Application for Massachusetts Case Mix and Charge Data (Non-Government)
[Exhibit A – Data Application]

I. INSTRUCTIONS

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

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

- Data Availability
- Fee Schedule
- Data Request Process

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

The Application and all attachments must be uploaded to 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:	Cannabinoid hyperemesis syndrome – resources and costs for outpatients and inpatients in Massachusetts pre- and post-cannabis legalization
IRBNet Number:	1926741-1
Organization Requesting Data (Recipient):	Tufts Medical Center, Inc.
Organization Website:	**Tuftsmedicalcenter.org**
Authorized Signatory for Organization:	Danielle Riggs
Title:	Director, Research Administration, Tufts Medical Center, Inc.
E-Mail Address:	tuftsmcgrantscontracts@tuftsmedicine.org
Telephone Number:	617-636-3566
Address, City/Town, State, Zip Code:	800 WASHINGTON AVENUE, BOSTON, MA, 02111
Data Custodian: **(individual responsible for organizing, storing, and archiving Data)**	**Sushrut Jangi**
Title:	Assistant Professor of Medicine
E-Mail Address:	sjangi@tuftsmedicalcenter.org
Telephone Number:	617 636 5883
Address, City/Town, State, Zip Code:	800 WASHINGTON STREET, BOSTON, MA 02111
Primary Investigator (Applicant): **(individual responsible for the research team using the Data)**	Sushrut Jangi
Title:	MD
E-Mail Address:	sjangi@tuftsmedicalcenter.org
Telephone Number:	617 636 5883
Address, City/Town, State, Zip Code:	800 WASHINGTON STREET, BOSTON, MA 02111
Names of Co-Investigators:	Julia Loughman
E-Mail Addresses of Co-Investigators:	Julia.Loughman@tufts.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   ☒ 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.

In 2004, cannabinoid hyperemesis syndrome (CHS) was first classified by the Rome IV committee. The definitions of CHS is consisted of following criteria: (1) stereotypical episodic vomiting resembling cyclical vomiting syndrome in terms of onset, duration and frequency (2) presentation after prolonged use of cannabis (3) relief of vomiting episodes by sustained cessation of cannabis use. With widespread national legalization of cannabis, the relationship among CHS and associated healthcare costs and utilizations are remained unclear. Thus, it is important to assess the shifts in healthcare utilization and estimated costs of hospital admissions related to the CHS. We have previously assessed the prevalence and costs of CHS-related hospitalizations at Tufts Medical Center (Marshall et al, 2023, Journal of Clinical Gastroenterology). However, we want to expand this to involve hospitals and community practices across the state. This study aims to describe the demographics, inpatient utilization, outpatient utilization, and cost of services among patients diagnosed with CHS predating and postdating marijuana legalization in Massachusetts based on all the medical centers' records in Massachusetts.

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

☐ Yes [*If yes, a copy of the approval letter and protocol <u>must</u> 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.*

This project will use the inpatient and outpatient data from all the medical centers in Massachusetts to evaluate the increasing incidence and prevalence of cannabinoid hyperemesis syndrome. Our study is specifically trying to describe the demographics, inpatient utilization, and costs of services to help formulate public policy. Additionally, it will help promote more efficient use of health care system to improve quality and access of health care.

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 ☒2021

Describe how your research objectives require Inpatient Discharge data:
We are using inpatient data to extract demographics (gender, age, self-reported cannabis exposure) and clinical variables (length of inpatient stay, frequency of utilization of lab panels, antiemetics, intravenous fluids, endoscopies, imaging, gastroenterology consults and intensive care unit days) alongside charges of the relevant hospitalizations.

☒ **Outpatient Hospital Observation Stay Data**
☐ 2004 ☐2005 ☐2006 ☐2007 ☐2008 ☐2009 ☐2010 ☐2011 ☒2012 ☒2013 ☒2014 ☒2015 ☒ 2016 ☒ 2017 ☒2018 ☒2019 ☒2020 ☒2021

Describe how your research objectives require Outpatient Hospital Observation Stay data:
We are using outpatient data to extract demographics (gender, age, self-reported cannabis exposure) and clinical variables (medications prescribed, duration of symptoms, frequency of utilization of lab panels, antiemetics, intravenous fluids, endoscopies, imaging, gastroenterology consults etc.) alongside charges of the relevant outpatient visits.

☒ **Emergency Department Data**
☐ 2004 ☐2005 ☐2006 ☐2007 ☐2008 ☐2009 ☐2010 ☐2011 ☒2012 ☒2013 ☒2014 ☒2015 ☒ 2016 ☒ 2017 ☒2018 ☒2019 ☒2020 ☒2021

Describe how your research objectives require Emergency Department data:
We are using ED visit data to extract demographics (gender, age, self-reported cannabis exposure) and clinical variables (frequency of utilization of lab panels, antiemetics, intravenous fluids, endoscopies, imaging, gastroenterology consults), alongside charges of the ED visits.

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^{TM} Software, and to the 3M APR^{TM} 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: Click here to enter text.			

Demographic Data

Select *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: Click here to enter text.	

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 individual dates, including the date - so that we can determine if the patient had multiple admissions, discharges, or procedures - including during the same month.		

Practitioner 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.

Click here to enter text.

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.

Click here to enter text.

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.

Click here to enter text.

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

Click here to enter text.

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 anticipate publishing this data in a peer-reviewed journal. The journal may be open-access depending on the journal to which this is submitted; if the journal is not Open Access, then the data can be made available to other researchers by deposition of the data and results in the journal's database repository (de-identified). No publications or data presentations will display a cell less than 11. To ensure this, we will collapse cells, coarsen data, or suppress cells as needed to protect the identity of individuals.

Furthermore, no identifying information is available for the individuals whose data is being analyzed in this study. Data being analyzed is not traceable back to specific individuals and as mentioned above, there will be cell suppression enacted if cell values are < 11.

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.

N/A

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. 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.

I have previously utilized single-center hospital data in retrospective studies. These data were previously collected following Institutional Review Board Approval, in which medical records were abstracted for relevant information, with statistical analysis performed on de-identified datasets. The majority of my prior work has examined the risk factors and clinical factors that play a role in exacerbating disease among patients with ulcerative colitis.

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.

-No agents or contracts will be used.

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.

N/A

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

N/A

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

    ☐ 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.

N/A

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

N/A

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

    ☐ Yes
    ☐ No

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

[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)	*Danielle Riggs*
Printed Name:	**Danielle Riggs**
Title:	Director, Research Administration, Tufts Medical Center
Date:	08/07/2023

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.