CHIA
center for health information and analysis

Non-Governmental Application for Massachusetts Case Mix and Charge 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 casemix.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 Case Mix and Charge Data.

2. After reviewing the Fee Schedule, if you have any questions about the application or data fees, contact casemix.data@state.ma.us.

3. If you believe that you qualify for a fee waiver, complete and submit the Fee Remittance Form and attach it and all required supporting documentation with your application. Refer to the Fee Schedule (effective Feb 1, 2017) for fee waiver criteria.

4. Applications will not be reviewed until the application fee is received.

5. Data for approved Applications will not be released until the payment for the Data is received.

III. ORGANIZATION AND INVESTIGATOR INFORMATION

Project Title:	**Differences in access to coordinated specialty care in first episode psychosis in Massachusetts**
IRBNet Number:	**1382624**
Organization Requesting Data (Recipient):	Massachusetts General Hospital
Organization Website:	**http://www.massgeneral.org/monganhealthpolicycenter**
Authorized Signatory for Organization:	**John Hsu, MD, MBA, MSCE**
Title:	Director, Clinical Economics and Policy Analysis Program
E-Mail Address:	john.hsu@mgh.harvard.edu
Address, City/Town, State, Zip Code:	100 Cambridge St, 15th Floor, Boston, MA 02114
Data Custodian: **(individual responsible for ogranizing, storing, and archiving Data)**	**Nicole Benson, MD**
Title:	Fellow in Clinical Informatics
E-Mail Address:	nbenson@mgh.harvard.edu
Telephone Number:	617-726-2000
Address, City/Town, State, Zip Code:	55 Fruit St, Boston, MA 02114
Primary Investigator: **(individual responsible for the research team using the Data)**	**John Hsu, MD, MBA, MSCE**
Title:	Director, Clinical Economics and Policy Analysis Program
E-Mail Address:	john.hsu@mgh.harvard.edu
Telephone Number:	617-643-7767
Names of Co-Investigators:	Nicole Benson, MD; Vicki Fung, PhD, Dost Ongur, MD, PhD
E-Mail Addresses of Co-Investigators:	NBENSON@MGH.HARVARD.EDU vfung@mgh.harvard.edu DONGUR@PARTNERS.ORG

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)

N/A

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.

There is a critical shortage of acute inpatient psychiatric hospital beds across the state of Massachusetts, with dire shortages in specific areas, particularly for certain populations, e.g., children. Furthermore, the composition of acute inpatient psychiatric

hospital beds has changed over the last fifty years, with an overall decrease in total number of beds and a shift from primarily state hospital-owned beds in the 1970's towards a mixture of state, private, and general hospital psychiatric beds (1).

More recently, there has been a modest relative growth in the number of psychiatric hospital beds within Massachusetts, but considerable variation at the local area as several private hospitals have both opened and closed. Understanding how mental health care has changed in the state during this time period is critical as there are increasingly concerning issues around Emergency Department (ED) crowding and access to hospitals, both psychiatric and acute care.

At the same time, psychiatric care is evolving. For example, in recent years there has been major growth in the evidence base supporting Coordinated Specialty Care (CSC) for first episode psychosis (FEP), and new federal/state policies to support FEP care (2-9). Despite this evolution in policy and delivery, there is limited information on which patients receive care from clinics offering FEP or CSC care, or on the real-world effects of CSC on clinical event rates during the initial years after onset. In theory, CSC starting soon after the onset of psychotic symptoms could help many patients and families adapt to their disease and improve long-term outcomes.

This project will evaluate differences between the way mental health and non-mental health services are provided and the differences in care received by patients with and without psychiatric illness. For example, as part of this project, we will examine the impact of the changing supply of psychiatric hospital beds as well as psychiatric providers, focusing initially on the impact of supply constraints on care upstream from the hospital, i.e., in the Emergency Department (ED). We will also assess the impact of changing state capacity for other types of care (e.g., first episode psychosis care) on care patterns and clinical event rates (e.g., Emergency Department [ED] visits or hospitalizations) in Massachusetts.

We will assess the care and services rendered to patients with and without mental health conditions. We will exploit ongoing state-level natural experiments created by the changing supply of free-standing psychiatric hospital beds, with emphasis on supply shocks occurring as the number of beds increase or decrease, as well as state-level programs (e.g., first episode psychosis specialty care clinics). We will examine our outcomes for both children and adolescents (e.g., <18 years or <21 years) versus adults (e.g., 18+ years or 21+ years). We will examine these age cut-offs because coordinated specialty care clinic availability varies by age, inpatient psychiatric bed availability varies with age (e.g., adolescent units are only available for those <18), physician availability varies by age, and insurance reimbursements and eligibility varies by age (e.g., those <21 are eligible for MassHealth Standard). We also will stratify resources by age, e.g., the EDs by relevant charactertistics (size, presence of dedicated psychiatric beds, etc.). This information could help both national and state policy makers, as well as clinicians, patients, and families.

