

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

I. INSTRUCTIONS

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

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

- [Data Availability](#)
- [Fee Schedule](#)
- [Data Request Process](#)

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

The Application and all attachments must be uploaded to IRBNet. All Application documents can be found on the [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@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:	Quantifying the burden of epilepsy using novel data sources
IRBNet Number:	STUDY00002464
Organization Requesting Data (Recipient):	Emory University (Department of Health Policy and Management, Rollins School of Public Health)
Organization Website:	https://www.emory.edu/home/index.html https://www.sph.emory.edu/
Authorized Signatory for Organization:	Rajsekhar Guddneppanavar, PhD
Title:	Assistant Director, Licensing
E-Mail Address:	ottmta@emory.edu
Telephone Number:	404-727-2211
Address, City/Town, State, Zip Code:	Emory University Office of Technology Transfer 1599 Clifton Road NE, 4 th Floor Atlanta, GA 30322
Data Custodian: (individual responsible for organizing, storing, and archiving Data)	David Howard
Title:	Professor
E-Mail Address:	david.howard@emory.edu
Telephone Number:	404-727-3907
Address, City/Town, State, Zip Code:	Department of Health Policy and Management 1518 Clifton Road NE Atlanta, GA 30322
Primary Investigator (Applicant): (individual responsible for the research team using the Data)	David Howard
Title:	Professor
E-Mail Address:	david.howard@emory.edu
Telephone Number:	404-727-3907
Address, City/Town, State, Zip Code:	Department of Health Policy and Management 1518 Clifton Road NE Atlanta, GA 30322
Names of Co-Investigators:	Lidia Moura, Ioannis Karakis, Kenneth E. Thorpe, Nada Boualam
E-Mail Addresses of Co-Investigators:	lidia.moura@mgh.harvard.edu, ioannis.karakis@emory.edu, kthorpe@emory.edu, nada.boualam@emory.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 written request to CHIA, with approval being subject to CHIA's regulatory restrictions and approval process. Unauthorized use is a material violation of your institution's Data Use Agreement with CHIA.

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

- | | | |
|---|--|---|
| <input checked="" type="checkbox"/> Epidemiological | <input type="checkbox"/> Health planning/resource allocation | <input checked="" type="checkbox"/> Cost trends |
| <input type="checkbox"/> Longitudinal Research | <input type="checkbox"/> Quality of care assessment | <input type="checkbox"/> Rate setting |
| <input type="checkbox"/> Reference tool | <input checked="" type="checkbox"/> Research studies | <input type="checkbox"/> Severity index tool (or other derived input) |
| <input type="checkbox"/> Surveillance | <input checked="" type="checkbox"/> Student research | <input type="checkbox"/> Utilization review of resources |
| <input type="checkbox"/> Inclusion in a product | <input type="checkbox"/> 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.

Epidemiological data suggests that 10% of Americans will suffer a seizure at some point in their lifetime (i.e., more than 33 million people). Epilepsy, a condition generally characterized by recurrent, unpredictable, spontaneous seizures, is the fourth most common neurological condition in the US (Zack & Kobau, 2017). Nearly 3 million adults in the US currently live with active epilepsy, a heterogeneous group of chronic disorders with multiple etiologies (e.g., generic, acquired), each presenting with a variety of seizure types (e.g., focal vs generalized onset), and subcategorizations (e.g., motor, impaired awareness) (Scheffer et al., 2017). The advent of newer generation antiepileptic medications such as ezogabine, clobazam, perampanel, eslicarbazepine, brivaracetam, and cannabidiol (Rudzinski et al., 2016) has expanded treatment options. The shift away from older generation anticonvulsants to newer, better-tolerated drugs and their more economical generic formulations has substantially modified patients' access and adherence to treatment.

The overarching goal of our project is to estimate the costs incurred and treatments received by patients with epilepsy and/or seizure. (We include seizure because epilepsy is underdiagnosed, and patients with epilepsy may only have "seizure" recoded on claims for emergency department or hospital encounters.) We will describe differences in annual health care costs between persons with epilepsy and matched controls (Massachusetts residents without claims for epilepsy). We will describe differences in cost by patient subgroup (based on patient age, sex, race, and insurance type). We will describe trends in average costs over time and the patterns of receipt of antiepileptic medications. We will also compare use of various antiseizure medications by physician characteristics (for example, age, specialty) and study whether physicians change antiseizure medications after patients visit the emergency department for epilepsy/seizure. We will develop manuscripts for publication in peer-reviewed journals.

