center for health information and analysis

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. Organiations 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 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 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 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:	Disparities in the effect of state policy for the newborn screening for critical congenital heart diseases
IRBNet Number:	1867139-1
Organization Requesting Data (Recipient):	The Lundquist Institute for Biomedical Innovation
Organization Website:	https://lundquist.org/
Authorized Signatory for Organization:	Allison Weber
Title:	Director, Pre Award Research Administration
E-Mail Address:	aweber@lundquist.org
Telephone Number:	(424) 201-3000
Address, City/Town, State, Zip Code:	1124 W Carson St, Torrance, CA 90502
Data Custodian: **(individual responsible for organizing, storing, and archiving Data)**	Dr. Rie Sakai-Bizmark
Title:	Assistant Professor/Principal Investigator
E-Mail Address:	rsakaibizmark@lundquist.org
Telephone Number:	310-222-3699
Address, City/Town, State, Zip Code:	1124 W Carson St, Torrance, CA 90502
Primary Investigator (Applicant): **(individual responsible for the research team using the Data)**	Dr. Rie Sakai-Bizmark
Title:	Assistant Professor/Principal Investigator
E-Mail Address:	rsakaibizmark@lundquist.org
Telephone Number:	310-222-3699
Address, City/Town, State, Zip Code:	1124 W Carson St, Torrance, CA 90502
Names of Co-Investigators:	Click here to enter text.
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 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]

☐ 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.

Currently, all 50 states and D.C. have enacted legislation to mandate critical congenital heart disease (CCHD) screening with pulse oximetry (POx) between 24 hours of birth and newborn discharge. (1) The objective of this study is to assess inequities in the effect of state-mandated policies for CCHD screening between infants from historically marginalized and under-resourced populations and their more privileged counterparts, with analyses conducted at the individual level. Although advances in echocardiography enable many types of congenital heart disease to be diagnosed prenatally, inequities are substantial. For example, a 71-100% prenatal detection rate has been reported in teaching hospitals, contrasted with a 0-39% prenatal detection rate in non-teaching hospitals. (2-4) Marginalized mothers may have access only to lower-resourced hospitals, or come from socio-economically under-resourced groups including rural, uninsured, publicly insured, low-income, or minority racial or ethnic groups.

The specific outcomes to be evaluated in this study are as follows: 1] Infant mortality among CCHD patients: Early CCHD detection by POx screening should drive early intervention and reduce mortality for marginalized patients with limited or no access to prenatal detection. 2] Infant mortality due only to missed or late diagnoses: POx screening mandates should reduce missed or late diagnoses. 3] Healthcare utilization: Early detection of CCHD would be expected to reduce long-term healthcare utilization costs, re-admissions, and length of stays from secondary morbidities. Overall, we hypothesize that after implementation of state CCHD screening mandates, health outcomes improved and healthcare utilization decreased more for marginalized or under-resourced groups, given large inequities in prenatal detection of CCHD. Results will be submitted for publication in peer-reviewed journals and presented at academic conferences.

1. Kumar P. Universal Pulse Oximetry Screening for Early Detection of Critical Congenital Heart Disease. Clin Med Insights Pediatr. 2016;10:35-41.
2. Case AP, Miller SD, McClain MR. Using State Birth Defects Registries to Evaluate Regional Critical Congenital Heart Disease Newborn Screening. Birth Defects Res. 2017;109(18):1414-1422.
3 Fixler DE, Xu P, Nembhard WN, Ethen MK, Canfield MA. Age at Referral and Mortality From Critical Congenital Heart Disease. Pediatrics. 2014;134(1):E98-E105.
4. Abouk R, Grosse SD, Ailes EC, Oster ME. Association of US State Implementation of Newborn Screening Policies for Critical Congenital Heart

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**: 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.

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.*

Critical congenital heart disease (CCHD) is a dangerous condition with 7,200 US cases and 1,260 infant deaths annually. (1) Up to 25% of newborns with CCHD were discharged from hospitals without diagnosis before mandatory state screening policies were implemented. (2) A recent study found mandated screening reduced CCHD deaths by 33%. (4) Given inequities stemming from higher prevalence of CCHDs especially among Black infants, and unequal access to prenatal screening echocardiograms, (4,5) early detection of CCHDs through universal screening at birth could be critical to reducing mortality and morbidity of infants.

