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. 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 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:	Pediatric Inpatient Capacity and Emergency Department Pediatric Volume Patterns during the 2022 Pediatric Respiratory Surge
IRBNet Number:	**2327734**
Organization Requesting Data (Recipient):	Boston Children's Hospital, Division of Emergency Medicine
Organization Website:	www.childrenshospital.org/departments/emergency-medicine
Authorized Signatory for Organization:	August P Cervini MBA
Title	Sr. VP of Research Administration, Research Integrity Officer
Email 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)	Piotr Sliz
Title:	Chief Research Information Officer
Email address:	Piotr.Sliz@childrens.harvard.edu
Telephone Number:	617-919-1422
Address, City/Town, State, Zip Code:	300 Longwood Ave, BCH3396, Boston, MA 02215
Primary Investigator (Applicant): **(individual responsible for the research team using the Data)**	Joyce Li
Title:	Assistant Professor of Pediatrics and Emergency Medicine, Harvard Medical School
E-Mail Address:	Joyce.li@childrens.harvard.edu
Telephone Number:	617-255-6000 pager 6134
Address, City/Town, State, Zip Code:	300 Longwood Ave, Boston, MA 02115
Names of Co-Investigators:	Sarita Chung, Michael Monuteaux, David Nelson
E-Mail Addresses of Co-Investigators:	Sarita.Chung@childrens.harvard.edu, Michael.Monuteaux@childrens.harvard.edu, David.Nelson@uvmhealth.org

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 (the "Project"). 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, with approval being subject to CHIA's regulatory restrictions and approval process. Unauthorized use is a material violation of your Organization's Data Use Agreement with CHIA.

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

X Epidemiological X Health planning/resource allocation ☐Cost trends

☐ Longitudinal Research ☐ Quality of care assessment ☐ Rate setting

☐ Reference tool X 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)

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.

Surge events, due to infectious disease, mass shooting incidents and natural disasters, are increasing in number and magnitude nationally and worldwide.[1-2] The US Health and Human Services Assistant Secretary for Preparedness and Response recommends increasing hospital beds by 20% in surge situations. However, pediatric inpatient capacity is decreasing with as many as 75% of critical access hospitals losing all pediatric capacity. Despite national recommendations, there is no available means to collect real-time inpatient pediatric capacity in US. Most normal operations and planned pediatric surge capacity is based on only theoretical estimates [3-5]; relying on pediatric bed licensing, which does not account for staffing and equipment and does not include planned surge bed utilization. States do not require hospitals to plan for increases in pediatric bed capacity during a surge event, even in rural areas. Our study team has previously published that state-wide Massachusetts hospitals would not be able to meet the ASPR standard.[6] There is little to no published data on the successes and failures of planned inpatient surge capacity in real-time surge events. There is a gap in knowledge of how planned surge capacity is utilized in a real time event.

Between September and December 2022, a surge of pediatric patients with viral illness, specifically covid-19, influenza and respiratory syncytial virus known as the "tripledemic," causing a tremendous strain on emergent pediatric capacity nationally.[7] Although the impact on emergency department (ED) access during this period had been described, the impact of the tripledemic on pediatric inpatient capacity has not been well defined.[8] Understanding the utilization patterns in this recent surge is a critical learning opportunity to optimize pediatric regional and hospital disaster plans. For this project, we will expand our network to include all Vermont hospitals, of which all are rural with nearly half being critical access hospitals. Our goal is to describe actual pediatric surge utilization in Massachusetts and Vermont by comparing ED pediatric volume and pediatric inpatient capacity in community hospitals and academic pediatric hospitals during non-winter months and during the 2022 tripledemic. We will perform a retrospective multi-state study utilizing existing surge data from both states, Massachusetts administrative data and collecting ED and inpatient data from Vermont hospitals during the study period.