References:

1. Geller JL, Biebel K. The premature demise of public child and adolescent inpatient psychiatric beds : part I: overview and current conditions. Psychiatr Q. 2006;77:251-271.
2. Kane JM, Robinson DG, Schooler NR, et al. Comprehensive versus usual community care for first-episode psychosis: 2-year outcomes from the NIMH RAISE early treatment program. *The American journal of psychiatry.* 2016;173(4):362-372.
3. McGorry PD. Early intervention in psychosis: obvious, effective, overdue. *The Journal of nervous and mental disease.* 2015;203(5):310-318.
4. Nordentoft M, Rasmussen JO, Melau M, Hjorthoj CR, Thorup AA. How successful are first episode programs? A review of the evidence for specialized assertive early intervention. *Current opinion in psychiatry.* 2014;27(3):167-172.
5. National Institute of Mental Health. Recovery After an Initial Schizophrenia Episode (RAISE). http://www.nimh.nih.gov/health/topics/schizophrenia/raise/index.shtml. Accessed Apr 10, 2017.
6. Carey B. New plan to treat schizophrenia is worth added cost, study says. *The New York Times.* Feb 1, 2016.
7. International Early Psychosis Association. IEPA history. http://iepa.org.au/iepa-history/. Accessed Apr 10, 2017.
8. International Early Psychosis Association. Publications. http://iepa.org.au/publications/. Accessed Apr 10, 2017.
9. Heinssen RK, Goldstein AB, Azrin ST. Evidence-based treatments for first episode psychosis: components of coordinated specialty care. *NIMH White Paper* 2014; http://www.nimh.nih.gov/health/topics/schizophrenia/raise/nimh-white-paper-csc-for-fep_147096.pdf. Accessed May 5, 2017.

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.*

The Commissioners of Public Health, Mental Health, and Insurance have outlined clear guidelines that, under Mental Health Parity and Addiction Equity Act, insurance carriers offering health plans in Massachusetts are mandated to provide medically necessary behavioral health treatment. Among these guidelines, these governing bodies have specified that covered members requiring hospitalization should not spend prolonged periods of time in the Emergency Department waiting for care (7). To mitigate prolonged ED holding time, the policies call for an escalation of work-flow to assist these patients and providers during periods when patients are experiencing extended ED lengths of stay. The effects of these policies and requirements on all patients have not been assessed; nor has the variability in mental health resources on access to care been studied to determine how this variability affects patient wait time and outcomes and overall spending of healthcare dollars. In addition, the underlying causes of the variability in access to care, including provider capacity and hospital bed supply, are not known. Because little is known about the lasting effects on individual patient care and the overall healthcare system when there are significant delays in care, there is a need to quantify these effects and to look for factors that could help improve care for all patients, those with and without mental illness. Further, despite recent increases in funding to support coordinated specialty care clinics for first episode psychosis, there is limited information on which patients receive care from clinics offering FEP or CSC care, or on the real-world effects of CSC on clinical event rates during the initial years after onset. This project will evaluate the growth of specialized FEP clinics in Massachusetts, changes in the composition of patients seen in the clinics or elsewhere, and assess potential differential access to care because of distance, timing, or insurance rules to inform future funding and policy decisions.

References:
7. Commissioner of Insurance, Commissioner of Mental Health, Commissioner of Public Health: Prevention of Emergency Department Boarding of Patients with Acute Behavioral Health and/or Substance Use Disorder Emergencies. https://www.mass.gov/files/documents/2018/01/10/BULLETIN 2018-01 %28E D Boarding%29.pdf2018.

VI. DATASETS REQUESTED

The Massachusetts Case Mix and Charge Data are comprised of Hospital Inpatient Discharge, Emergency Department and Outpatient Hospital Observation Stay Data collected from Massachusetts' acute care hospitals, and satellite emergency facilities. Case Mix and Charge Data are updated each fiscal year (October 1 – September 30) and made available to approved data users. For more information about Case Mix and Charge Data, including a full list of available elements in the datasets please refer to release layouts, data dictionaries and similar documentation included on CHIA's website.

