center for health information and analysis

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

I. INSTRUCTIONS

This form is required for all Applicants, except Government Agencies as defined in 957 CMR 5.02, requesting protected health information. *All Applicants must also complete the Data Management Plan, attached to this Application. The Application and the Data Management Plan must be signed by an authorized signatory of the Organization. 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. Applicants 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.

All attachments must be uploaded to IRBNet with your Application. All Application documents can be found on the CHIA website in Word and in PDF format or on IRBNet in Word format. If you submit a PDF document, please also include a Word version in order to facilitate edits that may be needed.

Applications will not be reviewed until the Application and all supporting documents are complete and the required application fee is submitted. A Fee Remittance Form with instructions for submitting the application fee is available on the CHIA website and IRBNet. If you are requesting a fee waiver, a copy of the Fee Remittance Form and any supporting documentation must be uploaded to IRBNet.

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:	MIT LEAPS Rheumatoid Arthritis Regimen Optimization Pilot
IRBNet Number:	1421740-1
Organization Requesting Data (Recipient):	MIT Center for Biomedical Innovation
Organization Website:	http://cbi.mit.edu/
Authorized Signatory for Organization:	Michael Leskiw
Title:	International Senior Contract Administrator, OSP
E-Mail Address:	mleskiw@mit.edu
Address, City/Town, State, Zip Code:	77 Mass Ave., Cambridge MA 02139-4307
Data Custodian: **(individual responsible for organizing, storing, and archiving Data)**	Korynn Stoyanoff
Title:	LEAPS Project Coordinator
E-Mail Address:	kstoyano@mit.edu
Telephone Number:	617-324-7763
Address, City/Town, State, Zip Code:	77 Mass Ave. Bld E19-604, Cambridge MA 02139-4307
Primary Investigator (Applicant): **(individual responsible for the research team using the Data)**	Kay Larholt
Title:	Director of Integrated Knowledge Systems
E-Mail Address:	klarholt@mit.edu
Telephone Number:	617-253-7333
Names of Co-Investigators:	Mark Trusheim, Daniel Mytelka, Steven Fox
E-Mail Addresses of Co-Investigators:	trusheim@mit.edu, mytelka@mit.edu, dsfox@mit.edu

IV. PROJECT INFORMATION

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
☐ Surveillance	☐ Student research	☐ Utilization review of resources
☐ Inclusion in a product	☒ Other (describe in box below)	

Characterize Rheumatoid Arthritis patient population and care in MA to identify treatment patterns, costs and opportunities for improvement.

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

The goal of the LEAPS Project is to design and pilot a learning ecosystem for rheumatoid arthritis that drives more value, faster, to patients, in ways that work for all stakeholders. This data will support the LEAPS feasibility study to identify the RA population, its characteristics, patient care patterns and opportunities for evidence generation to

improve that care.

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**: Applicants must provide 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 your 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.*

LEAPS generally, and the Rheumatoid Arthritis Massachusetts pilot (RAMA) specifically, aims to:

- Enhance evidence planning and production across the drug development life span to fuel sustainable, patient-centered innovation
- Apply systems engineering methods and tools to enable seamless, continuous learning and improvement across the innovation value chain (from R&D to care delivery) for a target disease
- Assess potential applications of transformative technologies and methods, such as blockchain and artificial intelligence/machine learning

This initial project will provide baseline data to assess the opportunities and feasibility of RAMA.

VI. DATA 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. Data requests will be fulfilled using the most current Release Version. For more information about the most current APCD Release Version, 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. 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. List years of data requested (only list years available in the current Release Version): 2012-2017

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

☒ One-Time Request **OR** ☐ Subscription

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:
Understanding the medical cost of Rheumatoid Arthritis patients and provide insights on differences in care and cost among sub-populations based on clinical and socio-economic factors.
☒ **Pharmacy Claims**
Describe how your research objectives require Pharmacy Claims data:
Characterize therapeutic use, sequencing, and switching times in general and by sub-populations.
☐ **Dental Claims**
Describe how your research objectives require Dental Claims data:
Not requested
☒ **Member Eligibility**
Describe how your research objectives require Member Eligibility data:
Care patterns can be influenced by insurer and continuity of coverage.
☒ **Provider**
Describe how your research objectives require Provider data:
Characterize differences in care based on sites of care such as RA 'centers of excellence' vs other specialists and/or primary care.
☒ **Product**
Describe how your research objectives require Product data:
Insurance coverage and medical policies influence therapeutic options available to RA patients.

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.

All-Payer Claims Database data is 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 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.

Geographic Subdivisions

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

☒ 3-Digit Zip Code (standard)	☐ 5-Digit Zip Code***
***If requested, provide justification for requesting 5-Digit Zip Code. Refer to specifics in your methodology:	

Date Resolution

Select *one* option from the following options.

☐ Year (YYYY) (Standard)	☐ Month (YYYYMM) ***	☒ Day (YYYYMMDD) *** [for selected data elements only]
*** If requested, provide justification for requesting Month or Day. Refer to specifics in your methodology: Time on therapy is an important indicator of therapy success and an opportunity for regimen improvement. Typical time to treatment discontinuation is 4-6 months so daily data is preferred to develop accurate estimates. Similarly understanding patient journeys among providers would best be done with daily data.		

