

Application for Massachusetts Case Mix and Charge 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 casemix.data@state.ma.us if you have additional questions about how to complete this form.

The Application and all attachments must be uploaded to <u>IRBNet</u>. All Application documents can be found on the <u>CHIA</u> 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 <u>Fee Remittance Form</u> 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 Case Mix and Charge Data.
- 2. After reviewing the Fee Schedule, if you have any questions about the application or data fees, contact casemix.data@state.ma.us.
- 3. If you believe that you qualify for a fee waiver, complete and submit the <u>Fee Remittance Form</u> and attach it and all required supporting documentation with your application. Refer to the <u>Fee Schedule</u> (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:	Understanding Trends in the Massachusetts Healthcare Market
IRBNet Number:	1661714-1
Organization Requesting Data (Recipient):	Beth Israel Lahey Health
Organization Website:	bilh.org
Authorized Signatory for Organization:	Pauline Lodge
Title:	SVP, Strategic Planning & Business Development
E-Mail Address:	Pauline.Lodge@bilh.org
Telephone Number:	781-744-7891
Address, City/Town, State, Zip Code:	25 Mall Road Burlington, MA 01803
Data Custodian:	Ayad Shammout
(individual responsible for organizing, storing, and archiving	Royce Cheng
Data)	Aj Fadel
Title:	Director, Data Management & Analytics
E-Mail Address:	Ayad.Shammout@bidmc.harvard.edu
Telephone Number:	617-754-8224
Address, City/Town, State, Zip Code:	1135 Tremont St, 6 th Flr, Boston, MA, 02120
Primary Investigator (Applicant):	Emilie Downing
(individual responsible for the research team using the Data)	
Title:	Director, Market Analytics & Intelligence
E-Mail Address:	Emilie.downing@bilh.org
Telephone Number:	781-744-7278
Address, City/Town, State, Zip Code:	25 Mall Road Burlington, MA 01803
Names of Co-Investigators:	Mercedes Lane, Alexandria McPherson, Lisa Neveling, Katie Wilson, Alan Bengzon, Wendy Hawkins, Jon Blair, Erin Hiltz, Lisa Neveling, Ayad Shammout, Wenlei Cao, Gail Piatkowski, Huili Shao
E-Mail Addresses of Co-Investigators:	Mercedes.lane@bilh.org Alexandria.mcpherson@bilh.org Lisa.Neveling@bilh.org Katie.wilson@bilh.org Alan.bengzon@bilh.org Wendy.hawkins@bilh.org Jonathan.blair@bilh.org Erin.hiltz@bilh.org Charlotte.Brown-Zalewa@bilh.org Ayad.shammout@bidmc.harvard.edu Wcao2@bidmc.harvard.edu gpiatkow@bidmc.harvard.edu hshao@bidmc.harvard.edu

IV. PROJECT INFORMATION

. What will be the use of the CHIA Data requested? [Check all that apply]					
⊠ Epidemiological	⊠ Health planning/resource allocation	□Cost trends			
☐ Longitudinal Research	☐ Quality of care assessment	☐ Rate setting			
☐ Reference tool	☐ Research studies	☐ Severity index tool (or other derived input)			
☐ Surveillance	☐ Student research	☐ Utilization review of resources			
☐ Inclusion in a product	Other (describe in box below)				

Click here to enter text.

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

The purpose and objectives of BILH's project is to peform analyses to better understand the MA health care market, utilizing the inpatient, observation and ED datasets, to inform system and institutional level strategic planning. Some examples of analyses BILH will perform include: market landscape and competitor profiles, service area assessments, IP discharge, observation and ED visit trends, service line and diagnosis code assessments to better understand the health needs of the population we are serving.

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

\square Yes [If yes, a copy of the approval letter of	and protocol <u>must</u> be include	d with the Application pa	ckage on IRBNet.]
⊠ No, this Project is not human subject rese	earch and does not require IR	B review.	

4. <u>Research Methodology</u>: Applicantions 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 BILH project titled "Understanding Trends in the MA Healthcare Market" will consist of a variety of analyses that serve to help BILH better understand the competitive MA health care landscape. The inpatient, observation and ED datasets will be utilized in both routine and ad hoc analyses. Routine use includes examining trends in utilization such as volume trends by service, geographic location, payor, age, and gender. Examples of ad hoc analyses include studying the incidence of preventable conditions and length of stay trends by DRG, diagnosis and/or procedures.