Data requests are typically fulfilled on a one time basis, however; certain Projects may require years of data not yet available. Applicants who anticipate a need for future years of data may request to be considered for a subscription. Approved subscriptions will receive, upon request, the same data files and data elements included in the initial release annually or as available. Please note that approved subscription request will be subject to the Data Use Agreement, will require payment of fees for additional Data, and subject to the limitation that the Data can be used only in support of the approved Project.

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

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

2. Specify below the dataset(s) and year(s) of data requested for this Project, and your justification for requesting *each* dataset. Data prior to 2004 is not available.

☒ Hospital Inpatient Discharge Data

☐2004 ☐2005 ☐2006 ☐2007 ☐2008 ☐2009 ☐2010 ☐2011 ☐2012 ☐2013 ☒2014 ☒2015 ☒ 2016

Describe how your research objectives require Inpatient Discharge data:
This project will assess the care and services rendered to patients with and without mental health conditions in relation to delivery system variability over time, by examining supply changes in the system as psychiatric resources fluctuate throughout the system (e.g., hospitals open or close, variable capacity, changes in provider availability). Therefore, we will use the hospital inpatient discharge data to determine time and length of services, conditions and procedures done, and the associated charges. Notably, psychiatric patients often could be admitted to non-freestanding psychiatric hospitals (i.e., regular medical hospitals) when there are no available psychiatric hospital beds. We are requesting data from 2014 through 2018.

☒ Outpatient Hospital Observation Stay Data

☐2004 ☐2005 ☐2006 ☐2007 ☐2008 ☐2009 ☐2010 ☐2011 ☐2012 ☐2013 ☒2014 ☒2015 ☒ 2016

Describe how your research objectives require Outpatient Hospital Observation Stay data:
This project will assess system variability over time, by examining supply changes in the system as psychiatric and non-psychiatric resources fluctuate throughout the system (e.g., hospitals open or close, variable capacity, changes in provider availability). Therefore, we will use the outpatient hospital observation stay data to determine time and length of services, conditions and procedures done, and the associated charges. We are requesting data from 2014 through 2018.

☒ Emergency Department Data

☐2004 ☐2005 ☐2006 ☐2007 ☐2008 ☐2009 ☐2010 ☐2011 ☐2012 ☐2013 ☒2014 ☒2015 ☒ 2016

Describe how your research objectives require Emergency Department data:
We will use the Emergency Department data to determine time and length of services, how patients access services (e.g., mode of transport), conditions and procedures done, and the associated charges. We are requesting data from 2014 through 2018.

VII. DATA ENHANCEMENTS REQUESTED

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

Case Mix and Charge Data are grouped into six "Levels" or Limited Data Sets (LDS) for release, depending on the fiscal year. Data for FY 2004 – 2014 are organized into Levels. Level 6 Data will be released to Government Applicants only. *CHIA staff will use the information provided in this section to determine the appropriate Level of Data justified for release.*

Data for FY 2015 and later are organized into LDS's. All applicants receive the "Core" LDS, but may also request the data enhancements listed below for inclusion in their analyses. Requests for enhancements will be reviewed by CHIA to determine whether each represents the minimum data necessary to complete the specific Project objective.

For a full list of elements in the release (i.e., the "Core" elements and enhancements), please refer to release layouts, data dictionaries and similar documentation included on CHIA's website.

1. Specify below which enhancements you are requesting in addition to the "Core" LDS. CHIA will use this information to determine what Level of data is needed for pre-FY 2015 data requests.

Geographic Subdivisions

State, five-digit zip code, and 3-digit code are available for patients residing in CT, MA, ME, NH, RI, VT, and NY. City or Town of residence is available for residents of MA only. States outside of this region will be coded as XX ("Other").

Select *one* of the following options.

☐ 3-Digit Zip Code (Standard)	☐ 3-Digit Zip Code & City/Town ***	☐ 5-Digit Zip Code ***	☒ 5-Digit Zip Code & City/Town ***

*****If requested, provide justification for requesting 5-Digit Zip Code or City/Town. Refer to specifics in your methodology:**

We use the 5-digit zip code to link the data with area-level datasets to assess local measures of socioeconomic status based on Census block group. Measures of interest include poverty, income, and education by area, as obtained from datasets such as the American Community Survey. Because these are area-based measures, the finer the geographic resolution, i.e., the smaller the area, the more precise the potential estimate. We also will use the 5-digit zip code centroid to calculate the mean distance between each subject's address (zip code centroid) and each potential ED and hospital. We will use this differential distance in our analyses.

Demographic Data

Choose *one* of the following options.

