

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

I. INSTRUCTIONS

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

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

- Data Availability
- Fee Schedule
- Data Request Process

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

The Application and all attachments must be uploaded to IRBNet. All Application documents can be found on the CHIA website.

Information submitted as part of the Application may be subject to verification during the review process or during any audit review conducted at CHIA’s discretion.

Applications will not be reviewed until the Application and all supporting documents are complete and the required application fee is received.

A Fee Remittance Form with instructions for submitting the application fee is available on the CHIA website. If you are requesting a fee waiver, a copy of the Fee Remittance Form and any supporting documentation must be uploaded to IRBNet. Please be aware that if your research is funded and under that funding you are required to release raw data to the funding source, you may not receive CHIA Data.

II. FEE INFORMATION

1. Consult the most current Fee Schedule for All-Payer Claims Database data.
2. After reviewing the Fee Schedule, if you have any questions about the application or data fees, contact apcd.data@state.ma.us.
3. If you believe that you qualify for a fee waiver, complete and submit the Fee Remittance Form and attach it and all required supporting documentation with your application. Refer to the Fee Schedule (effective Feb 1, 2017) for fee waiver criteria.
4. Applications will not be reviewed until the application fee is received.
5. Data for approved Applications will not be released until the payment for the Data is received.

III. ORGANIZATION & INVESTIGATOR INFORMATION

Project Title:	Cost Analysis of Plagiocephaly Treatment
IRBNet Number:	1811815-1
Organization Requesting Data (Recipient):	University of Massachusetts Chan Medical School, Division of Plastic and Reconstructive Surgery
Organization Website:	https://www.umassmed.edu/surgery/divisions-and-programs/plastic-surgery/about-us/
Authorized Signatory for Organization:	Janice F. Lalikos, MD
Title:	Professor of Surgery and Pediatrics
E-Mail Address:	janice.lalikos2@umassmed.edu
Telephone Number:	508-826-0911
Address, City/Town, State, Zip Code:	UMass Plastic Surgery Research Lab S4-745, 55 Lake Avenue North, Worcester MA 01655
Data Custodian: (individual responsible for organizing, storing, and archiving Data)	Jacob Wood, BS
Title:	Medical Student
E-Mail Address:	Jacob.wood@umassmed.edu
Telephone Number:	484-226-5502
Address, City/Town, State, Zip Code:	62 Dustin St, Unit 1, Worcester MA, 01604
Primary Investigator (Applicant): (individual responsible for the research team using the Data)	Janice F. Lalikos, MD
Title:	Professor of Surgery and Pediatrics
E-Mail Address:	Janice.lalikos2@umassmed.edu
Telephone Number:	508-826-0911
Address, City/Town, State, Zip Code:	UMass Plastic Surgery Research Lab S4-745, 55 Lake Avenue North, Worcester MA 01655
Names of Co-Investigators:	Sara Geraghty (Camilli), BS; Jing Xu, BS
E-Mail Addresses of Co-Investigators:	Scamilli@princeton.edu; jing.xu@umassmed.edu

IV. PROJECT INFORMATION

IMPORTANT NOTE: Organization represents that the statements made below as well as in any study or research protocol or project plan, or other documents submitted to CHIA in support of the Data Application are complete and accurate and represent the total use of the CHIA Data requested. Any and all CHIA Data released to the Organization under an approved application may ONLY be used for the express purposes identified in this section by the Organization, and for no other purposes. Use of CHIA Data for other purposes requires a separate Data Application to CHIA written request to CHIA, with approval being subject to CHIA’s regulatory restrictions and approval process. Unauthorized use is a material violation of your institution’s Data Use Agreement with CHIA.

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

- Epidemiological
- Longitudinal Research
- Reference tool
- Surveillance
- Inclusion in a product
- Health planning/resource allocation
- Quality of care assessment
- Research studies
- Student research
- Other (describe in box below)
- Cost trends
- Rate setting
- Severity index tool (or other derived input)
- Utilization review of resources

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.