BILH plans to utilize the case mix data to address some of the below research questions:

- How has BILH's volume trended over time, in comparison to other MA health systems?
- What are the service areas of BILH institutions (both owned and affiliated)? Have these shifted over time? Are we meeting the health needs of patients in these areas?
- What are the trends in ED care and what types of diagnoses are patients coming into the ED for? Based on this data, are there alternate sites of care that be located in these areas to provide timely care in a more cost effective setting?
- How does BILH volume, LOS and CMI compare to other MA hospitals?
- What do tertiary volume trends look like at MA hospitals? How can this help better understand how to assist complex patients with utilizing higher acuity settings and lower acuity patients with utilizing lower acuity settings?
- What does payer mix by service line, hospitals and geography look like across MA?
- Are there specific patterns in provider volume that we can analyze across MA hospitals?
- How can we identify readmissions, high utilizers of care and the services these patients are arriving at the hospital for to develop strategies to assist with this?

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.

BILH will use the case mix data to better understand and answer the project research questions posed above. In addition, having access to this data will allow for comparative analyses that will improve the quality of care delivered and ensure care is being provided in appropriate settings. These analyses have two primary goals which are in the public's interest – 1. Improving the quality of care delivered to patients and 2. Identifying more efficient ways to utilize health care resources.

VI. DATASETS REQUESTED

The Massachusetts Case Mix ("Case Mix") are comprised of Hospital Inpatient Discharge, Emergency Department and Outpatient Hospital Observation Stay Data collected from Massachusetts' acute care hospitals, and satellite emergency facilities. Case Mix Data are updated each fiscal year (October 1 – September 30) and made available to approved data users. For more information about Case Mix Data, including a full list of available elements in the datasets 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 years of data not yet available. Applicants who anticipate a need for future years of data may request to be considered for a subscription. Approved subscriptions will receive, upon request, the <u>same data files and data elements</u> included in the initial release annually or as available. Please note that approved subscription request will be subject to the Data Use Agreement, will require payment of fees for additional Data, and subject to the limitation that the Data can be used only in support of the approved Project.

1. 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. Specify below the dataset(s) and year(s) of data requested for this Project, and your justification for requesting <u>each</u> dataset. Data prior to 2004 <u>is not</u> available.
☐ Hospital Inpatient Discharge Data
\boxtimes 2017 \boxtimes 2018 \boxtimes 2019
Describe how your research objectives require Inpatient Discharge data: Inpatient discharge data is necessary to: • Analyze where BILH (owned and affiliate) patients seeking inpatient services are coming from
 Determine which clinical areas there is a need to build capacity in order to create better access for patients
Compare innatient discharges LOS and CMI across hospitals in MA

- Perform marketplace studies to analyze trends/patterns in inpatient visits over time in MA
- Analyze trends in IP discharges at both an organizational and state level
- Perform IP service line analyses

	Outpatient	Hospital	Observation	Stav	Data
_	Outpatient	HUSPItal	Obsci vanon	Diay	Dau

 $\square 2004 \ \square 2005 \ \square 2006 \ \square 2007 \ \square 2008 \ \square 2009 \ \square 2010 \ \square 2011 \ \square 2012 \ \boxtimes 2013 \ \boxtimes 2014 \ \boxtimes 2015 \ \boxtimes 2016 \ \boxtimes 2017 \ \boxtimes 2018 \ \boxtimes 2019$

Describe how your research objectives require Outpatient Hospital Observation Stay data:

Outpatient observation data is increasingly important as many hospitals experience a shift in discharges from inpatient to observation status. Outpatient observation data is necessary to:

- Analyze where BILH observation patients are coming from
- Compare BILH (owned and affiliate) hospitals' observation visits to other hospitals in the state
- Analyze trends in observation stays at both a hospital and organizational level

☐ Emergency Department Data

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□2004 l	$\square 200$)5 □	⊒2006 □	□2007 [□2008 [□2009 [$\square 2010$	\square 2011	$\square 2012$	$\boxtimes 2013$	$\square 2014$	⊠2015	⊠ 2016	
⊠ 2017	⊠20	18 🛭	⊠2019											

Describe how your research objectives require Emergency Department data:

Emergency department data is necessary to:

- Analyze trends in ED visits at both an organizational and state level
- Analyze ED usage by service area
- Better understand the types of patients that come into the ED in order to understand how to get complex patients to use higher-acuity settings and lower complexity patients to use lower cost settings
- Perform marketplace studies to determine patterns of ED care in MA
- Compare BILH (owned and affiliate) hospitals' ED visits to other hospitals in the state

VII. DATA ENHANCEMENTS REQUESTED

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

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

For a full list of elements in the release (i.e., the "Core" elements and enhancements), please refer to <u>release</u> <u>layouts</u>, <u>data dictionaries</u> and similar documentation included on CHIA's website.

Please note that CHIA Case Mix Data contain reports produced using proprietary computer software created, owned, and licensed by the 3M Company. All Copyrights in and to the 3M APRTM Software, and to the 3M APRTM DRG classification system(s) (including the selection, coordination and arrangement of all codes) are owned by 3M. All rights reserved.

