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:	**An assessment of the relationship between clinical volume and medical malpractice claims risk as a means of identifying patient safety vulnerabilities**
IRBNet Number:	
Organization Requesting Data (Recipient):	**CRICO**
Organization Website:	https://www.rmf.harvard.edu/
Authorized Signatory for Organization:	**Luke Sato, M.D.**
Title:	Senior Vice President and Chief Medical Officer, CRICO Assistant Clinical Professor of Medicine, Harvard Medical School
E-Mail Address:	LSato@rmf.harvard.edu
Address, City/Town, State, Zip Code:	1325 Boylston Street, 7th floor, Boston, MA 02215
Data Custodian: **(individual responsible for organizing, storing, and archiving Data)**	**Adam Schaffer, M.D., M.P.H.**
Title:	Senior Clinical Analytics Specialist, CRICO Assistant Professor of Medicine (Part-Time), Harvard Medical School
E-Mail Address:	ASchaffer@rmf.harvard.edu
Telephone Number:	617-450-6889
Address, City/Town, State, Zip Code:	1325 Boylston Street, 7th floor, Boston, MA 02215
Primary Investigator (Applicant): **(individual responsible for the research team using the Data)**	**Adam Schaffer, M.D., M.P.H.**
Title:	Senior Clinical Analytics Specialist, CRICO Assistant Professor of Medicine (Part-Time), Harvard Medical School
E-Mail Address:	ASchaffer@rmf.harvard.edu
Telephone Number:	617-450-6889
Names of Co-Investigators:	1325 Boylston Street, 7th floor, Boston, MA 02215
E-Mail Addresses of Co-Investigators:	ABabayan@rmf.harvard.edu (Astrid Babayan, Ph.D.)

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)

CRICO is the malpractice liability carrier for the Harvard Medical Institution, and CRICO would like to use the CHIA data in order to express medical malpractice claims rates as claims per unit of clinical volume. Specifically, we would use claims per patient encounter and claims per amount charged, both annualized, as more nuanced claims rates than what is available currently, which is claims per physician coverage year. More broadly, we want to examine the relationship between the volume, type, and setting of physicians' clinical activity and their malpractice claims risk. The overall goal is to be able to better explain the factors underlying trends in claims rates, in order to identify patient safety vulnerabilities so that they can be remedied.

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.

As noted above, CRICO is the malpractice liability carrier for the Harvard Medical Institution. CRICO is a captive insurer, meaning that it is owned by the Harvard Medical Institutions that it insures. As part of its data analytic operations, CRICO examines trends in the medical malpractice claims rates among the hospitals and various medical specialties it insures. Currently, malpractice claims rates are typically expressed as malpractice claims per physician coverage year (PCY). In a given year, some physicians may be engaged in patient care activities full time, whereas others may be predominantly performing research and have minimal clinical responsibilities. PCYs do not capture this difference between the clinical volume of various physicians. Unpublished pilot research CRICO has performed shows that clinical volume is an important determinant of malpractice risk. CRICO wants to use APCD data so that it can take clinical volume into account when examining claims rates and trends in claims rates. The two main clinical volume metrics that would be calculated by CRICO using APCD data are annual number of patient encounters and annual amount charged, both at the level of the individual physician. Having these metrics would allow CRICO to express malpractice claims rates as claims per patient encounter and claims per amount charged. These novel claims rates would allow CRICO to better assess whether volume is a factor underlying trends in claims rates. A typical use case would be that one of CRICO's members expands its emergency department, and subsequently an uptick in the number of emergency department malpractice claims is noted. Being able to calculate claims per patient encounter and claims per amount charged for the emergency department physicians would allow CRICO to determine whether or not the increase in the claims rate is being driven by an increase in clinical volume. By being able to tease out the contribution from clinical volume to trends in malpractice claims rates, CRICO can then determine when clinical volume does not appear to be driving claims rates trends, which could suggest a patient safety issue. Identifying such patient safety issues is a core part of CRICO's mission, which includes promoting patient safety. More broadly, we want to examine how the volume, type, and setting of physicians' clinical activity relates to their malpractice claims risk. We are not aware of any relevant published literature in this area.