Positional plagiocephaly is a skull deformity that can develop from an infant spending too much time on their back or in another position that applies pressure consistently to a certain part of the skull. There is little existing research focused on the financial costs of positional plagiocephaly treatment with orthotic helmets to either insurance providers or families of those affected. This study aims to analyze the current state of plagiocephaly treatment and diagnosis in Massachusetts and highlight communities that may need additional support and interventions. We will also investigate the willingness of insurance companies to provide coverage for orthotic helmet treatment as there is a history of limited insurance coverage (Jung and Yun, 2020). Upon evaluation of several insurance providers guidelines for coverage, most will consider coverage of orthotic devices in children under 12 months of age provided other more conservative and less expensive treatment options were previously explored (Aetna, United Healthcare, Premera (Blue Cross), and Cigna. Though we are interested in the rates of coverage by insurance companies for orthotic helmets, we are not interested in comparing the coverage offered by different companies nor are we interested in attempting to reverse engineer insurance plans. Our aim is to see what rates of insurance coverage are for this treatment as a whole with all companies averaged together.

The specific questions that we seek to answer with this study are...

- What proportion of positional plagiocephaly diagnoses are treated with orthotic helmets?
- Has the frequency of prescribing changed over the course of the years of data collected?
- How does the frequency of cranial orthotic prescribing differ between medically underserved areas (MUAs) and better served areas?
- What is the average cost of cranial orthotic devices through public insurance and private insurance?
- What is the frequency of insurance claim denials for cranial orthotic devices for positional plagiocephaly? Does this vary between private and public insurers?

References

Jung, B. K., & Yun, I. S. (2020). Diagnosis and treatment of positional plagiocephaly. *Archives of Craniofacial Surgery*, 21(2), 80–86. <https://doi.org/10.7181/acfs.2020.00059>

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

- Yes [If yes, a copy of the approval letter and protocol must be included with the Application package on IRBNet.]
- No, this Project is not human subject research and does not require IRB review.

4. **Research Methodology:** Applications must include either the IRB protocol or a written description of the Project methodology (typically 1-2 pages), which should state the Project objectives and/or identify relevant research questions. This document must be included with the Application package on IRBNet and must provide sufficient detail to allow CHIA to understand how the Data will be used to meet objectives or address research questions.

V. PUBLIC INTEREST

1. Briefly explain why completing this Project is in the public interest. Use quantitative indicators of public health importance where possible, for example, numbers of deaths or incident cases; age-adjusted, age-specific, or crude rates; or years of potential life lost. *Uses that serve the public interest under CHIA regulations include, but are not limited to: health cost and utilization analysis to formulate public policy; studies that promote improvement in population health, health care quality or access; and health planning tied to evaluation or improvement of Massachusetts state government initiatives.*

Completion of the project is in the public interest because one of the goals of this study is to identify communities in Massachusetts that are particularly vulnerable to positional plagiocephaly, which we hypothesize may be correlated with being medically underserved. This information would allow more targeted and focused attention on reducing the incidence of this condition in these communities.

VI. DATASETS REQUESTED

The Massachusetts All-Payer Claims Database is comprised of medical, pharmacy, and dental claims and information from the member eligibility, provider, and product files that are collected from health insurance payers licensed to operate in the Commonwealth of Massachusetts. This information encompasses public and private payers as well as data from insured and self-insured plans. APCD data are refreshed and updated annually and made available to approved data users in Release Versions that contain five calendar years of data and three months of run-out. For more information about APCD Release Versions, including available years of data and a full list of elements in the release please refer to release layouts, data dictionaries and similar documentation included on [CHIA's website](#).

Data requests are typically fulfilled on a one time basis, however; certain Projects may require future years of data that will become available in a subsequent release. Projects that anticipate a need for future years of data may request to be considered for a subscription. Approved subscriptions will receive, upon request, the same data files and data elements included in the initial Release annually or as available. Please note that approved subscription requests are subject to the Data Use Agreement, will require payment of fees for additional Data for Non-Government Entities, and subject to the limitation that the Data can be used only in support of the approved Project.