☐ Not Requested (Standard)	☒ Race & Ethnicity***

**** If requested, provide justification for requesting Race and Ethnicity. Refer to specifics in your methodology:**

We will use race/ethnicity to assess for disparities in clinical outcomes. One a priori concern is that there are potential disparities in care by race/ethnicity.

Date Resolution

Select *one* of the following options for dates of admissions, discharges, and significant procedures.

☐ Year (YYYY)(Standard)	☐ Month (YYYYMM) ***	☒ Day (YYYYMMDD)***

*****If requested, provide justification for requesting Month or Day. Refer to specifics in your methodology:**
Exact dates are needed for analyses of service use, e.g. to determine visit length of stay, readmission time intervals, and timing and patterns of care of encounters for our sample, particularly as exogenous factors change throughout the system (e.g., overall psychiatric bed supply changes, major incidents occur that may cause increased flow of patients). Indeed, time is a critical dimension for several study variables.

Practioner Identifiers (UPN)

Select *one* of the following options.

☐ Not Requested (Standard)	☐ Hashed ID ***	☒ Board of Registration in Medicine Number(BORIM) ***

*****If requested, provide justification for requesting Hashed ID or BORIM Number. Refer to specifics in your methodology:**
We will use BORIM link with provider datasets in order to determine characteristics of providers, their practices, and their networks, as well as the characteristics of the local area level for analyses of provider supply, e.g. area-level socioeconomic status and insurance mix.

Unique Health Information Number (UHIN)

Select *one* of the following options.

☐ Not Requested (Standard)	☒ UHIN Requested ***

***** If requested, provide justification for requesting UHIN. Refer to specifics in your methodology:**
We need to create longitudinal estimates of event rates (e.g., linkage at the individual patient level over time); the encrypted UHIN information will help permit this linkage. This information is critical as numerous past studies have found that past event rates are highly predictive of future event rates (e.g., for ED visits and hospitalizations). We also plan to use the UHIN to track patients seen in multiple settings (e.g., identify patients seen in the ED and in the inpatient setting).

Hashed Mother's Social Security Number

Select *one* of the following options:

☒ Not Requested (Standard)	☐ Hashed Mother's SSN Requested ***

***** If requested, provide justification for requesting Hashed Mother's SSN. Refer to specifics in your methodology:**
N/A

VIII. DATA LINKAGE

Data linkage involves combining CHIA Data with other data to create a more extensive database for analysis. Data

linkage is typically used to link multiple events or characteristics within one database that refer to a single person within CHIA Data.

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

☒ Yes

☐ No linkage or merger with any other data will occur

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

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

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

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

☒ Aggregate Data (e.g., Census data)

☐ Other (please describe):

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

We anticipate three levels of linkage:

1. Provider level – we have been using detailed information about physician characteristics from Doximity, Massachusetts Board of Registration of Medicine, or from the CMS-NPI file, e.g., specialty. We plan to use the MA BORIM number to link these data to MA licensing data. This linkage will also provide a dataset with a linkage to NPI. We believe that these data are more current than the the AMA Masterfile. Provider supply and specialty are essential parts of the project.
2. Facility level – we have been working with DMH on hospital information about the approved number of freestanding acute psychiatric hospital beds for adults and children/adolescents. This information about the timing in the changes in the potential hospital supply represents a critical component of the project. Further, DMH will also provide administrative data about the FEP clinics across the state (e.g., whether they are DMH funded). Though DMH also has clinical data about patients in these clinics, we do not plan to link these clinical data to the case-mix dataset.
3. Area level – to obtain additional information about the local area and the individual patient (e.g., imputed socio-economic status) we will use a number of data sources linkable using the five-digit zip code. Examples of the datasets include the following: 1) Area Health Resource File, another source of information on the area-level provider supply and facility information, plus details about area provider shortage status; 2) U.S. Census/American Community Survey, for local SES and insurance mix; and 3) Local Area Unemployment Statistics Database, to assess local unemployment levels. These measures represent potential explanatory variables and confounders.

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 will link our datasets using a deterministic algorithm. For example, we will be matching county in one file to county in another file or zip code in one file to zip code in another file. Providers will be linked using BORIM IDs.