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.*

As discussed above, the ultimate goal of the APCD data we are requesting is to support CRICO's mission of promoting patient safety. One of the limitations of the data the CRICO currently uses to examine malpractice claims rate trends is the lack of information on clinical volume. Given that an increase in clinical volume can drive an increase in malpractice claims rates, it is important for CRICO to be able to determine when an increase in the rate of malpractice claims is being driven by factors other than clinical volume, because this could suggest that there is a patient safety issue that needs to be addressed. The patient safety lessons that CRICO draws from it data analyses are shared with its member institutions (the Harvard-affiliated medical institutions), and many of CRICO's patient safety and data analytic publications are publicly available (https://www.rmf.harvard.edu/Clinician-Resources). CRICO's scope within Massachusetts is broad: 26 hospitals, 14,009 physicians, more than 300 other health care organizations, and in excess of 100,000 other clinicians and employees. CRICO insures 45.1% of all physicians in Massachusetts (40.9% exclusive of residents and fellows). Therefore, CRICO's activities advancing patient safety, which would be supported by the APCD data that CRICO is requesting, would promote an improvement in health care quality and population health within the Commonwealth.

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): 2013-2017 (or most recent current release)

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:

As described above, the two key metrics of physician volume we want to calculate using APCD data are number of patient encounters per year by physician, and the amount charged per year by physician. The amount charged is present as a column in the Medical Claims file. To calculate number of patient encounters, we would count the number of unique MEMBERLINKEID numbers per day by physician and sum those over the course of the year. Secondary patient care type attributes we are interested in are those that characterize the type, amount, and location

of care provided, such as principal diagnosis and other diagnoses, the procedure code cleaned, the procedure modifier, and any available variables specifying the site and setting of the clinical service provided.

☐ **Pharmacy Claims**

Describe how your research objectives require Pharmacy Claims data:

☐ **Dental Claims**

Describe how your research objectives require Dental Claims data:

☐ **Member Eligibility**

Describe how your research objectives require Member Eligibility data:

☒ **Provider**

Describe how your research objectives require Provider data:

Our objective is to link the information on physician volume with CRICO's malpractice claims data. To perform this linkage, we would need the unencrypted National Provider Identifier (NPI). We are also interested in examining other attributes of providers' practice patterns that may be associated with liability risk, including information on the practice settings and practice type that might be included with the provider file.

☐ **Product**

Describe how your research objectives require Product data:

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:**

Among the key clinical volume metrics we want to calculate as part of our project is the number of patient encounters at the physician level. Based on our experience analyzing the older APCD extract we received from CHIA, we are requesting the specific day (YYYYMMDD) of service, which we need in order to determine the number of unique patient encounters (and which we received as a dataset revision to our prior APCD extract). Since there can be multiple charges as part of each patient encounter, we would use the MEMBERLINKEID and specific day of service to determine the number of patients a clinician has seen on a given day. This would allow us to avoid counting an individual patient who has multiple charges on a given day multiple times.

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:**

We are requesting the decrypted National Provider Identifier since we want to link the physician-level clinical volume metrics we will calculate from the Medical Claims file to CRICO's physician-level malpractice claims data, for which we need a decrypted unique physician identifier, such as National Provider Identifier.

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.

Our analytic objectives for the MassHealth Data would mirror those for the other components of the APCD data. We would use any MassHealth data we receive to calculate the clinical volume of the physicians CRICO covers, based on the services the physicians have billed for (e.g., number of encounters and amount billed). Determination of the clinical volume of the physicians CRICO covers would, in turn, allow CRICO to tease out when increases in the malpractice claims rates are being driven by clinical volume, and when clinical volume is not the driver of increases in malpractice claims rates. When clinical volume is not the driver of an increase in malpractice claims rates, that suggests that a quality-of-care or patient safety issue may exist. We consider it important to identify any quality-of-care or patient safety issues, so that we can explore ways to remedy them with the affected institution. One way in which CRICO is uniquely situated to use clinical volume data, including MassHealth data, to promote patient safety is by serving a benchmarking role. As the malpractice insurer for all the Harvard-affiliated medical institutions, CRICO can compare malpractice claims rates per unit of clinical volume among its insured hospitals of similar size and other characteristics (e.g., academic or community), to see if there are institutions or departments that appear to be outliers in terms of malpractice claims per unit of clinical volume. When outliers are found, this suggests that a quality-of-care or patient safety issue may exist, which we would work to address. This is another way in which CRICO can identity patient safety vulnerabilities that need to be explored, consistent with its mission of promoting patient safety. If CRICO were fortunate enough to receive MassHealth data for analysis, we would, as appropriate, perform subgroup analyses using MassHealth data, to see if there were any patient safety issues we could identify that are specific to the MassHealth population. We believe our analysis using MassHealth data would be of benefit to MassHealth recipients and the Executive Office of Health and Human Services by helping to promote and enhance patient safety and quality of care among MassHealth recipients. MassHealth data would be aggregated at the level of the physician, with the smallest time period being one year, and so our analyses would not enable the identification of any individual MassHealth recipients.