1. Please indicate below whether this is a one-time request, or if the described Project will require a subscription.

One-Time Request **OR** Subscription
2. Select Release Version and years of data requested (Release Versions and years not listed are not available).

<input type="checkbox"/> Release Version 7.0 <input type="checkbox"/> 2013 <input type="checkbox"/> 2014 <input type="checkbox"/> 2015 <input type="checkbox"/> 2016 <input type="checkbox"/> 2017	<input checked="" type="checkbox"/> Release Version 8.0 <input checked="" type="checkbox"/> 2014 <input checked="" type="checkbox"/> 2015 <input checked="" type="checkbox"/> 2016 <input checked="" type="checkbox"/> 2017 <input checked="" type="checkbox"/> 2018
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3. Specify below the data files requested for this Project, and provide your justification for requesting each file.

Medical Claims

Describe how your research objectives require Medical Claims data:

In order for us to achieve our research objectives, it will be necessary to have access to healthcare codes so that we may identify relevant diagnoses and treatments. We would also need access to payment information to develop a full picture of the average costs of a cranial orthotic helmet to treat positional plagiocephaly.

<input type="checkbox"/> Pharmacy Claims
Describe how your research objectives require Pharmacy Claims data: Click here to enter text.
<input type="checkbox"/> Dental Claims
Describe how your research objectives require Dental Claims data: Click here to enter text.
<input type="checkbox"/> Member Eligibility
Describe how your research objectives require Member Eligibility data: Click here to enter text.
<input type="checkbox"/> Provider
Describe how your research objectives require Provider data: Click here to enter text.
<input type="checkbox"/> Product
Describe how your research objectives require Product data: Click here to enter text.

VII. DATA ENHANCEMENTS REQUESTED

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

All-Payer Claims Database data is released in Limited Data Sets (LDS). All Organizations receive the “Core” LDS, but may also request the data enhancements listed below for inclusion in their analyses. Requests for enhancements will be reviewed by CHIA to determine whether each represents the minimum data necessary to complete the specific Project objective.

For a full list of elements in the release (i.e., the core elements and additional elements), please refer to [release layouts](#), [data dictionaries](#) and similar documentation included on CHIA’s website.

1. Specify below which enhancements you are requesting in addition to the “Core” LDS, provide your justification for requesting each enhancement.

a. Geographic Subdivisions

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

<input type="checkbox"/> 3-Digit Zip Codes (standard)	<input checked="" type="checkbox"/> 5-Digit Zip Codes***
<p>***If requested, provide justification for requesting 5-Digit Zip Code. Refer to specifics in your methodology: We request 5-digit zip codes because an important aim of our project is to identify communities in which infants are particularly prone to the development of positional plagiocephaly, which requires the increased precision of a 5 digit zip code. We also aim to examine the rates of positional plagiocephaly diagnosis in medically underserved areas and compare them to better served areas. For us to do this we will need 5 digit zip codes so that we may use the HUD crosswalk files to create a map of medically underserved areas. This would not be possible with only 3 digit zip codes.</p>	

b. Date Resolution

Select one option from the following options.

<input checked="" type="checkbox"/> Year (YYYY) (Standard)	<input type="checkbox"/> Month (YYYYMM) ***	<input type="checkbox"/> Day (YYYYMMDD) *** [for selected data elements only]
*** If requested, provide justification for requesting Month or Day. Refer to specifics in your methodology: Click here to enter text.		

c. National Provider Identifier (NPI)

Select one of the following options.

<input checked="" type="checkbox"/> Encrypted National Provider Identifiers (standard)	<input type="checkbox"/> Decrypted National Provider Identifiers***
*** If requested, provide justification for requesting decrypted National Provider Identifier(s). Refer to specifics in your methodology: Click here to enter text.	

