center for health information and analysis

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@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:	Impact of physician innovation on clinical care
IRBNet Number:	2202875-1
Organization Requesting Data (Recipient):	Boston Children's Hospital
Organization Website:	**https://www.childrenshospital.org/**
Authorized Signatory for Organization:	**August P. Cervini, MBA**
Title:	Sr. Vice President of Research Administration Research Integrity Officer IACUC & IRB Institutional Official
E-Mail Address:	August.Cervini@childrens.harvard.edu
Telephone Number:	617-919-2272
Address, City/Town, State, Zip Code:	300 Longwood Avenue, Boston, MA 02115
Data Custodian: **(individual responsible for organizing, storing, and archiving Data)**	Wesley Greenblatt, MD, PhD
Title:	Staff physician, Boston Children's Hospital Instructor, Harvard Medical School
E-Mail Address:	Wesley.Greenblatt@childrens.harvard.edu
Telephone Number:	617-355-6000
Address, City/Town, State, Zip Code:	300 Longwood Ave, Boston, MA 02115
Primary Investigator (Applicant): **(individual responsible for the research team using the Data)**	Wesley Greenblatt, MD, PhD
Title:	Staff physician, Boston Children's Hospital Instructor, Harvard Medical School
E-Mail Address:	Wesley.Greenblatt@childrens.harvard.edu
Telephone Number:	617-355-6000
Address, City/Town, State, Zip Code:	300 Longwood Ave, Boston, MA 02115
Names of Co-Investigators:	N/A
E-Mail Addresses of Co-Investigators:	Click here to enter text.

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)	

N/A

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.

Practicing physicians are an important source of biomedical innovations, including publications, medical devices, new drugs and startups addressing unmet patient needs. While many individuals participate in biomedical research and development, physician involvement may be especially important as, due to their clinical experience, they may be more likely to develop unique or high-quality innovations.

For instance, many prominent anecdotes have emphasized the value of "bedside-to-bench" and "bench-to-bedside" research, such as a clinical encounter with patients with familial hypercholesterolemia inspiring the initial investigations which ultimately lead to the development of statins (Goldstein and Brown 1997, Rosenberg 1999). More systematically, startups founded by "user innovators" (i.e., those motivated by solving their own needs or use cases, such as a cardiologist developing a new catheter) are more likely to receive venture funding and generate high revenues (Kauffman Foundation 2012). In line with this, when orthopedists were precluded from working with medical device companies, affected firms had a decrease in their rate of innovation and a shift away from inventions in which physician knowledge is crucial (Chatterji and Fabrizio 2016). Indeed, it has been a long-standing policy goal of the medical elite to steer a larger number of physicians towards research careers (Wyngaarden 1979).

Despite how common such efforts are (Azoulay et al. 2007, Greenblatt 2021), little is systematically known about the impact of innovation activities on the quality of clinical care delivered. Does physician innovative efforts adversely effect the quality of care a physician provides, or alternatively, do they complement clinical activity? What strategies can individual physicians and healthcare delivery organizations employ to avoid or mitigate any potential tradeoffs between research and clinical care?

The most relevant prior literature has examined physician volume and clinical outcomes, generally finding across a range of practice settings that lower volume physicians have worse clinical outcomes (Birkmeyer et al 2003, Hillner et al. 2000, Joynt et al. 2013). This suggests physicians who spend substantial time on research activities with consequently low clinical volume may have worse patient outcomes, but this may be potentially mitigated by specialization and narrowing the scope of practice.

The overall aim of this project is to understand the relationship between a physician spending time on innovation and the quality of the clinical care they provide. The specific aims are as follows:
Aim 1: Descriptively characterize the clinical and research activity of physician-innovators in Massachusetts
Aim 2: Identify if physician involvement in innovation activities is correlated with clinical quality metrics
Aim 3: Explore how this relationship might vary across different practice settings, specialties, and degrees of overlap between research and clinical activities

The primary goal of this research is to produce a peer-reviewed academic journal publication.

References

Azoulay P, Michigan R, Sampat BN. (2007). "The Anatomy of Medical School Patenting." New England Journal of Medicine 357(20):2049.

Birkmeyer JR, Stukel TA, Siewers AE, Goodney PP, Wennberg DE, Lucas FL. (2003). "Surgeon Volume and Operative Mortality in the United States." New England Journal of Medicine 349:2117-2127.

Chatterji AK, Fabrizio KR. (2016). "Does the market for ideas influence the rate and direction of innovative activity? Evidence from the medical device industry." Strategic Management Journal 37(3):447-465.

Kauffman Foundation. (2012). "The Kauffman Firm Survey: Who are user Entrepreneurs? Findings on Innovation, Founder Characteristics, and Firm Characteristics." Ewing Marrion Kauffman Foundation, Kansas City.

Goldstein JL, Brown MS. (1997). "The clinical investigator: Bewitched, bothered and bewildered—But still beloved." Journal of Clinical Investigation 99(12):2803-2812.

Greenblatt WH. (2021). "Proportion, Type and Characteristics of Physician Entrepreneurship in Massachusetts." JAMA Network Open 4(1):e2026938.

Hillner BE, Smith TJ, Desch CE. (2000). "Hospital and physician volume or specialization and outcomes in cancer treatment: Importance of quality of cancer care." Journal of Clinical Oncology 18(11):2327-2340.

