's location, off-site server and/or database?

☐ Yes
☐ No

4. If yes and a Data Management Plan for this agent or contractor is not part of the Data Use Agreement, a separate Data Management Plan **must** be completed by the agent or contractor.

XIV. 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 its agents.

The Organization's use of the Data for this Project will be governed by the executed Data Management Plan(s), Data Use Agreement, and any Amendment thereto.

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)	
Printed Name :	

Attachments

A completed Application must have the following documents attached to the Application:

☐ 1. IRB approval letter and protocol (if applicable)
☐ 2. Research Methodology (if protocol is not attached)
☐ 3. CVs of Investigators (if not submitted previously)
☐ 5. Data Use Agreement

Applications will not be reviewed until they are complete, including all attachments. Applicant may not use the Extract for this Project until CHIA approval and the execution of an amendment to the Recipient's Data Use Agreement.

TRACKING TABLE (to be completed by CHIA staff only)	
Complete Application Received	
Application Fee Received	
Data Privacy Committee Review	
Data Release Committee Review	
Linkages Approved (as described)	
Executive Director Approval	
Data Fee Received	
Data of First Audit	
IT Extract #	

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

Attachment #2 – Data Management Plan(s)