1. Oster ME, Lee KA, Honein MA, Riehle-Colarusso T, Shin M, Correa A. Temporal Trends in Survival among Infants with Critical Congenital Heart Defects. Pediatrics. 2013;131(5):e1502-1508.
2. Peterson C, Ailes E, Riehle-Colarusso T, et al. Late Detection of Critical Congenital Heart Disease Among US Infants Estimation of the Potential Impact of Proposed Universal Screening Using Pulse Oximetry. JAMA Pediatr. 2014;168(4):361-370.
3. Eckersley L, Sadler L, Parry E, Finucane K, Gentles TL. Timing of Diagnosis Affects Mortality in Critical Congenital Heart Disease. Arch Dis Child. 2016;101(6):516-520.
Disease With Early Infant Cardiac Deaths. JAMA.2017;318(21):2111-2118.
4. Pinto NM, Nelson R, Puchalski M, Metz TD, Smith KJ. Cost-effectiveness of Prenatal Screening Strategies for Congenital Heart Disease. Ultrasound Obstet Gynecol. 2014;44(1):50-57.
5. Sklansky MS, DeVore GR. Fetal Cardiac Screening. J Ultrasound Med. 2016;35:679–681.

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 same data files and data elements 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 *each* dataset. Data prior to 2004 is not available.

☒ Hospital Inpatient Discharge Data
☐2004 ☐2005 ☐2006 ☐2007 ☐2008 ☐2009 ☐2010 ☒2011 ☒2012 ☒2013 ☒2014 ☒2015 ☒ 2016 ☒ 2017 ☐2018 ☐2019 ☐2020

Describe how your research objectives require Inpatient Discharge data:
We are requesting PELL (Pregnancy to Early Life Longitudinal Data System) records, which contain hospital inpatient discharge data. These records are necessary because we are investigating mortality and healthcare utilization for infants with critical congenital heart disease and other target conditions.

☐ Outpatient Hospital Observation Stay Data

☐2004 ☐2005 ☐2006 ☐2007 ☐2008 ☐2009 ☐2010 ☐2011 ☐2012 ☐2013 ☐2014 ☐2015 ☐ 2016 ☐ 2017 ☐2018 ☐2019 ☐2020
Describe how your research objectives require Outpatient Hospital Observation Stay data: Click here to enter text.
☐ **Emergency Department Data** ☐2004 ☐2005 ☐2006 ☐2007 ☐2008 ☐2009 ☐2010 ☐2011 ☐2012 ☐2013 ☐2014 ☐2015 ☐ 2016 ☐ 2017 ☐2018 ☐2019 ☐2020
Describe how your research objectives require Emergency Department data: Click here to enter text.

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 release layouts, data dictionaries 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 APR™ Software, and to the 3M APR™ 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 *one* of the following options:

☐ 3-Digit Zip Code (Standard)	☐ 3-Digit Zip Code & City/Town ***	☒ 5-Digit Zip Code ***	☐ 5-Digit Zip Code & City/Town ***

*****If requested, provide justification for requesting 5-Digit Zip Code or City/Town. Refer to specifics in your methodology:**

A secondary exposure variable of interest is socioeconomic status (SES). A composite index of postal-code-level socioeconomic indicators will be created using Principal Component Analyses to avoid multicollinearity. To create the SES index, we will use U.S. Census data to determine i] median household income, ii] median house value, and iii] percent of population on public assistance for each zip code in the state. The zip code of residence variable in the PELL records will be used to link individuals to the appropriate SES index created from aggregate census data. The scale will be divided into quartiles. An additional secondary exposure variable of interest will be urban/rural residence. The zip

code of residence will be used to categorize each subject as an urban or rural resident based on the Rural-Urban Commuting Area (RUCA) code. The zip code variable will be removed from the dataset after creation of the SES index and urban/rural residence variables.

Demographic Data

Selcect *one* of the following options:

☐ Not Requested (Standard)	☒ Race & Ethnicity***

**** If requested, provide justification for requesting Race and Ethnicity. Refer to specifics in your methodology:**

The primary exposure variable of interest is race/ethnicity, which will be grouped into non-Hispanic White, non-Hispanic Black, Hispanic and other. The purpose of the study is to assess disparities in the effect of state policy for the newborn screening for critical congenital heart diseases based on social determinants of health, such as race and ethnicity.

Date Resolution

Select *one* of the following options for dates of admissions, discharges, and significant procedures.

☐ Year (YYYY)(Standard)	☐ Month (YYYYMM) ***	☒ Day (YYYYMMDD)***

*****If requested, provide justification for requesting Month or Day. Refer to specifics in your methodology:**

We are requesting date of birth, date of death, and date of inpatient admission(s). Dates are necessary to determine eligibility and cohort assignment and to identify patients who were diagnosed with CCHD as newborns, based on number of days between birth and hospital admission. The data set will meet the definition of a "limited data set" under HIPAA.

Practioner Identifiers (UPN)

Select *one* of the following options.

☒ Not Requested (Standard)	☐ Hashed ID ***	☐ Board of Registration in Medicine Number(BORIM) ***

*****If requested, provide justification for requesting Hashed ID or BORIM Number. Refer to specifics in your methodology:**

Click here to enter text.

Unique Health Information Number (UHIN)

Select *one* of the following options.

☒ Not Requested (Standard)	☐ UHIN Requested ***

***** If requested, provide justification for requesting UHIN. Refer to specifics in your methodology:**

Click here to enter text.