References

- Rudzinski, L. A., Vélez-Ruiz, N. J., Gedzelman, E. R., Mauricio, E. A., Shih, J. J., & Karakis, I. (2016). New antiepileptic drugs: focus on ezogabine, clobazam, and perampanel. *Journal of Investigative Medicine*, 64(6), 1087-1101.
- Scheffer, I. E., Berkovic, S., Capovilla, G., Connolly, M. B., French, J., Guilhoto, L., . . . Moshé, S. L. (2017). ILAE classification of the epilepsies: position paper of the ILAE Commission for Classification and Terminology. *Epilepsia*, 58(4), 512-521.
- Zack, M. M., & Kobau, R. (2017). National and state estimates of the numbers of adults and children with active epilepsy—United States, 2015. *MMWR. Morbidity and mortality weekly report*, 66(31), 821.

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.*

Estimates of the health care costs incurred by individuals with epilepsy are useful for prioritizing resources for the treatment and prevention of epilepsy and seizure. Estimates of hospital and emergency-department spending are useful for identifying opportunities to improve the diagnosis and outpatient management of epilepsy to prevent acute exacerbations. Descriptions of treatment patterns can identify opportunities to improve quality and reduce costs by increasing access to antiseizure medications and switching patients to less costly drugs.

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 insured and self-insured plans. APCD data are refreshed and updated annually and made available to approved data users in Release Versions that contain five calendar years of data and three months of run-out. For more information about APCD Release Versions, including available years of data and a full list of elements in the release please refer to release layouts, data dictionaries and similar documentation included on [CHIA's website](#).

Data requests are typically fulfilled on a one time basis, however; certain Projects may require future years of data that will become available in a subsequent release. Projects that anticipate a need for future years of data may request to be considered for a subscription. Approved subscriptions will receive, upon request, the same 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. Select Release Version and years of data requested (Release Versions and years not listed are not available).

- | | |
|--|--|
| <input type="checkbox"/> Release Version 8.0 | <input checked="" type="checkbox"/> Release Version 10.0 |
| <input checked="" type="checkbox"/> 2014 | <input checked="" type="checkbox"/> 2016 |
| <input checked="" type="checkbox"/> 2015 | <input checked="" type="checkbox"/> 2017 |
| <input type="checkbox"/> 2016 | <input checked="" type="checkbox"/> 2018 |
| <input type="checkbox"/> 2017 | <input checked="" type="checkbox"/> 2019 |
| <input type="checkbox"/> 2018 | <input checked="" type="checkbox"/> 2020 |

3. Specify below the data files requested for this Project, and provide your justification for requesting *each* file.

<input checked="" type="checkbox"/> Medical Claims
Describe how your research objectives require Medical Claims data: We will estimate costs and patterns of care (e.g., office visits, emergency department visits, hospitalizations) for patients with epilepsy.
<input checked="" type="checkbox"/> Pharmacy Claims
Describe how your research objectives require Pharmacy Claims data: We will estimate health care costs incurred from drugs received by patients with epilepsy and describe the diffusion of newer anti-seizure drugs and how use of anti-seizure medications varies between physicians and insurance plans.
<input type="checkbox"/> Dental Claims
Describe how your research objectives require Dental Claims data: Click here to enter text.
<input checked="" type="checkbox"/> Member Eligibility
Describe how your research objectives require Member Eligibility data: We want to identify the dates over which enrollees were eligible for purposes of identifying the sample. We also want to be able to identify non-epilepsy control enrollees who did not use any services during the year (and who would thus not show up in claims).
<input checked="" type="checkbox"/> Provider
Describe how your research objectives require Provider data: We will determine how provider characteristics (age, specialty, practice location) influence the treatments patients receive and whether they visit the emergency department.
<input checked="" type="checkbox"/> Product
Describe how your research objectives require Product data: Insurance type and payment type data. We will study the relationships between insurance types and costs and drugs received.

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

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

<input type="checkbox"/> 3-Digit Zip Codes (standard)	<input checked="" type="checkbox"/> 5-Digit Zip Codes***
***If requested, provide justification for requesting 5-Digit Zip Code. Refer to specifics in your methodology: We will use 5 digit zip codes to measure individuals’ area-level socioeconomic status by linking zip code to Census data measuring educational attainment and the proportion of residents in households below the poverty level.	

b. Date Resolution

Select one option from the following options.

<input type="checkbox"/> Year (YYYY) (Standard)	<input type="checkbox"/> Month (YYYYMM) ***	<input checked="" type="checkbox"/> Day (YYYYMMDD) *** https://www.chiamass.gov/ma-apcd/
*** If requested, provide justification for requesting Month or Day. Refer to specifics in your methodology: As part of the algorithm for identifying patients with epilepsy, we will be checking for two separate claims with an epilepsy or seizure diagnosis that are at least 30 days apart, which requires exact dates. Furthermore, we will use dates of service (day and month) to measure treatment patterns for patients with epilepsy/seizure who change treatment regimens during the course of the year and whether emergency department visits and inpatient admissions for seizure lead to medication changes.		

c. National Provider Identifier (NPI)

Select one of the following options.

