center for health information and analysis

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@chiamass.gov if you have additional questions about how to complete this form.

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

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

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

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

II. FEE INFORMATION

1. Consult the most current Fee Schedule for 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@chiamass.gov.

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:	"Too many, too much, too young": Trends of Pediatric Psychotropic Polypharmacy in Massachusetts Before and During the COVID-19 Pandemic
IRBNet Number:	2228515-1
Organization Requesting Data (Recipient):	University of Massachusetts Boston
Organization Website:	https://www.umb.edu/
Authorized Signatory for Organization:	**Shala Bonyun**
Title:	Associate Director of ORSP Pre-Award Services
E-Mail Address:	Shala.Bonyun@umb.edu
Telephone Number:	617.287.5592
Address, City/Town, State, Zip Code:	100 Morrissey Blvd, Boston, MA 02125
Data Custodian: **(individual responsible for organizing, storing, and archiving Data)**	**Alison Murray**
Title:	Senior Information Security Specialist
E-Mail Address:	alison.murray@umb.edu
Telephone Number:	617.287.6711
Address, City/Town, State, Zip Code:	100 Morrissey Blvd, Boston, MA 02125
Primary Investigator (Applicant): **(individual responsible for the research team using the Data)**	Lisa Cosgrove and Gianna D'Ambrozio
Title:	Professor
E-Mail Address:	Lisa.cosgrove@umb.edu
Telephone Number:	617.287.7748
Address, City/Town, State, Zip Code:	100 Morrissey Blvd, Boston, MA 02125
Names of Co-Investigators:	Gianna D'Ambrozio
E-Mail Addresses of Co-Investigators:	Gianna.dambrozio001@umb.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 **or** written request to CHIA, with approval being subject to CHIA's regulatory restrictions and approval process. Unauthorized use is a material violation of your Organizations'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.

The purpose of this study is to assess the current practice of and factors associated with the use of polypharmacy in pediatric populations in Massachusetts. Youth in the U.S. and internationally are increasingly being diagnosed with depression and related psychiatric conditions (Murthy, 2021) many of whom are being subjected to non-evidence-based, or what has been termed irrational, psychotropic polypharmacy (Barnett & Concepcion Zayas, 2019). Psychotropic polypharmacy can be defined as "the use of 2 or more psychiatric medications in the same patient" (Zito et al., 2021), though definitions can vary. In psychopharmacology, there are five major classes of psychotropic medications to treat mental health disorders: anxiolytics, antidepressants, antipsychotics, anticonvulsants, and stimulants. Therefore, based on the definition used in the current study, if a child is prescribed two or more of these medications concurrently, whether it is within class (e.g., three antipsychotics) or multi-class (e.g., an antidepressant and an anxiolytic), it would be considered psychotropic polypharmacy.

In this study, the characteristics and demographics of children in Massachusetts who have the highest utilization rate of psychotropic polypharmacy will be identified (e.g., health insurance type (public insurance, private insurance, etc.), age (aged 17 years or younger), sex (female, male, intersex, etc.), geographic area (based on zip-code poverty rates), and psychiatric diagnosis. Thus, the results of this study can help identify which children are most at-risk for psychotropic polypharmacy. In turn, the data can be used to inform MLPs and public policy in Massachusetts. Past research has evaluated psychotropic polypharmacy rates in the United States as a whole, with some research on individual states (see also, Radel et al., 2023; Chiang et al., 2024; Zhu et al., 2024); however, there has not been research conducted on psychotropic polypharmacy in children in Massachusetts.

Additionally, this study will analyze the changes in pediatric psychotropic polypharmacy rates before the COVID-19 pandemic (2018-2019) and during the pandemic (2020-2022). Investigating the changes in pediatric psychotropic polypharmacy rates by year can give insight to the effects of COVID-19 on mental health diagnoses and prescribing practices in Massachusetts based on health insurance, age, sex, and geographic area. Lastly, this study will identify which classes of psychotropic medications are being prescribed concurrently at the highest rates by year and investigate if the COVID-19 pandemic influenced changes in prescription combinations. There is a gap in the research on examining the pediatric psychotropic polypharmacy changes during the COVID-19 pandemic in the United States as a whole and in individual states. Therefore, my main research questions are:

1. What are the factors associated with high rates of polypharmacy? For example, can health insurance type (public insurance, private insurance, etc.), age (ages 5 and under, ages 6-11, and ages 12-17), sex (female, male, intersex, etc.), and geographic area (based on zip-code poverty rate) predict the risk for pediatric polypharmacy?
2. What psychiatric diagnoses are highly associated with psychotropic polypharmacy?
3. Was there an increase in pediatric psychotropic polypharmacy rates in Massachusetts during the COVID-19 pandemic (2020-2022) as compared to the rates two years before the pandemic (2018 and 2019)?
4. Which classes of psychotropic medications are being prescribed concurrently at the highest rates by year from 2018 to 2022?