National Provider Identifier (NPI)

Select *one* of the following options.

☐ Encrypted National Provider Identifier(s) (standard)	☒ Decrypted National Provider Identifier(s)***
*** If requested, provide justification for requesting decrypted National Provider Identifier(s). Refer to specifics in your methodology: Decrypted identifiers necessary to distinguish RA centers of excellence, specialists, and general practitioners.	

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.

Characterize Rheumatoid Arthritis patient population and care in MA to identify treatment patterns, costs, and opportunities for improvement.

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.

The physician master file will be used as a lookup to identify rheumatologists and rheumatology centers of excellence.

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.

We'll be using the AMA file as a lookup for specialty.

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.

All APCD variables plus the following specialty and demographics physician fields: (1) Specialty-primary and secondary: for COE and specialty grouping, (2) Hospital affiliation: to cross check APCD claims, (3) Type of practice: to aid in COE assignment, and (4) Graduation year: basic demographic.

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

All research results will be grouped by center of excellence, speciality, or similar and not by individual provider.

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.

The summary results of our analysis could appear in LEAPS issued publications such as Research Briefs and white papers and potentially in conference poster presentations, conference presentations or journal publications. We do not intend to publish/disseminate/re-release the underlying detailed data in any way.
We will comply fully with the Data Use Agreement and use a combination of programming and manual QC review of any results to ensure that a cell count of less than 11 will not be disclosed.

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 expect to use CHIA data for non-commercial exploratory work supportive of the overall LEAPS project goals - to design and pilot a learning ecosystem for rheumatoid arthritis that drives more value, faster, to patients, in ways that work for all stakeholders. This data will support the LEAPS feasibility study to identify the RA population, its characteristics, patient care patterns and opportunities for evidence generation to improve that care.

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?

We will summarize data on treatment patterns at the level of Rheumatology Centers of Excellence (COEs) in Massachusetts.

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?

9. If you have answered "yes" to questions 5, 6, 7 or 8, please describe the types of products, software, services, or tools.

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?

XII. 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.

Dr. Larholt is a seasoned statistical professional with 30 years of experience in the Pharmaceutical, Biotechnology, and Medical Device industry. She has global experience with all phases of clinical trials and regulatory submissions. An experienced statistical collaborator providing strategic input to clinical program design and analysis, she has supervised large groups of statisticians, statistical programmers, data managers and medical writers. In addition to her experience with the approval process for therapeutics and devices, Dr. Larholt has applied her expertise to the post-approval setting, in particular studying the effectiveness of products and their value to patients and medical providers in the real world. Dr. Larholt has extensive experience in the design, implementation and analysis of prospective observational studies and Pragmatic Clinical Trials including integrating administrative claims data with clinical data to answer real-world research questions. She has implemented technology solutions to enhance the capability of the group and oversaw integration of administrative claims data into the design and analysis of pragmatic studies.

Mark Trusheim used commercial and Medicare claims data in his role as Monsanto Health Solutions VP of Technology Businesses to create a Virtually Integrated Health Management System as implemented in California and the subject of US patent 6,385,589.

Dr. Fox has significant research experience analyzing claims-based and other big data. Most recently, he oversaw analysis of both Optum and Humana derived claims data to assess the impact of primary and secondary preventative treatment for cardiovascular diseases. He has also recently analyzed EHR-derived data from the Sutter Health System to assess the clinical effectiveness of a pharmacist-led program to reduce hospital readmissions, and EHR data from the VA to determine the comparative effectiveness of various direct acting anti-viral agents to treat Hepatitis C infection. His earlier work included collaborating on a large Medicare claims-based analysis examining the impact of physician care continuity on patient outcomes.

Dr. Mytelka has significant experience designing and interpreting studies that utilize claims data. He has also worked extensively with other large datasets including patient data (clinical trials, EHR, chart extractions), where he has personally led some analyses in addition to design and interpretation roles. Recent publications involving claims data include analyses of the costs of rare genetic disorders, gastric cancer and pancreatic cancer.

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.)

XIII. USE OF AGENTS AND/OR CONTRACTORS

By signing this Application, the Agency assumes all responsibility for the use, security and maintenance of the CHIA Data by its agents, including but not limited to contractors. The Agency 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:	
Company Website	
Contact Person:	
Title:	
E-mail Address:	
Address, City/Town, State, Zip Code:	
Telephone Number:	
Term of Contract:	

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

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.

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.

AGENT/CONTRACTOR #2

INFORMATION	
Company Name:	
Company Website:	
Contact Person:	
Title:	
E-mail Address:	
Address, City/Town, State, Zip Code:	
Telephone Number:	
Term of Contract:	

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

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.

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]

IVX. 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.

Applicants 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) that the requested Data is the minimum necessary to accomplish the purposes described herein; (3) 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 (4) to my authority to bind the Organization.

Signature: (Authorized Signatory for Organization)	
Printed Name:	M
Title:	International Senior Contract Administrator, Office of Sponsored Programs, MIT

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.

[INSERT IRB approval letter and protocol, or research methodology]