1. Specify below which enhancements you are requesting in addition to the "Core" LDS. CHIA will use this information to determine what Level of data is needed for pre-FY 2015 data requests.

Geographic Subdivisions

State, five-digit zip code, and 3-digit code are available for patients residing in CT, MA, ME, NH, RI, VT, and NY. City or Town of residence is available for residents of MA only. States outside of this region will be coded as XX ("Other").

Select <u>one</u> of the follow	ving option	s:				
☐ 3-Digit Zip Code (Standard)	☐ 3-Digit	t Zip Code &	⊠ 5-Digit Zip Coo	de ☐ 5-Di City/To	git Zip Code & wn ***	_
in your methodology The 5-digit zip code is nec coming from, in comparison their sociodemographic/co	eessary for BI on to previous ommunity hea it the needs o ort strategic pl	LH to perform services years. This level of lth needs in order to a four patients. This learning efforts.	e area analyses and ana detail will help BILH b make more informed do	lyze which specification and extra sections about allowers.	own. Refer to specifics fic towns/areas our patients are our patient population and ocating or reallocating health o code to pre-defined service	
☐ Not Requested (Sta			☐ Race & Ethnic	itv***		_
** If requested, prov		ation for reques			o specifies in your	_
methodology: BILH is requesting race ar community health needs o	nd ethnicity d f our patients ting and reall	ata to better understanderstanderstanderstanders This information, in ocating health care se	nd BILH's patient popu n addition to the 5-digit prvices to best benefit o	llation and identife zip code, will he ur patients' needs	Ty the sociodemographic and lp us make more informed This data will also allow for	
Date Resolution Select <u>one</u> of the follow	ving option	s for dates of adm	issions, discharges	and significar	nt procedures.	
☐ Year (YYYY)(Star	ndard)	☐ Month (YYY	YMM) ***	⊠ Day (YYY	YYMMDD)***	-
***If requested, prov methodology: BILH is requesting year/m data by day will also help	onth/day deta	ail to allow for the an	alysis of trends by mor	th or by day for v	various services. Looking at	
Practioner Identifiers (U	UPN)					
Select <u>one</u> of the follow	ving option	S.				
☐ Not Requested (Sta	andard)	☐ Hashed ID **	**	⊠ Board of F Number(BOF)	Registration in Medicine RIM) ***	
***If requested, pro in your methodology	_	ication for reque	sting Hashed ID o	r BORIM Nu	mber. Refer to specifics	

BILH is requesting the Board of Registration in Medicine Number (BORIM) to understand and analyze patterns in phy volume at various hospitals within MA.	sician
Unique Health Information Number (UHIN) Select <u>one</u> of the following options.	
☐ Not Requested (Standard) ☐ UHIN Requested ***	
*** If requested, provide justification for requesting UHIN. Refer to specifics in your method BILH is requesting the UHIN to perform more detailed analyses around readmissions and high utilizers of care.	lology:
Hashed Mother's Social Security Number Select <u>one</u> of the following options:	
*** If requested, provide justification for requesting Hashed Mother's SSN. Refer to specification methodology: Not needed.	s in your
VIII. DATA LINKAGE	
Data linkage involves combining CHIA Data with other data to create a more extensive database fo Data linkage is typically used to link multiple events or characteristics within one database that refe person within CHIA Data.	•
 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 ☐ 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 will be linked and the purpose for each linkage.	elements
CHIA data will be compared with previous years' data, from both CHIA and MHDC, to discern patterns and time. Routine analyses will be used to compare more recent CHIA data to data from previous years. The foldata elements will be linked:	

- 1) Diagnosis Code/DRG/Procedure Code will link to internal BILH DRG/ICD-9 and ICD10 diagnoses and procedural level service line files. These codes are grouped into the service lines that we utilize for our service line analyses, based on clinical input from BILH leaders.
- 2) Zip Code will link to our Zip Code Reference file. This reference file links the zip codes in the CHIA dataset to specific towns, states or pre-defined service areas.
- 3) Hospital ID will link to the hospital reference file which contains all information on specific organization, parent companies, and affiliations.
- 4) BORIM will link to external datasets to assist with understanding additional provider attributes.

Aggregate data will be used in combination with:

- Prior year Case Mix Data from MHDC and CHIA
- 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.

Deterministic algorithms are used to link CHIA data with the reference tables mentioned above e.g. unique zip codes, Org. ID, and DRG codes to produce the same output. For example, zip codes in the CHIA data will be mapped to our pre-defined service areas, regions, etc. in order to compare where BILH and our owned hospitals' patients are coming from in comparison to other hospitals in MA.

5. If yes, attach or provide below a complete listing of the variables from <u>all sources</u> to be included in the final linked analytic file.