Specific aim 1: To describe the monthly and seasonal trends in ED pediatric volume and pediatric inpatient capacity in all Massachusetts and Vermont community and academic pediatric hospitals between January 1, 2022 – December 31, 2023. We will perform negative binomial regressions to capture cyclical (ie, seasonal) patterns. We hypothesize that there will be seasonal trends in pediatric ED volumes and pediatric inpatient capacity in community hospitals and academic pediatric hospitals.
Specific aim 2: To compare the pediatric inpatient capacity of community hospitals to academic pediatric hospitals in Massachusetts and Vermont, from January 1, 2022 - December 31, 2023. We will perform a multivariable linear regression to compare mean occupied inpatient pediatric capacity between hospital types. We hypothesize that: 1) During the 2022 pediatric respiratory viral surge and the 2023 winter months, Massachusetts and Vermont community hospitals had statistically lower occupied pediatric inpatient capacity compared to academic pediatric hospitals with similar pediatric ED patient volume trends; and 2) During non-winter months in 2022 and 2023, Massachusetts and Vermont community hospitals and academic pediatric hospitals will have similar occupied pediatric inpatient capacity and pediatric ED patient volume trends.

There will be additional state only sub-analyses for Massachusetts and Vermont. With the information from this study, short term we will present this data to healthcare coalitions in Massachusetts and Vermont. As a part of the Massachusetts analysis and feedback to Massachusetts healthcare coalitions, we will track and map interfacility transfers to see which hospitals were the most affected in terms of being over-capacity and those that have admission capabilities were under-capacity. We plan to publish the overall results of the combined data in a peer reviewed journal. Our long-term overall goal is to use this data to develop an innovative model to not only accurately assess regional surge capacity but also create realistic surge plans that meet pediatric healthcare needs across the country.

References:
1. Michelson KA, Rees CA, Sarathy J, et al. Interregional Transfers for Pandemic Surges. *Clin Infect Dis*. 2021;73(11):E4103-E4110. doi:10.1093/CID/CIAA1549
2. U.S. Billion-dollar Weather and Climate Disasters, 1980 - present. *National Centers for Environmental Information*. Published online 2020. doi:10.25921/STKW-7W73
3. Anthony C, Thomas TJ, Berg BM, Burke R V., Upperman JS. Factors associated with preparedness of the US healthcare system to respond to a pediatric surge during an infectious disease pandemic: Is our nation prepared? *Am J Disaster Med*. 2017;12(4):203-226. doi:10.5055/AJDM.2017.0275
4. Kanter RK, Moran JR. Hospital emergency surge capacity: an empiric New York statewide study. *Ann Emerg Med*. 2007;50(3):314-319. doi:10.1016/J.ANNEMERGMED.2006.10.019
5. Kanter RK. Strategies to improve pediatric disaster surge response: potential mortality reduction and tradeoffs. *Crit Care Med*. 2007;35(12):2837-2842. doi:10.1097/01.CCM.0000287579.10746.43
6.. Li J, Baker AL, D'Ambrosi G, Monuteaux MC, Chung S. A Statewide Assessment of Pediatric Emergency Care Surge Capabilities. *Pediatrics*. 2023;151(4). doi:10.1542/peds.2022-059459
7. Furlow B. Triple-demic overwhelms paediatric units in US hospitals. *Lancet Child Adolesc Health*. 2023;7(2):86. doi:10.1016/S2352-4642(22)00372-8
8. Janke AT, Mangus CW, Fung CM, et al. Emergency Department Care for Children During the 2022 Viral Respiratory Illness Surge. *JAMA Netw Open*. 2023;6(12):e2346769. doi:10.1001/jamanetworkopen.2023.46769

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

X 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 states the Project objectives and/or identifies 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.*

Members of our study team (Drs Li, Chung, Monuteaux) developed a survey to assess planned surge capacity and capabilities for Massachusetts. With 91% of hospitals responding, Massachusetts hospitals on a state-wide level would not be able to meet the ASPR standard based on their surge plans. This was most apparent between September and December 2022, when a surge of pediatric patients with viral illness, specifically covid-19, influenza and respiratory syncytial virus known as the "tripledemic", caused a tremendous strain on emergent pediatric capacity within Massachusetts and nationally. In addition, every winterthere is a relative surge of pediatric patients needing admission for respiratory illnesses. During these times, children and their families often experience long waiting times to be seen in EDs and must wait in the ED for prolonged periods (>8 hours) for an inpatient bed (known as boarding) due to overcrowding. Despite national recommendations and known season surges, there is no available means to collect real-time inpatient pediatric capacity in US, including New England. Most normal operations and planned pediatric surge capacity are based on only theoretical estimates. The goal of this study is to understand the utilization patterns in this recent surge to develop optimal Massachusetts and New England pediatric regional and hospital disaster plans to ultimately decrease boarding and long wait times for children during any type of surge event.