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.*

Youth in the U.S. and internationally are increasingly being diagnosed with depression and related psychiatric conditions (Office of the Surgeon General, 2021), many of whom are being subjected to non-evidence-based, or what has been termed irrational, psychotropic polypharmacy (Barnett & Concepcion Zayas, 2019). Pediatric psychotropic polypharmacy in the United States and internationally has increased in the past 25 years (Steinhausen, 2015). Contributing factors include unsupported assumptions about the efficacy of combinations, limited professional awareness of the side effects of using multiple medications, and practicing medicine in a culture that values expediency over patient-centered care (Zito et al., 2021; Rosenheck, 2005; Glickel, 2009). Over the last decade, there has been increased concern about concomitant psychotropic drug use in pediatric populations, especially for youth living in poverty, in foster care, or who are racialized or marginalized. The fact that the long-term effects of polypharmacy are unknown is particularly concerning. There are also no data to support its safety and efficacy in children and adolescents (Jureidini et al., 2013; McLaren & Lichtenstein, 2019; Linton et al., 2013; Burcu et al., 2017), and there is emerging evidence of a poor risk-benefit ratio for harms (Al Jumaili et al., 2022; Brophy et al., 2018; Sarkar, 2017; Gopal et al., 2012). Inappropriate off-label use of psychotropics, particularly antipsychotics for behavioral control, appears to be a driving force (Meng et al., 2022; Hoekstra & Dietrich, 2022; Kelleher et al., 2020). In the U.S., researchers found that in at least 5 states, one-third of children in foster care who were prescribed psychiatric medications did not receive treatment planning or adequate monitoring (Levinson, 2018). Some states are providing greater oversight in prescribing psychotropic medications and this study's results could help inform Massachusetts' prescribing legislation. Fortunately, as more attention is being placed on the unsupported practice of pediatric polypharmacy, new laws are being developed that use a human rights framework. For example, in California, a child in foster care cannot be administered medications for psychiatric conditions unless there is judicial approval (Gretter, 2021). Youth are specifically asked about their feelings on starting to take medication and there is a form (albeit optional) in which child welfare staff seek out feedback from the children they serve, allowing for greater engagement and more genuine participation in treatment decisions. Similarly, Missouri recently enacted legislation that is congruent with the right to be heard "in any judicial and administrative proceedings affecting the child" (Missouri Department of Social Services, n.d.). Following a meeting with their prescriber, children ages 12 and older have the right to refuse psychotropic medication and have a judge review their refusal to assent (Gretter, 2021). As a result of this legislation, there has already been a reduction in psychotropic drugs prescribed to children in foster care in these two states (Missouri Department of Social Services, n.d.; Nunes et al., 2022).

This study aims to shed light on the overmedicalization and overtreatment of children who have been exposed to psychotropic polypharmacy in Massachusetts, as well as contribute to the human rights efforts in this area. The data results from this study could inform the practice of medical-legal partnerships in Massachusetts. A medical-legal partnership (MLP) is a "collaborative intervention that embeds civil legal aid professionals in healthcare settings to address seemingly intractable social problems that contribute to poor health outcomes and health disparities" (Regenstein et al., 2018, para. 1). The first MLP was established in Massachusetts at the Pediatrics Department at Boston Medical Center in 1993; MLPs have now expanded to more than four hundred in the nation and twelve in Massachusetts alone (MLPB, 2022). MLPs address health-harming legal needs and social determinants of health in an accessible healthcare setting to promote health equity.

This study will identify the characteristics and demographics of children in Massachusetts with the highest utilization rate of pediatric psychotropic polypharmacy. In doing so, the results may help MLPs in Massachusetts identify subpopulations of children who are most vulnerable to psychotropic polypharmacy and may need intervention and support from a medical-legal partnership. Since MLPs can operate at both the individual and population levels, the results of this study may identify a health inequity at the population level of children in Massachusetts. Thus, I could consult with local MLPs, such as the Medical Legal Partnership Boston at Boston Medical Center and the Children's Law Center of Massachusetts at Massachusetts General Hospital-Chelsea HealthCare Center (MGH-Chelsea), to develop specific strategies to address the problem of psychotropic polypharmacy in marginalized populations of children based on the study's findings of potential identified health inequities. These strategies could include the involvement of health care advocates at psychiatric appointments and the promotion of family-based wraparound services for children and adolescents. Additionally, the results of this study can influence public policy. MLPs advocate for structural policy changes at an institutional, local, state, and federal level. MLP attorneys bring a "patient-to-policy" perspective, identifying needs in the communities they serve, and then they work to improve policies and laws that impact those communities and ultimately, the social determinants of individual and population health (Bowen Matthew, 2017).