5. If yes, attach complete listing of the variables from all sources to be included in the final linked analytic file.

Patient level variables

- Demographic information, e.g., age, gender, race/ethnicity
- SES information, e.g., zip code based SES measure

Insurance variables

- Insurance type, e.g., Medicare v. Medicaid v. Group commercial v. Individual commercial v. uninsured
- Managed care plan status, e.g., Medicare Advantage, Medicaid Managed Care plan, HMO status
- Benefit design, e.g., deductible presence, ED visit cost-sharing, hospital cost-sharing

ED visit variables

- Visit date and arrival time / time of day
- Visit discharge time and total length of stay
- Arrival mechanism, e.g., ambulance v. other
- Diagnoses
- ED identifier
- Hospital co-location status
- Hospital system identifier

Patient-ED distance variables

- Mean distance to each potential ED (or other care locations such as urgent care clinics) within 50 miles
- Mean travel time to each potential ED (or other care locations) within 50 miles

Hospitalization variables

- Visit date and arrival time / time of day
- Visit discharge time and total length of stay
- Arrival mechanism, e.g., ambulance v. other
- DRG
- Diagnoses
- Hospital identifier

Patient-hospital distance variables

- Mean distance to each potential hospital within 50 miles
- Mean distance to each potential freestanding psychiatric hospital within 100 miles
- Mean travel time to each potential hospital within 50 miles
- Mean travel time to each potential freestanding psychiatric hospital within 100 miles

Physician supply variables

- HRSA provider shortage status
- Psychiatrist counts per 10,000 population in the county
- Presence of psychiatrists in ED

Hospital supply variables

- Psychiatric hospital beds

Area variables

- Rural vs urban

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

Linking to these aggregate datasets will not increase the ease or likelihood of identifying individual patients as the information is provided in aggregate form. Moreover, we will take extensive steps to ensure the confidentiality of the data.

IX. PUBLICATION / DISSEMINAITON / 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 results will be submitted for publication in academic, peer-reviewed journals and presented as appropriate at academic conferences and workshops. All results will be reported as aggregate relationships and summary statistics (and therefore no cells from the case-mix dataset will be published). Thus, no identification of patients, providers, EDs, or hospitals will be possible. We also would welcome the opportunity to share our findings with CHIA.

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 have no plans to disclose CHIA Data, or any data derived or extracted from such data, outside of the study staff, except as previously described at academic conferences or for publication.

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?

All results will be reported as aggregate relationships and summary statistics. At the lowest level, geographic data will be presented at the county or HRR levels. Thus, no identification of patients will be possible.

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?

N/A

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

N/A

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?

N/A

XI. INVESTIGATOR QUALIFICATIONS

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

Vicki Fung, PhD, is an Assistant Professor of Medicine at Harvard Medical School and a Senior Scientist at the Mongan Institute Health Policy Center, Massachusetts General Hospital. She received her doctoral training in Health Services and Policy Analysis at the University of California, Berkeley and post-doctoral training at the Philip R. Lee Institute for Health Policy Studies at the University of California, San Francisco. She has extensive experience conducting health policy research using large claims datasets, including within the Medicare program.

John Hsu, MD, MBA, MSCE, is the Director of the Program for Clinical Economics and Policy Analysis within the Mongan Institute Health Policy Center at the Massachusetts General Hospital, Assistant Professor of Medicine at Harvard Medical School, and Associate Professor of Health Policy at the Department of Health Care Policy, Harvard Medical School. He is the principal investigator of a number of federally funded studies examining innovations in health care financing and delivery using large datasets. He also serves on the CHIA Data Release Committee.

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Nicole Benson, MD is in her first year of the Partners Clinical Informatics and Innovation Fellowship. She is also a child and adolescent psychiatrist at Massachusetts General Hospital and McLean Hospital. She has extensive experience using and analyzing large claims datasets.

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Dost Öngür, MD, PhD is a co-investigator on the project. As a world-renowned psychiatrist with experience treating patients with severe mental illness/first episode psychosis, he will advise the project and provide expertise regarding the patient population of interest.

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 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 work with the CHIA Data. [*Add agents or contractors as needed.]*

AGENT/CONTRACTOR #1 INFORMATION	
Company Name:	**Biostat Data Consulting Inc.**
Company Website:	N/A
Contact Person:	**Mary Price**
Title:	Biostatistical Consultant
E-mail Address:	mprice4@mgh.harvard.edu
Address, City/Town, State, Zip Code	1840 Lincoln Ave, St. Paul, MN 55105
Telephone Number:	651-690-1981
Term of Contract:	Duration of project

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

Mary Price will conduct the data management and analysis for this project. She is a long-standing programmer/analyst with Drs. Fung and Hsu, and has extensive experience working with and conducting analysis using large claims files, including Medicare claims and large commercial claims databases. She has a masters degree in biostatistics from the University of California, Berkeley. Under the supervision of study investigators, she will create and manage the appropriate data structures required for this project.

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.

We meet with Mary regularly (at least weekly) to plan activities and monitor progress, as well as regular project meetings with the entire research team.