VIII. MEDICAID (MASSHEALTH) DATA

1. Please indicate whether you are seeking Medicaid Data:

- Yes
 No

2. Federal law (42 USC 1396a(a)7) restricts the use of individually identifiable data of Medicaid recipients to uses that are directly connected to the administration of the Medicaid program. If you are requesting MassHealth Data, please describe, in the space below, why your use of the Data meets this requirement. *Your description should focus on how the results of your project could be used by the Executive Office of Health and Human Services in connection with the administering the MassHealth program*. Requests for MassHealth Data will be forwarded to MassHealth for a determination as to whether the proposed use of the Data is directly connected to the administration of the MassHealth program. CHIA cannot release MassHealth Data without approval from MassHealth. This may introduce significant delays in the receipt of MassHealth Data.

We would need access to Medicaid data to complete this project because we hope to compare the costs and coverage rates of orthotic helmet treatment for positional plagiocephaly between public and private insurance. Additionally, if we lacked data for patients using Medicaid, we would miss a large proportion those diagnosed with positional plagiocephaly which would have the potential to skew the results from this study and limit its utility.

3. Organizations approved to receive Medicaid Data will be required to execute a Medicaid Acknowledgment of Conditions. MassHealth may impose additional requirements on applicants for Medicaid Data as necessary to ensure compliance with federal laws and regulations regarding Medicaid.

IX. DATA LINKAGE

Data linkage involves combining CHIA Data with other data to create a more extensive database for analysis. Data linkage is typically used to link multiple events or characteristics within one database that refer to a single person within CHIA Data.

1. Do you intend to link or merge CHIA Data to other data?

Yes

No linkage or merger with any other data will occur

2. If yes, please indicate below the types of data to which CHIA Data will be linked. [Check all that apply]

Individual Patient Level Data (e.g. disease registries, death data)

Individual Provider Level Data (e.g., American Medical Association Physician Masterfile)

Individual Facility Level Data (e.g., American Hospital Association data)

Aggregate Data (e.g., Census data)

Other (please describe):

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

We plan reference a list of medically underserved areas as defined by the Health Services Administration, which will be converted from census tracts to 5 digit zip codes with the use of the HUD USPS Zip Code Crosswalk files to develop a map of medically underserved areas based on Zip code. This map we have created from HSA defined medically underserved areas will be used to see which patients in the database are from medically underserved areas so that we may analyze their data and compare it to those not residing in medically underserved areas.

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.

Zip codes and census tracts do not always match exactly so the zip code assigned to communities where this occurs will be selected based on which contains the largest proportion of the population, which is a suggested method of analysis by the HUD

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.

Source: <https://data.hrsa.gov/tools/shortage-area/mua-find>

List:

Medically Underserved Area/Population ID (MUA/P ID)

Service Area name

Designation type

Primary State name

County
 Index of medical underservice score
 Status
 Rural status
 Designation date
 Update date

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

To prevent the identification of individual patients we will not report information from any zip code on this map of medically underserved areas with a total number of patients less than 11.

X. PUBLICATION/DISSEMINATION/RE-RELEASE

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

We anticipate that the results of our analysis will be published in a professional journal, poster presentation, and/or a professional conference. After analysis of data, any cell that is less than 11 will be masked and not reported in any publications/presentations/etc.

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 only plan to disseminate the results of our analysis publically.

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?

The lowest geographical level of data that we expect to present is at the 5 digit zip code level. We will likely want to present a map. To ensure that individuals cannot be identified we will mask any regions with a total less than 11.

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

- Yes
 No

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

- Yes

No

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

Yes

No

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

Yes

No

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

Yes

No

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

Click here to enter text.

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

Click here to enter text.

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

Click here to enter text.

XI. APPLICANT QUALIFICATIONS

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

We do not have previous experience using claims data, but are accustomed to working with data that includes sensitive/private health information.