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 fully-insured and self-insured plans. APCD data are refreshed and updated annually and made available to approved data users. For more information about APCD data, including available years of data and a full list of elements in the database, please refer to 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 are 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. CHIA is currently supporting requests for claims data from 2016 to 2022. Requests made outside of these years may not be supported by CHIA and will be considered on a case-by-case basis. Please specify the years of data that are being requested: 2018-2022.

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: The research objectives require Medical Claims data as I seek to select members with psychosocial disabilities and analyze the healthcare utilization of psychotropic medications to assess the current practice of and factors associated with the use of polypharmacy in pediatric populations in Massachusetts.
☒ **Pharmacy Claims**
Describe how your research objectives require Pharmacy Claims data: The research objectives require Pharmacy Claims data as I seek to analyze psychotropic polypharmacy in the pharmacy claims in members by month, in order to determine the the characteristics and demographics of children in Massachusetts who have the highest utilization rate of psychotropic polypharmacy.
☐ **Dental Claims**
Describe how your research objectives require Dental Claims data: Click here to enter text.
☒ **Member Eligibility**
Describe how your research objectives require Member Eligibility data: The research objective requires Member Eligibility for member selection criteria (amount of continuous enrollment to ensure the detection of diagnosis/treatment, demographic/geographic features, insurance type, and possibly, in Medicaid, a flag for disability status, and for descriptive categorization of the data (age groups, rurality).
☒ **Provider**
Describe how your research objectives require Provider data: The research objective requires Provider data to link prescriber data to NPPES data to determine provider specialty.
☐ **Product**
Describe how your research objectives require Product data:

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

ZIP code and state geographic subdivisions are available for Massachusetts residents and providers only. Small population ZIP codes are combined with larger population ZIP codes. One ZIP Code per person (MEID) per year has been assigned based on the ZIP code/state reported in the member eligibility record's earliest submission year month. If the record does not have an MEID, assignment is based on distinct OrgID/Carrier Specific Unique Member ID.

Non-Massachusetts ZIP codes and state codes except for CT, MA, ME, NH, NY, RI, and VT are suppressed.

Select *one* of the following options.

☐ 3-Digit Zip Codes (standard)	☒ 5-Digit Zip Codes***
***If requested, provide justification for requesting 5-Digit Zip Code. Refer to specifics in your methodology: I would like to merge in demographics data from the Census. Since Census data is available at the Census tract level, which is a finer unit than county, I would like to have the 5-digit zip code. Demographics data would be part of the covariates.	

b. 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: The primary outcome measure will include psychotropic medications prescribed based on pharmacy claims. The psychotropic medications will be defined by their class: antidepressants, anxiolytics, stimulants, antipsychotics, and anticonvulsants. Polypharmacy will be defined as the prescription of 2 or more psychiatric medications (whether within class or multi-class) per participant in a 3-month period from January 1, 2018 to December 31, 2022. The 3-month period was chosen because prescribing rates can more precisely be assessed in 3-month increments (quarter of a year), rather than 12-month increments (one year). This will be essential for determining more precise prescribing rate changes before and after the COVID-19		

pandemic in the United States, with the CDC announcing the first laboratory confirmed case in the United States in January 2020 and state-wide shutdowns beginning in March 2020.

c. National Provider Identifier (NPI)

Select *one* of the following options.

☐ Encrypted National Provider Identifiers (standard)	☒ Decrypted National Provider Identifiers***

***** If requested, provide justification for requesting decrypted National Provider Identifier(s). Refer to specifics in your methodology:**
I require unencrypted NPI numbers in order to link APCD data to external data NPPES data to determine their prescriber specialties. These variables are critical to determine the rate of psychotropic polypharmacy by different prescriber specialties.

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 identifiable 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.

Researchers must provide the following information for MassHealth to determire how the disclosure of indentifiable MassHeath claims data is directly related to the administration of the MassHealth program:

· How does the project relate directly to the administration of the Medicaid program?
The study of individuals with psychosocial disabilities and psychotropic polypharmacy use is directly related to the Medicaid population and improving public and population health strategies. The proposed study is looking to identify factors (demographics/characteristics, usage trends, etc.) associated with the use of polypharmacy in pediatric populations in Massachusetts using administrative claims data, which would help assist the MassHealth administration to identify individuals with psychosocial disabilities on multiple psychotropic medications and help to manage the medical complexities of that population. Understanding patterns of health care utilization and prescribing practices among persons with psychosocial disabilities may identify opportunities for cost savings that can also improve quality of care for individuals who have psychosocial disabilities. This project may also highlight health equity issues for persons with psychosocial disabilities, providing information that MassHealth can use to improve health care access for this population. Current bills in Massachusetts that could benefit from the results of this study include S. 68, an Act establishing a bill of rights for children in foster care, which advocates for a child's right to discuss any questions or concerns the child has relating to medication with a social worker or healthcare provider and to understand each of the medications the child takes, its purposes, and side effects in a developmentally-appropriate way.