VI. DATASETS REQUESTED

The Massachusetts Case Mix and Charge Data ("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.

X 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 ☐2021 X 2022 X 2023
Describe how your research objectives require Inpatient Discharge data: Our specific aim 2 is to compare the pediatric inpatient capacity of community hospitals to academic pediatric hospitals in Massachusetts, with a sub-analysis of rural hospitals, from January 1, 2022 - December 31, 2023. We will require the inpatient data to calculate the daily capacity.
☐ **Outpatient Hospital Observation Stay Data** ☐2004 ☐2005 ☐2006 ☐2007 ☐2008 ☐2009 ☐2010 ☐2011 ☐2012 ☐2013 ☐2014 ☐2015 ☐2016 ☐2017 ☐2018 ☐2019 ☐2020 ☐2021 X 2022 X 2023
Describe how your research objectives require Outpatient Hospital Observation Stay data: During the respiratory surge, there was a dearth of inpatient beds and many hospitals reporting prolonged boarding times and difficulty with pediatric interfacility transfers for appropriate inpatient beds. While our specific aims are to compare the pediatric and ED inpatient capacity of community hospitals to academic pediatric hospitals in Massachusetts, with a sub-analysis of rural hospitals, from January 1, 2022 - December 31, 2023, there are likely patients who were admitted to observation status during their prolonged stay and/or admitted to specific observation units due to the lack of beds. This metric will be used to illustrate the strain on hospitals as well as the alternative routes to care that hospitals used due to lack of beds.
☐ **Emergency Department Data** ☐2004 ☐2005 ☐2006 ☐2007 ☐2008 ☐2009 ☐2010 ☐2011 ☐2012 ☐2013 ☐2014 ☐2015 ☐2016 ☐2017 ☐2018 ☐2019 ☐2020 ☐2021 X 2022 X 2023

Describe how your research objectives require Emergency Department data:
Our specific aim 1 is to describe the monthly and seasonal trends in ED pediatric volume and pediatric inpatient capacity in all Massachusetts and Vermont community and pediatric academic hospitals between January 1, 2022 – December 31, 2023. For this aim, we will need ED visit data to calculate the pediatric volume.

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.

Geographic Subdivisions

State code, five-digit ZIP code, and 3-digit ZIP 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").

☐ 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:**
Click here to enter text.

Demographic Data

Select *one* of the following options:

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

**** If requested, provide justification for requesting Race and Ethnicity. Refer to specifics in your methodology:**
We would use this data to fully assess and characterize the demographics of the sample to establish generalizability for other states populations and assess for potential bias in care.

Date Resolution

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

X Year (YYYY)(Standard)	X Month (YYYYMM) ***	X Day (YYYYMMDD)***
***If requested, provide justification for requesting Month or Day. Refer to specifics in your methodology: The goal of our study is to compare inpatient capacity for pediatric patients based on hospital characteristics during normal operations and during the recent tripledemic. We can only distinguish the normal operation period against the tripledemic period with data including the dates of admission and discharges.		

Practioner Identifiers (UPN)

Select *one* of the following options.

X 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)	X UHIN Requested ***
As a part of the Massachusetts analysis and feedback to Massachusetts healthcare coalitions, we will use the UHIN to track interfacility transfers to see which hospitals were the most affected in terms of being over-capacity and those that have admission capabilities were under-capacity.	

Hashed Mother's Social Security Number

X 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

X 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.

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.

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.

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

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 have both plans for publication and presentations. For publication and national presentations, we will only be presenting data in aggregate either for the total data for both Vermont and Massachusetts and on a state level in regards to Vermont and Massachusetts.