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 will be linking the physician-level clinical volume metrics we will calculate from the Medical Claims file to CRICO's medical malpractice claims data for its insured physicians. This will allow us to determine the average claims rate among physicians at different clinical volume strata. The primary clinical volume metrics we will be linking to our insured physicians and malpractice claims data are amount charged and number of patient encounters. Other variables that we plan to link to our data include those that characterize the type, amount, and location of care provided, such as amount allowed, principal diagnosis and other diagnoses, the procedure code cleaned, the procedure modifier, and any available variables specifying the site and setting of the service provided. The overall goal is to examine the relationship between amount and type of clinical services provided and malpractice claims rate.

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.

The linkage between the physician-level Medical Claims data from CHIA and malpractice claims data from CRICO will be performed using deterministic matching based on NPI.

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.

CHIA variables to be included: NPI, NATIONALBILLINGPROVIDERIDCLEANED, MEDICALCLAIMID, Date of Service (YYYYMMDD), MEMBERLINKEID, LINECOUNTER, VERSIONNUMBER, VERSIONINDICATOR, HIGHESTVERSIONDENIED, HIGHESTVERSIONINDICATOR , MEMBERGENDERCLEANEDLDS, MEMBERSTATEORPROVINCELDS, ADMISSIONDATEYEAR, ADMISSIONTYPE, SERVICEPROVIDERNUMBER_LINKAGE_ID, SERVICEPROVIDERSPECIALTYCLEANED, SERVICEPROVIDERSTATELDS, SERVICEPROVIDERZIP_3, ADMITTINGDIAGNOSISCLEANED, ECODECLEANED, PRINCIPALDIAGNOSISCLEANED, OTHERDIAGNOSIS1CLEANED, OTHERDIAGNOSIS2(-12)CLEANED, PROCEDURECODECLEANED, REVENUECODECLEANED, E&M code (Y/N), PROCEDUREMODIFIER1, PROCEDUREMODIFIER2, QUANTITY, ICD9CMPROCEDURECODECLEANED, QUANTITY, CHARGEAMOUNTCLEANED, PAIDAMOUNTCLEANED, ALLOWEDAMOUNTCLEANED, NONCOVEREDAMOUNTCLEANED, PAYMENTARRANGEMENTTYPECLEANED, OTHERICD9CMPROCEDURECODE1CLEANED, OTHERICD9CMPROCEDURECODE2CLEANED, GLOBALPAYMENTFLAG, DENIEDFLAG, PROVIDERLOCATION_LINKAGE_ID
These CHIA variables would be linked via NPI to the following CRICO variables:
Insured physician, did the insured physician have a malpractice claim (Y/N) and, if so, the malpractice claim ID. These CRICO variables would be stratified by year.
No information on individual providers would be reported. The type of analysis that would be reported would be average malpractice claims per 100 PCY, per 1000 patient encounters, and per $10,000 charged, all broken down by a clinical volume percentile (likely 5- or 10-percentile increments), which would mean > 1000 physicians in each cell.