· What specific Medicaid program, policy, rule or law will be affected or changed based on the outcome of this project?
As this is a preliminary study, I do not anticipate that the results will lead to specific changes in the MassHealth Medicaid program, policies, rules or laws at this time.

· How will MassHealth's objectives be helped or impaired by approving this project?
MassHealth's objectives will be helped by approving this project, as the anticipated results will allow the Executive Office to support alignment and transparency across programs and evaluate quality program activities, including those related to healthcare access and delivery, and make recommendations for improvement and best practices. It also may show potential areas for improvement around behavior health reform and the MassHealth Health Equity Initiative in particular.

· Will the results of the research have the potential for:
- o reducing cost of the Medicaid program,
- o improving access for recipients, and/or
- o increasing quality of care to recipients?

As mentioned above, understanding patterns of health care utilization and prescribing practices among persons with psychosocial disabilities may identify opportunities for cost savings that can also improve quality of care for individuals who have psychosocial disabilities. For example, this project will explore prescribing patterns of psychotropic polyphamacy for pediatric populations in MA which can have implications for the overall cost and quality of healthcare for these populations. This project may also highlight health equity issues for persons with psychosocial disabilities, providing information that MassHealth can use to improve health care access for this population. For example, people with psychosocial disabilities may face limitations in the types of health care they can readily access, compared to people without psychosocial disabilities. In addition, the results of the study can inform and advocate for the importance of marginalized children of having a voice and informed consent in their healthcare.

· Please describe the project deliverables the researchers will provide to MassHealth
The summary of findings and analysis can be provided to MassHealth upon project completion.

· Please describe how MassHealth can use the project deliverables in administration of the MassHealth program.
The MassHealth program may use the project deliverables to understand patterns of health care utilization and prescribing patterns among persons with psychosocial disabilities and help identify opportunities for cost savings that can also improve quality of care for these individuals.

3. Organizations approved to receive Medicaid Data will be required to execute a Medicaid Acknowlegment 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.

National Plan & Provider Enumeration System (NPPES) – Link from National Provider Identifier (NPI) in claims data to provider taxonomies (primary, secondary) in NPPES database. I will utilize NPI from the NPPES database for consistency across the analytic process. The purpose of having the provider taxonomies via this linking is for production of the deliverable (i.e., to provide plain-English descriptions of provider taxonomies and describe provider specialties that may not be captured solely by the primary taxonomy identified in the claims data).

Census Data - Link CHIA data to Census data in order to build a richer demand model that accounts for demographics.

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.

National Plan & Provider Enumeration System (NPPES) – Deterministic link matched on unique provider NPI to their corresponding taxonomies.

Census Data - I will link CHIA data, at the 5-digit zip code level, to US Census data on demographics such as average home price. I will create a match from the 5-digit zip code to the suitable Census unit, likely a Census county or tract.

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.

NPPES: Provider primary and secondary taxonomy codes
Census data: age, sex, race, income, household size

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

The additional linked information is descriptive in nature only and descriptive of information provided in the MA CHIA database. The linkage does not add metadata about the individual; it does not enhance the ability to constructively identify an individual.

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.

I expect the research project to lead to a dissertation publication and at least one publication in a peer-reviewed medical or public health journal, as well as to be presented at a national or international conference. Data will only be reported at the aggregate level. Small cell sizes (less than 11) will be suppressed in accordance with the MA CHIA DUA.

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.

Data will only be reported at the aggregate level. Small cell sizes (less than 11) will be suppressed in accordance with the MA CHIA DUA.

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 and rural/urban areas; city/town/zip level will not be published. No maps will be utilized.

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.

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.

The PI and co-investigator have extensive experience using the Open Payments database, which is a national disclosure program that promotes a more transparent and accountable health care system and is a publicly accessible database of payments that reporting entities, including drug and medical device companies, make to covered recipients like physicians. Using this database, we led a recent project that was published in the BMJ in January 2024 (https://www.bmj.com/content/384/bmj-2023-076902), along with similar past projects using this database. Other members of the lab and dissertation committee members have experience with healthcare claims data and will be guiding the co-investigator through the process.

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 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:	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)	DocuSigned by: 2E0A674F71C141B... Drag signature image here or delete and physically sign
Printed Name:	**Shala Bonyun**
Title:	Associate Director of ORSP Pre-Award Services
Date:	9/11/2024 Click here to enter text.

Acknowledgement Signature: (co-Investigator)	DocuSigned by: Gianna D'Ambrozio F2347ECD6DCC451... Drag signature image here or delete and physically sign
Printed Name:	**Gianna D'Ambrozio, LMSW**
Title:	Counseling Psychology Ph.D. Candidate
Date:	9/10/2024 Click here to enter text.

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