We will also present the Massachusetts-only data to Massachusetts health care coalitions to help enhance pediatric surge planning specifically for those health care coalitions. Health care coalitions are multi-agency coordinating groups that include all health care entities within their region to assist with future disaster and surge planning. For these presentations, we would only present on a region-level within Massachusetts.
Given the above, it is very unlikely we would have any cell less than 11 but if we do have a cell less than 11, we will not include this data and would either completely omit this cell or label this cell as Not available.

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.

As above, we do plan to present the Massachusetts-only data to Massachusetts health care coalitions to help enhance pediatric surge planning specifically for those health care coalitions. Health care coalitions are multi-agency coordinating groups that include all health care entities within their region to assist with disaster and surge planning. For these presentations, we would only present on a region level within Massachusetts.

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?

State level data only will be used for publication that could include overall state maps. For healthcare coalition presentations, we would still only use state level maps but may have the additional regional divisions within the maps.

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

☐ Yes

X No

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

☐ Yes

X No

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

☐ Yes

X 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

X No

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

☐ Yes

X 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.

Drs Li and Monuteaux have extensive experience using hospital data. Michael Monuteaux has co-authored over 350 studies, most as the primary statistician, many of which used patient-level administrative and clinical data. Dr Li has had extensive experience and publications utilizing large databases including NEDS, SEDDS, SIDDS, and NHAMCS. Both have completed the HCUP data usage training, have collaborated repeatedly in prior studies, and have extensive experience in ensuring patient privacy in publications and presentations.

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:	Boston Children's Hospital
Company Website	www.childrenshospital.org/departments/emergency-medicine
Contact Person:	Michael Monuteuax
Title:	Senior Epidemiologist/Biostatistician Boston Children's Hospital Division of Emergency Medicine, Associate Professor of Pediatrics, Harvard Medical School
E-mail Address:	Michael.monuteaux@childrens.harvard.edu
Address, City/Town, State, Zip Code:	300 Longwood Ave, Boston, MA 02115
Telephone Number:	617-355-6624
Term of Contract:	5/21/2025-12/31/26 (or until accepted for publication)

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

Dr. Monuteaux will be doing all data management and analysis. He will combine the data with the Vermont data and perform all data analysis. He has the expertise and training necessary to successfully complete the project. He is an Associate Professor of Pediatrics at Harvard Medical School, Senior Biostatistician and Epidemiologist with the Division of Emergency Medicine, Boston Children's Hospital and the Assistant Director of the Biostatistics and Research Design Center at the Institutional Centers for Clinical and Translational Research at Boston Children's Hospital. Throughout his career he has contributed to the design and analysis of numerous research projects, observational cohorts and clinical trials, collaborating with numerous physician investigators. Through his work he has co-authored over 350 manuscripts that have been published in peer-reviewed biomedical journals.

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.

Boston Children's Hospital has a secure firewall behind which all data will be stored. Further, access to the data will be password protected and available only to Drs Li and Monuteaux.

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
X No

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

AGENT/CONTRACTOR #2 INFORMATION	
Company Name:	Boston Children's Hospital
Company Website	www.childrenshospital.org/departments/emergency-medicine
Contact Person:	Joyce Li
Title:	Associate Physician, Boston Children's Hospital, Division of Emergency Medicine, Assistant Professor of Pediatrics and Emergency Medicine, Harvard Medical School
E-mail Address:	Joyce.li@childrens.harvard.edu
Address, City/Town, State, Zip Code:	300 Longwood Ave, Boston, MA 02115
Telephone Number:	617-255-6000 pager 6134
Term of Contract:	5/21/2025-12/31/26 (or until accepted for publication)

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

Dr Li will be overseeing the data analysis by Dr Monuteaux and may need to review the primary raw data if questions arise from the results. Dr Li has extensive experience with overseeing studies from large databases with over 30 publications.

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.

Boston Children's Hospital has a secure fire wall for which all data will be kept behind that is password protected that will be available only to Dr Li and Monuteaux.

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
X 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)	August Cervini
Printed Name:	August Cervini
Title:	Senior Vice President
Date:	6/24/2025

Attachments:
A completed Application must have the following documents attached to the Application or uploaded separately to IRBNet:
X1. IRB approval letter and protocol (if applicable), or research methodology (if protocol is not attached)
X2. 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);
X3. CVs of Investigators (upload to IRBNet)

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