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, 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.

N/A

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

N/A

3. Will the agent or contractor have access to 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.

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 :	**John Hsu, MD, MBA, MSCE**
Title:	Director, Clinical Economics and Policy Analysis Program

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.

CHIA Case Mix Data Request (PI: Hsu)
Differences in access to coordinated specialty care in first episode psychosis in Massachusetts
Research Methodology

Study design overview:
In this project, we will compare the care and service use of patients with and without mental health conditions as the delivery system changes over time by examining supply changes to the system such as psychiatric hospital bed supply changes (e.g., hospitals open and close, capacity changes, provider availability varies) . We will use longitudinal, quasi-experimental methods to assess the associations between psychiatric resource availability and provider supply on clinical outcomes (e.g., difference-in-difference approach with fixed effects regression models).

Study measures:
Predictors:
Psychiatric Resource Availability. Our primary predictors of interest include psychiatric resources and provider supply. We will integrate information on supply changes to the system such as psychiatric hospital bed supply changes (e.g., hospitals open or close) and the changing supply and capacity of clinics offering coordinated specialty care for patients with a first episode of psychosis (FEP) throughout the state. The case-mix dataset includes comprehensive information on hospital and Emergency Department visits including socio-demographic characteristics of patients, medical diagnoses, treatment and services rendered, hospital admission lengths of stay, how patients presented to the hospital, and service specific charges billed by the hospital, as well as information about the providers. We will examine how patients' service use (e.g., rate of hospitalization, rate of ED presentation) varies based on the psychiatric resource availability. We will examine the effects of state policies, e.g., how lengths of stay in the ED change based on how bed supply changes before and after implementation of Massachusetts state guidelines for escalation of work-flow to mitigate prolonged lengths of stay and impact of federal/state policies to support FEP care

Provider supply. We will synthesize information on provider supply and availability, by specialty and provider type, at multiple levels by geographic area and insurance plan. We will estimate provider supply measures at the state and local levels (e.g., by ZIP code, county, Hospital Referral Region, or mental health catchment area) and link with individuals by area of residence and/or payer/plans. We will explore various measures of provider supply including per capita supply levels (e.g., number of psychiatrists per area population or plan enrollees) as well as measures that incorporate patient travel times and distance to the nearest provider based on geospatial analyses linking locational information on beneficiaries (centroid of 5-digit ZIP) and providers (business address).

Outcomes:
Medical Care Use. To assess changes in medical care, we will start by examining all outpatient visits by all subjects. We will then decompose visits into visits to PCPs and to specialists (e.g., psychiatrists) and by provider type (e.g., physician vs. nurse practitioner).

Clinical Events. Clinical events will include ED visits and hospitalizations, excluding or separating elective or ambulatory surgery hospitalizations and inter-hospital transfers, which are unlikely to represent adverse clinical events resulting from acute changes in disease status. We will examine

all-cause ED visit and hospitalizations, as well as for specific diagnoses, e.g., clinical events with a primary mental health diagnosis or events that reflect the quality of primary care, such as cardiovascular events (e.g., acute coronary syndrome). In particular, we will explore additional clinical event measures including length of stay, and measures that might be more likely to reflect quality of care including readmissions.

Spending. We will examine medical spending using the dollar amounts captured in the case-mix charges. We will also differentiate spending by network status and setting.

Analysis:
We will start by examining the patient and area-level characteristics associated with higher and lower provider supply and benefit generosity, e.g., sociodemographic characteristics (such as age, gender, median household income), urban/rural status, and local insurance mix (e.g., % Medicaid, Medicare, commercially insured, uninsured) using data from the case-mix and supplemental data sources such as the American Community Survey and Area Health Resource File.

Our primary analyses will examine the associations between psychiatric resource availability and delivery system changes with care and service use of patients with and without mental illness. In multivariate analyses, most of our outcomes will be structured as repeated measures over time periods (e.g., months or quarters) and the primary unit of analysis will be the person-time period (e.g., person-month). Our primary estimation approach for the repeated outcome measures will be fixed effects (FE) estimation methods (e.g., Linear Unobserved Effects Model) that account for time stable unmeasured differences across comparison groups. The key assumption in FE analyses is that there are no unmeasured time-changing confounders that differentially affect our comparison groups. Thus, our models will include a number of time-changing covariates that could be related to care utilization, quality, clinical events, or charges, including age, comorbidities, risk scores, utilization history, and clinical history. We will also conduct sensitivity analyses to examine the potential effects of other provider- and system-level variables and incorporate these characteristics into the analyses if appropriate, as well as clustering of patients at different levels. We will include a series of potential geographic and system-level traits, linked to individuals, including measures of provider supply using the measures described above.