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

The CRICO data we are linking to concerns malpractice claims against physicians, and this malpractice data does not contain the name or other personally identifying information about the patient (claimant). The data linkage will not significantly increase the likelihood of individual patients being identified in the APCD data compared to the unlinked APCD data. We have no interest in identifying individual patients and would never attempt to do so. As described in more detail below, the types of analyses CRICO would report would include > 1000 physician in each cell, and so there is no significant risk of any individual physician being identifiable in any analysis reported by CRICO. Moreover, the APCD data, and linked data, will remain behind the CRICO firewall, accessible only from password-protected computers with antivirus software. The malpractice claims data against physicians is sensitive for the physicians. Malpractice claims data is one of the core types of data collected and analyzed by CRICO, and CRICO has data privacy and security protocols in place, as described in the Data Security and Integrity section, to ensure the security of the data. In addition, CRICO has a Chief Security Officer and Security Engineer to ensure CRICO adheres to best practices with respect to information security.

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 would try to publish our results in a peer-reviewed academic journal, if they are of sufficient interest. I would expect the analysis we would publish would report physician malpractice risk per unit of clinical volume versus a measure of physician clinical volume, such as clinical volume ventile or decile, based on amount charged. Publication of such an analysis would not pose a risk of exposing data on individual patients or providers.

The following approximate calculations should provide a general sense of the cell sizes in our analysis. Our prior APCD dataset had about 1 billion rows of data in the Medical Claims file. CRICO insures about 10,050 physicians (excluding residents and fellows, who typically do not submit charges to health insurers). Based on a 2016 Massachusetts Physician Workforce Profile from the Association of American Medical Colleges Center for Workforce Studies (https://www.aamc.org/download/484550/data/massachusettsprofile.pdf), there were 30,213 (total)-5,630 (residents)=24,583 active physicians in Massachusetts in 2016 (excluding residents). Thus CRICO insures about 40.9% of Massachusetts physicians, and we would only be using the medical claims from physicians insured by CRICO. We would stratify malpractice risk by clinical volume. In past similar analyses, we have divided clinical volume into ranked ventiles (5-percentile increments). Assuming, to be conservative, that we divided clinical volume into ranked 1-percentile increments, we would expect our cells sizes to be approximately=(1,000,000*0.409)/100=4088. Though these calculations are approximate, they show that the rough cell sizes used in our analysis would be more than two orders of magnitude greater than the minimum cell size.

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 will report the results of our analyses to CRICO's member institutions, which include the Harvard-affiliated medical institutions, as well as to the corporate parents of the Harvard-affiliated medical institutions, such as Partners HealthCare and Beth Israel Lahey Health.

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 not be presenting any geographical analysis, and will not be presenting any maps.

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.

The two investigators who will be involved with using the APCD dataset, if provided, are Adam C. Schaffer, M.D., M.P.H. and Astrid K. Babayan, Ph.D. Both are employed by CRICO, and, as part of CRICO policy, have received training regarding HIPAA compliance and safeguarding protected health information. Both also have extensive experience using sensitive medical malpractice data. Both have previously worked with an APCD dataset (IRBNet# 770331-1) similar to the one being requested as part of this application.

Adam C. Schaffer, M.D., M.P.H.
Adam is a Senior Clinical Analytics Specialist at CRICO, and has performed analyses using malpractice claims data, National Practitioner Data Bank data, APCD data, and clinical volume data provided by one of the Harvard-affiliated medical institutions. Adam received a B.A. from Yale College, an M.D. from the University of Pennsylvania School of Medicine, and an M.P.H. from the Harvard T.H. Chan School of Public Health. Adam also serves as a practicing hospitalist physician at Brigham and Women's Hospital and is an Assistant Professor of Medicine, Part-time, at Harvard Medical School.

Astrid K. Babayan, Ph.D.
Astrid is CRICO's Data Scientist. She serves as an in-house expert to research, evaluate, and implement advanced analytic techniques for malpractice data evaluation. Astrid performs SAS programming, data analysis, statistical modeling, and other analytical work needed to support the work of the CRICO Patient Safety department. In her current role, she has worked with large datasets such as the APCD, mentors other team members on quantitative methodologies, and has introduced various tools including, JMP, Power Pivot, and Tableau, which have now been incorporated into other's work. Astrid received her Ph.D. in Industrial Engineering and Operations Research from the University of Illinois at Chicago and her M.S. in Applied Mathematics from Yerevan State University in Armenia.

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.]* **No contractors will have access to the data.**

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:	**Luke Sato, M.D.**
Title:	Senior Vice President and Chief Medical Officer, CRICO Assistant Clinical Professor of Medicine, Harvard Medical School

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)