<input checked="" type="checkbox"/> Encrypted National Provider Identifiers (standard)	<input type="checkbox"/> Decrypted National Provider Identifiers***
*** If requested, provide justification for requesting decrypted National Provider Identifier(s). Refer to specifics in your methodology: We can obtain the information we need about physicians from the Provider File.	

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.

For Medicaid recipients, estimates of the burden and cost of epilepsy are useful for prioritizing resources for the treatment and prevention of epilepsy and seizure. Estimates of hospital and emergency-department spending are useful for calling attention to opportunities to improve the diagnosis and outpatient management of epilepsy to prevent acute exacerbations. Descriptions of treatment patterns can identify opportunities to improve quality and reduce costs by increasing access to antiseizure medications and switching patients to less costly drugs.

3. Organizations approved to receive Medicaid Data will be required to execute a [Medicaid Acknowledgment 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)
 Individual Provider Level Data (e.g., American Medical Association Physician Masterfile)
 Individual Facility Level Data (e.g., American Hospital Association data)
 Aggregate Data (e.g., Census data)
 Other (please describe):

3. If yes, describe the dataset(s) to which the CHIA Data will be linked, indicate which CHIA Data elements will be linked and the purpose for each linkage.

We will link patients to Census data (American Community Survey) by 5-digit zip code to identify patients' area-level socioeconomic status (median income, % completing college).

4. If yes, for each proposed linkage above, please describe your method or selected algorithm (e.g., deterministic or probabilistic) for linking each dataset. If you intend to develop a unique algorithm, please describe how it will link each dataset.

We will use deterministic matching on exact zip code. We will drop individuals for which we cannot match census data on zip code from analyses where we make use of zip code-level socioeconomic status.

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.

The final data set will be a member-year-plan level data set. The majority of the elements will come from the CHIA data, including member identification number, year, subscriber zip code, member gender, member age, coverage type, coverage length, indicators for whether the member meets our definitions of an incident or prevalent case of epilepsy, and a series of cost and utilization indicators derived from the medical and pharmacy claims files.

In addition, the following variables from the American Community Survey will be merged into the analytic file based on zip code:

Zip code-level education (i.e., percent of residents who attended college).

Zip code-level poverty level (i.e., percent of households with incomes below the federal poverty level).

Zip code-level median income

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

The linked data will be at the zip-code level and therefore will not change the risk of identification of individual patients.

X. PUBLICATION / DISSEMINATION / RE-RELEASE

1. Do you anticipate that the results of your analysis will be published or made publically available? If so, how do you intend to disseminate the results of the study (e.g.; publication in professional journal, poster presentation, newsletter, web page, seminar, conference, statistical tabulation)? Any and all publication of CHIA Data must comply with CHIA's cell size suppression policy, as set forth in the Data Use Agreement. Please explain how you will ensure that any publications ***will not disclose a cell less than 11***, and percentages or other mathematical formulas that result in the display of a cell less than 11.

We will produce manuscripts for peer-reviewed medical journals. We will disclose aggregate results, making sure to suppress results with a cell size smaller than 11 patients or percentages based on cell sizes smaller than 11. We will not release the raw data.

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.

None

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?

We will not present data for specific geographic areas (other than the entire state). We will describe differences in use of services by characteristics of geographic areas (for example, the proportion of people with epilepsy who have emergency department visits in areas with median incomes above or below \$50,000). We will categorize geographic areas to ensure that cell sizes always include at least 11 individuals.

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 tool, 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.

David Howard is a Professor in Emory University’s Department of Health Policy and Management. He has over 20 years' experience using Medicare and private claims to analyze treatment patterns and costs of care. For example, Dr. Howard recently used Medicare claims to assess costs and treatment patterns for patients with metastatic castration-resistant prostate cancer (Howard et al., Cancer, 2021). He identified episodes of care beginning with the initiation of a drug indicated for metastatic castration-resistant prostate cancer and ending with death or the end of the study period. He measured lifetime costs and life expectancy over the episode, comparing trends over time to assess the cost-effectiveness of recently-approved drugs.

Nada Boulam and Martha Wetzel are both doctoral students in Emory’s Department of Health Policy and Management. They will use the MA APCD under Dr. Howard’s supervision. Both are currently analyzing APCD data from Virginia and Colorado. Ms. Wetzel was previously a biostatistician in Emory’s Department of Pediatrics, where she analyzed claims and administrative data for peer-reviewed publications.

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)	Drag signature image here or delete and physically sign
Printed Name:	Rajsekhar Guddneppanavar, PhD
Title:	Assistant Director, Licensing
Date:	Click here to enter text.

Attachments:

A completed Application must have the following documents attached to the Application or uploaded separately to IRBNet:

- 1. IRB approval letter and protocol (if applicable), or research methodology (if protocol is not attached)
- 2. Data Management Plan (including one for each agent or contractor that will have access to or store the CHIA Data at a location other than the Organization's location, off-site server and/or database);
- 3. CVs of Investigators (upload to IRBNet)

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