Hashed Mother's Social Security Number

Select *one* of the following options:

☒ Not Requested (Standard)	☐ Hashed Mother's SSN Requested ***

***** If requested, provide justification for requesting Hashed Mother's SSN. Refer to specifics in your methodology:**
Click here to enter text.

VIII. 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.

Individual Patient Level Data Linkage: We are requesting individual patient level data from the PELL database, which contains linked birth, death, and inpatient discharge records.
Individual Facility Level Data Linkage: Facility name or code will be linked with teaching status from the American Hospital Association database or publicly-available data for teaching status. Teaching status will be combined with hospital case volume to create a categorical hospital characteristics variable. Hospital characteristics will be included in the model as an adjustment variable.
Aggregate Data Linkage: We will use U.S. census data to determine the median household income, median house value, and percent of population on public assistance for each zip code in the state. This information will be used to create a composite index of postal-code-level socioeconomic indicators (SES index). The zip code of residence variable in the PELL records will be used to link individuals to the appropriate SES index created from aggregate census data. The zip code of residence will also be used to categorize each subject as an urban or rural resident based on the Rural-Urban Commuting Area (RUCA) code. Both SES and urban/rural residence are considered social determinants of health (SDOH), and will be included in the model as secondary exposure variables of interest.

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.

Individual Patient Level Data Linkage: Linkage has already been performed by PELL data analysts
Individual Facility Level Data Linkage: Deterministic linking between facility name or code and teaching status
Aggregate Data Linkage: Deterministic linking between zip code and US census information.

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.

Individual Patient Level Data Linkage: Please see attached PELL variable lists
Individual Facility Level Data Linkage: Dichotomous variable for teaching status
Aggregate Data Linkage:
1) SES index (a composite index of postal-code-level socioeconomic indicators created from U.S. Census data including i] median household income, ii] median house value, and iii] percent of population on public assistance for each zip code in the state)
2) Dichotomous urban/rural residence variable created from the Rural-Urban Commuting Area (RUCA) code for each zip code

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

No attempt will be made to identify individual subjects. Results of this research project will be reported in aggregate without identification of individual patients, physicians or facilities. We will not release or disclose information where the number of observations (i.e., individual records) in any given tabulated data cell is less than or equal to 10. Zip code of residence will be removed from the dataset after the SES index and urban/rural designation is calculated for each subject. Facility name and number will be removed from the dataset after teaching status and case volume is assigned to each hospital record.

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.

Yes, results will be submitted for publication in peer-reviewed journals and presented at academic conferences. Results of this research project will be reported in aggregate without identification of individual patients, physicians or facilities. We will not release or disclose information where the number of observations (i.e., individual records) in any given tabulated data cell is less than or equal to 10. We will not use percentages or other mathematical formulas that may result in the

disclosure of a cell less than 10. In addition, we will use complementary cell suppression techniques to ensure that cells with fewer than 10 observations cannot be identified by manipulating other cells.

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.

We anticipate that all of our results will be disseminated to the public via peer-reviewed journals and/or presentations at academic conferences.

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?

This is a multi-state study and the lowest geographic level of data that will be presented is the state level. Although we are requesting zip code of residence for each subject, results will not be presented at the zip code level. Zip code will be removed from the dataset after using that variable to calculate socioeconomic status and urban versus rural residence. Maps will not be presented.

4. Will you be using CHIA Data for consulting purposes?

☐ Yes
☒ No

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

☐ Yes
☒ No

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

☐ Yes
☒ No

7. Will you be using CHIA Data as in input to develop a product (i.e., severity index took, risk adjustment tool, reference tool, etc.)

☐ Yes
☒ No

8. Will you be reselling CHIA Data in any format not noted above?

☐ Yes
☒ No

If yes, in what format will you be reselling CHIA Data?

Click here to enter text.

9. If you have answered "yes" to questions 5, 6, 7 or 8, please provide the name and a description of the products, software, services, or tools.

Click here to enter text.

10. If you have answered "yes" to questions 5, 6, 7 or 8, what is the fee you will charge for such products, software, services or tools?

Click here to enter text.

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.

This study will utilize linked birth, death, and hospital records from the PELL database. The primary investigator, Dr. Rie Sakai-Bizmark, is currently using PELL records, in addition to linked vital statistics and inpatient discharge records from other states, to complete an NIH-funded study investigating the cost-effectiveness of critical congenital heart disease screening. In the past, she has successfully completed analyses with linked vital statistics and inpatient discharge records from New York, South Carolina, and Pennsylvania.

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.)

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 **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 #2 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.

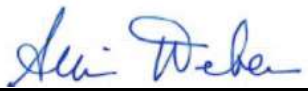
[INSERT A NEW SECTION FOR ADDITIONAL AGENTS/CONTRACTORS AS NEEDED]

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)	
Printed Name:	Allison Weber
Title:	Director, Pre Award Research Administration
Date:	5/19/22

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.