Janice F. Lalikos, MD is a board certified plastic surgeon and professor of surgery and pediatrics at UMass Chan Medical School with extensive experience in craniofacial surgery and treatment of positional plagiocephaly. She is the director of the craniofacial clinic and the section head of pediatric plastic surgery at UMass Memorial Medical Center.

Jacob Wood, BS and Jing Xu, BS are medical students at UMass Chan Medical School.

Sara Geraghty, BS is a PhD candidate at Princeton University. She has extensive experience working with large databases and an advanced knowledge of computer science and statistics.

2. **Resumes/CVs:** When submitting your Application package on IRBNet, include résumés or curricula vitae of the principal investigator and co-investigators. (These attachments will not be posted on the internet.)

XII. USE OF AGENTS AND/OR CONTRACTORS

By signing this Application, the Organization assumes all responsibility for the use, security and maintenance of the CHIA Data by its agents, including but not limited to contractors. The Organization must have a written agreement with the agent or contractor limiting the use of CHIA Data to the use approved under this Application as well as the privacy and security standards set forth in the Data Use Agreement. CHIA Data may not be shared with any third party without prior written consent from CHIA, or an amendment to this Application. CHIA may audit any entity with access to CHIA Data.

Provide the following information for **all** agents and contractors who will have access to the CHIA Data. [*Add agents or contractors as needed.*]

AGENT/CONTRACTOR #1 INFORMATION	
Company Name:	Click here to enter text.
Company Website	Click here to enter text.
Contact Person:	Click here to enter text.
Title:	Click here to enter text.
E-mail Address:	Click here to enter text.
Address, City/Town, State, Zip Code:	Click here to enter text.
Telephone Number:	Click here to enter text.
Term of Contract:	Click here to enter text.

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

Click here to enter text.

2. Describe the Organization's oversight and monitoring of the activities and actions of the agent or contractor for this Project, including how the Organization will ensure the security of the CHIA Data to which the agent or contractor has access.

Click here to enter text.

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

Yes

No

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

AGENT/CONTRACTOR #1 INFORMATION	
Company Name:	Click here to enter text.
Company Website	Click here to enter text.
Contact Person:	Click here to enter text.
Title:	Click here to enter text.
E-mail Address:	Click here to enter text.
Address, City/Town, State, Zip Code:	Click here to enter text.
Telephone Number:	Click here to enter text.
Term of Contract:	Click here to enter text.

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

Click here to enter text.

2. Describe the Organization’s oversight and monitoring of the activities and actions of the agent or contractor for this Project, including how the Organization will ensure the security of the CHIA Data to which the agent or contractor has access.

Click here to enter text.

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

- Yes
- No

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


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

XIII. ATTESTATION

By submitting this Application, the Organization attests that it is aware of its data use, privacy and security obligations imposed by state and federal law *and* confirms that it is compliant with such use, privacy and security standards. The Organization further agrees and understands that it is solely responsible for any breaches or unauthorized access, disclosure or use of CHIA Data, including, but not limited to, any breach or unauthorized access, disclosure or use by any third party to which it grants access.

Organizations approved to receive CHIA Data will be provided with Data following the payment of applicable fees and upon the execution of a Data Use Agreement requiring the Organization to adhere to processes and procedures designed to prevent unauthorized access, disclosure or use of data.

By my signature below, I attest: (1) to the accuracy of the information provided herein; (2) this research is not funded by a source requiring the release of raw data to that source; (3) that the requested Data is the minimum necessary to accomplish the purposes described herein; (4) that the Organization will meet the data privacy and security requirements described in this Application and supporting documents, and will ensure that any third party with access to the Data meets the data use, privacy and security requirements; and (5) to my authority to bind the Organization.

Signature: (Authorized Signatory for Organization)	
Printed Name:	Janice E. Lalikos, M.D.
Title:	Professor of Surgery and Pediatrics, Craniofacial Clinic Director
Date:	09/12/21

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.