Joynt KE, Orav EJ, Jha AK. (2013). "Physician volume, specialty, and outcomes of care for patients with heart failure." Circulation 6(5):890-897.

Rosenberg LE. (1999). "The physician-scientist: An essential—and fragile—link in the medical research chain." Journal of Clinical Investigation 103(12):1621-1626.

Wyngaarden JB. (1979). "The clinical investigator as an endangered species." New England Journal of Medicine 301(23):1254-1259.

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.

The IRB protocol is included in the application package.

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.*

A significant fraction of healthcare is delivered by academic medical centers and physicians actively engaging in innovation. While these efforts expand the biomedical scientific frontier and lead to new and improved therapeutics and care pathways, little is known about the impact of innovation activities on the quality of care provided by the physicians themselves taking part in innovation, and the extent to which these activities are complements or substitutes. This work has implications for how medical care is organized and delivered and what organizational and individual strategies might be employed to mitigate any potential adverse impact of innovation activities on the quality of care delivered by physician researchers.

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 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. 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: _____.
   2017-2022
3. Specify below the data files requested for this Project, and provide your justification for requesting *each* file.

☒ **Medical Claims**
Describe how your research objectives require Medical Claims data: Medical claims are crucial in identifying measures of clinical activity, such as clinical volume and breadth of practice, as well as measures of the quality of care such as readmission rates.
☐ **Pharmacy Claims**
Describe how your research objectives require Pharmacy Claims data: N/A
☐ **Dental Claims**
Describe how your research objectives require Dental Claims data: N/A
☐ **Member Eligibility**
Describe how your research objectives require Member Eligibility data: N/A
☒ **Provider**
Describe how your research objectives require Provider data:

The central aspect of this study requires linking physician providers to their innovative activities in the form of publications, grants and patents. Doing so requires having access to deidentified providers. Provider specialty and practice location will provide important controls facilitating comparison of clinical activity and innovation across different physicians.
☐ **Product**
Describe how your research objectives require Product data: N/A

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: Click here to enter text.	

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:		

Some measures of clinical quality of care, such as perioperative complications, readmission rate, and length of stay, require being able ot measure the number of days between two clinical events.

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:**
The central aspect of this study requires linking physician providers to their innovative activities in the form of publications, grants and patents. Doing so requires having access to decrypted national provider identifiers so this linkage can be made.

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.

N/A

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)
- ☒ 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 linked to three data sets: publication data from PubMed, grant data from the National Institutes of Health, and patent data from the US Patent and Trademark Office. The only element from CHIA data that will be linked is individual provider npi. Together, these datasets will allow characterization of a provider's innovative activity in the form of publications, grants and patents.

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.

A similar process will be used to deterministically link healthcare providers in CHIA data to publications in PubMed, grant data from the National Institutes of Health, and patent data from the US Patent and Trademark Office. In each case, linkage will rely on matching both provider name, which is present in each data set, as well as academic affiliation (location of clinical work, author affiliation, grant academic affiliation, and patent assignee for CHIA, PubMed, National Institutes of Health, US Patent and Trademark Office and data, respectively). This will rely on previous work by the principal investigator and prior scholars to disambiguate each of the non-CHIA datasets.

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.

Publication count, citations, publication research breadth, patents, patent citations, patent breadth, grant funding, clinical volume, clinical breadth, research-clinical overlap, readmission rate, perioperative complication rate, care intensity, year, practice setting, specialty.

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

Patient information will consist exclusively of de-identified medical claims data from the Massachusetts All-Payer Claims Database. Only the minimum fields necessary to measure physician clinical activity and quality will be requested. The final data set will include only provider-level measures with no patient-level information. All data files will be stored on the firewalled, password-protected hospital IT server. Access to

data will be limited to the principal investigator. Prior to inclusion of any data or finding, the principal investigator will apply cell aggregation and/or recategorization to avoid any cells with less than 11 observations.

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.

The primary purpose of this project will be publication in an academic journal. Study findings may also be shared through academic conferences and seminars. In all cases, prior to inclusion of any data or finding, the principal investigator will apply cell aggregation and/or recategorization to avoid any cells with less 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.

There are no plans to use or present any data derived from CHIA except in academic journal publication and academic conferences and seminars.

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?

No geographic level data or maps will be presented. Analysis will be at the state level, with controls included but not presented for location.

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?

N/A

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.

N/A

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?

N/A

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.

I hold a Ph.D. from the MIT Sloan School of Management where, methodologically, I focused on applied microeconomic analysis and frequently worked with "big data." I have extensive experience working with publication, grant, and patent data sets. I can also leverage my clinical expertise as a practicing physician, as well as the literature and colleagues at Boston Children's Hospital and Harvard Medical School, to facilitate claims analysis.

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:	**N/A**
Company Website	Click here to enter text.
Contact Person:	**N/A**
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.

N/A

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.

N/A

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:	**N/A**
Company Website	Click here to enter text.
Contact Person:	**N/A**
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.

N/A

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.

N/A

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.

N/A

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)	DocuSigned by: Gus Cervini 7CE08C061ADE446... Drag signature image here or delete and physically sign
Printed Name:	Gus Cervini Click here to enter text.
Title:	Senior Vice President Click here to enter text.
Date:	7/16/2024 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.