Zip Code – Internal town/state reference file

DRG - Internal DRG service line reference file

ICD-9/10 Diagnosis Code – Internal diagnosis code reference file, Sg2 CARE families

Procedural Code – Internal procedural code reference file

Organization – Internal hospital/system reference file

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

No disclosure or publication of data will occur that exposes identifiable data. Data disclosures and publications will strictly abide by the requirements of 957 CMR 5.02.

IX. 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 currently do not anticipate that the results of our analyses will be published or made publically available. This is an internal data source to assist us in making operational and strategic decisions and to develop health improvement initiatives of the population served.

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.

BILH does not anticipate that any analysis will be published nor made publically available.

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?

Zip code level detail may be presented to for strategic planning purposes but will always be aggregated to eliminate the ability for patient identification and will suppress cells less than 11. Mapping will be utilized to visualize hospital areas and will less frequently be utilized to visualize volume coming from specific towns. Maps will include aggregated data again not visualizing less than 11.

4. Will you be u □ Yes ⊠ No	using CHIA Data for consultin	ng purposes?		
5. Will you be s □ Yes ⊠ No	selling standard report product	ts using CHIA Data?		
6. Will you be s □ Yes ⊠ No	selling a software product usin	ng CHIA Data?		
7. Will you be reference tool, e □ Yes □ No		to develop a product (i.e., s	severity index took, risk adjustment	tool,

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?
NA
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.
NA
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?
NA

X. APPLICANT QUALIFICATIONS

1. Describe your previous experience using hospital data. This question should be answered by the primary investigator and any co-investigators who will be using the Data.

The BILH Market Analytics & Intelligence and Strategic Planning & Business Development teams have many years of experience utilizing the case mix data from CHIA and previously MHDC. Over the past years, these teams have utilized this data to further the strategic planning of the legacy BIDMC and Lahey organizations. All investigators are familiar with the restrictions of working with PHI and this level of hospital data. They have all been educated about CHIA's specific rules and regulations. Additionally, the investigators have experience in hospital finance and analytics which assists all investigators in understanding how to handle this level of data.

2. <u>Resumes/CVs</u>: 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.)

XI. 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 <u>all</u> agents and contractors who will have access to the CHIA Data. [Add agents or contractors as needed.]

AGENT/CONTRACTOR #1 INFORMATION				
Company Name:	Sg2			
Company Website	Sg2.com			
Contact Person:	Aj Fadel			
Title:	Associate Vice President			
E-mail Address:	ajfadel@sg2.com			
Address, City/Town, State, Zip Code:	5250 Old Orcharge Road Skokie, IL 60077			
Telephone Number:	847-779-5459			
Term of Contract:	3 years – until 1/1/2023			

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

Sg2's analytics-based health care expertise helps hospitals and health systems integrate, prioritize and drive growth and performance across the continuum of care. Over 1,200 organizations around the world rely on Sg2's analytics, intelligence, consulting and educational services. Using their proprietary models, Sg2 will use the CHIA inpatient discharge data as baseline data to forecast market demand for the state of MA and for BILH institutions.

All users coming into contact with this data have been trained in HIPAA compliance and are subject to both Sg2 and CHIA's policies and procedures, with regard to the protection of the data.

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.

The Organization has shared the Data Use Agreement with the contractor and has educated them on CHIA's policies regarding data security. Additionally, the data management plan contains further detail around the techniques in place for data safety and security.

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

✓ Yes✓ No

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

AGENT/CONTRACTOR #2 INFORMATION	
Company Name:	The Chartis Group
Company Website	www.chartis.com
Contact Person:	Royce Cheng
Title:	Associate Principal
E-mail Address:	rcheng@chartis.com
Address, City/Town, State, Zip Code:	29 Commonwealth Ave. 10 th Floor, Boston, MA
	02116
Telephone Number:	626.592.0213
Term of Contract:	Ad hoc basis

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

The Chartis Group will be analyzing historic trends across various clinical services, with the intent of better understanding opportunities to retain and coordinate care. The analysis will be conducted for multiple subgeographies across Eastern Massachusetts, with the goal of evaluating how services might be deployed and resources allocated to better meet the needs of patients.

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.

The Organization will ensure that The Chartis Group complies with both the Data Management Plan and the Data Use Agreement that the Organization is responsible for abiding by. Additionally, The Chartis Group has been educated on CHIA's policies regarding data security. The Organization's Data Management Plan contains further detail around the techniques and safeguards in place to ensure data safety and security.

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

✓ Yes✓ No

4. If yes, a separate Data Management Plan <u>must</u> be completed by the agent or contractor.

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

XII. 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)	Sauline M Lodge
Printed Name:	Pauline Lodge
Title:	SVP, Strategic Planning & Business Development
Date:	9/21/2020

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.