Partners Human Research
Partners HealthCare
399 Revolution Drive, Suite 710
Somerville, MA 02145
Tel: 857-282-1900
Fax: 857-282-5693

Notification of IRB Review

Protocol #: 2019P002097

Date:	September 16, 2019	
To:	Hsu, John, MD MGH Partners > MGH > Medical Services > Health Policy Center	
From:	Partners Human Research 399 Revolution Drive, Suite 710 Somerville, MA 02145	
Title of Protocol:	Differences in access to coordinated specialty care in first episode psychosis in Massachusetts	
Version/Number:		
Version Date:		
Sponsor/Funding/Support:	Proposal Title:	Laboratory for Early Psychosis Research (LEAP) – LEAP Administrative Core
	Principal Investigator:	Hsu, John
	Immediate Sponsor:	McLean Hospital Corporation
	Originating Sponsor:	NIH-National Institutes of Health
	Award Number:	1P50MH115846-01A1
	Fund #:	234791
IRB Review Type:	Expedited	
Expedited Category/ies:	(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101 (b)(4). This listing refers only to research that is not exempt.)	
IRB Approval Date:	09/16/2019	
Approval/Activation Date:	09/16/2019	
Next Review:	**IRB Review**	
IRB Expiration Date:	**09/16/2020**	

This project has been reviewed and approved by the **PHS IRB**. During the review of this project, the IRB specifically considered (i) the risks and anticipated benefits, if any, to subjects; (ii) the selection of

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subjects; (iii) the procedures for obtaining and documenting informed consent; (iv) the safety of subjects; and (v) the privacy of subjects and confidentiality of the data.

Please note that if an IRB member had a conflict of interest with regard to the review of this project, consistent with IRB policies and procedures, the member was required to recuse him/herself and, if applicable, leave the room during the discussion and vote on this project except to provide information requested by the IRB.

Health/Medical Records

As Principal Investigator, you are responsible for ensuring that this project is conducted in compliance with all applicable federal, state and local laws and regulations, institutional policies, and requirements of the IRB, which include, but are not limited to, the following:

1. Submission of any and all proposed changes to this project (e.g., protocol, recruitment materials, consent form, status of the study, etc.) to the IRB for review and approval prior to initiation of the change(s), except where necessary to eliminate apparent immediate hazards to the subject(s). Changes made to eliminate apparent immediate hazards to subjects must be reported to the IRB as an unanticipated problem.
2. Submission of a continuing review submission or institutional status report as required by the IRB and/or institution to continue the research, and submission of a final report when the project has been closed or completed.
3. Submission of any and all unanticipated problems, including adverse event(s) in accordance with the IRB's policy on reporting unanticipated problems including adverse events.
4. Obtaining informed consent from subjects or their legally authorized representative prior to initiation of research procedures when and as required by the IRB and, when applicable, documenting informed consent current IRB approved consent form(s) with the IRB-approval stamp in the document footer.
5. Informing all investigators and study staff listed on the project of changes and unanticipated problems, including adverse events, involving risks to subjects or others.
6. When investigator financial disclosure forms are required, submitting updated financial disclosure forms for yourself and for informing all site responsible investigators, co-investigators and any other members of the study staff identified by you as being responsible for the design, conduct, or reporting of this research study of their obligation to submit updated Investigator Financial Disclosure Forms for this protocol to the IRB if (a) they have acquired new financial interests related to the study and/or (b) any of their previously reported financial interests related to the study have changed.

IMPORTANT REMINDER: THE IRB HAS THE AUTHORITY TO TERMINATE PROJECTS THAT ARE NOT IN COMPLIANCE WITH THESE REQUIREMENTS.

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Study Staff Added:

- Benson, Nicole, McLean > Psychotic Disorders Division, Co-Investigator
- Fung, Vicki, MGH > Medical Services > Health Policy Center, Co-Investigator
- Hsu, John, MD, MGH > Medical Services > Health Policy Center, Principal Investigator
- Ongur, Dost, McLean > Psychotic Disorders Division, Co-Investigator

Financial Delegate:

- Fund #234791 - Hsu, John

Questions related to this project may be directed to **Deena Segal | Tel: 857-282-1910 | Email: DSEGAL@PARTNERS.ORG**

cc:

John Hsu, MD, Principal Investigator, Health Policy Center, Medical Services

Nicole Benson, Co-Investigator, Psychotic Disorders Division

Title: Differences in access to coordinated specialty care in first episode psychosis in Massachusetts
Sponsor Name: McLean Hospital Corporation
PI Name: Hsu, John **Protocol #:** 2019P002097 **Type:** Current View
Date Received: August 13, 2019

Study Staff

Name	Role	Degree	Organization	Citi Certified
Benson, Nicole	Co-Investigator		McLean > Psychotic Disorders Division	05/21/18
Fung, Vicki	Co-Investigator		MGH > Medical Services > Health Policy Center	04/16/19
Hsu, John	Principal Investigator	MD	MGH > Medical Services > Health Policy Center	04/15/19
Ongur, Dost	Co-Investigator	MD, Ph.D	McLean > Psychotic Disorders Division	06/12/19

Funding source

Record #	Fund	Project Period	PI Name	Sponsor	Record Type	Process	Link Date	Link Status
2018A007219	234791	05/15/19-03/31/23	Hsu, John	McLean Hospital Corporation	RM – Funded Agreement	IR	09/16/19	Approved

Signatures

PI Name: Hsu, John, MD
Authenticated: August 01, 2019

InitialReview

Title:

Differences in access to coordinated specialty care in first episode psychosis in Massachusetts

The Partners Human Research Committee has created several forms for review of human subjects research. This questionnaire includes a series of questions to identify the form (s) you need to complete for your research project.

1. Intervention/Interaction
2. Health / Medical Information
3. Excess Human Material and Related Health / Medical Information
4. Secondary Use of Research Samples and/or Data (samples/data from another research study)
5. Research Data Repository (collecting and storing health/medical information for future research)
6. Tissue or Sample Repository
7. Coordinating Center / Core Labs
8. Emergency / Single Patient Use of Investigational Products

1. Intervention and/or Interaction

Does your research involve an **intervention** and/or **interaction** with subjects for the collection of specimens or biological material or data (including health or clinical data, surveys, focus groups or observation or behavior)?

NOTE: Do not answer YES if this protocol is to establish a Research Data Repository or Sample/Tissue Repository. There are separate forms for Data and Tissue Repositories.

○ Yes ◉ No

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2. Health / Medical Information

Is your research limited to the use of health / medical information?

◉ Yes ○ No

Sponsor Funding: McLean Hospital Corporation [Non-Profit]

Select the source of funding that will be used to support the proposed research:

◉ Government / Foundation / Other Non-Profit
○ Corporate
○ Institutional Award
○ Department Funds
○ None

Indicate application type:

◉ Grant / Contract (direct award to an Institution)
○ Subcontract (from another Institution)

Indicate the applicant institution:

○ BWH
○ MGH
○ SRH
○ McLean
○ Faulkner
○ Broad Institute
○ Other

Enter Principal Investigator name (if different):

Enter title of proposal (if different):

Laboratory for Early Psychosis Research (LEAP) – LEAP Administrative Core

Enter grant number (if known):

1P50MH115846-01A1

Example of NIH grant number:

Insight Agreement Proposal Number (read-only field):

Has the project been awarded at the time of this submission?

◉ Yes ○ No

NOTE: For HHS-funded research: The IRB requires investigators to provide a copy of the entire grant application when there is a direct award to a Partners' Institution. Salary information (not % effort) may be redacted. Exception: Copies of HHS cooperative group umbrella grants do not need to be submitted.

For NIH-sponsored cooperative group multi-center trials: The IRB requires a copy of the cooperative group protocol and sample informed consent documents be submitted for review and comparison with the documents submitted for local IRB review.

For guidance, refer to, "IRB Review of Applications for HHS Support."

Medicare Coverage Analysis Requirement

Does the protocol for this study involve any items or services that will be billed to Medicare/private insurance, including study-specific procedures or those considered usual and customary care ("standard of care") outside the trial context?

○ Yes ◉ No

NOTE: If you are unsure how to answer this question, please contact Sarah Bednar at Partners Clinical Trials Office at 617-954-9364, or for NWH investigators, please contact Jayita Sen at 617-243-6517 for more information.

Is this the primary source of funding?

◉ Yes ○ No ○ Not applicable

Will the funding cover all subject study-related drugs, devices, procedures, tests, and visits?

○ Yes ○ No ◉ Not applicable (no subject study-related costs)

Health / Medical Records

The Health/Medical Records specialized form is to be used for studies that are limited in scope to review of health or medical information from medical records or other sources, including use of datasets that were not collected for research purposes, e.g., CMS or other third party insurer datasets.

Do not use the health/medical records form for research that involves contacting subjects, e.g., a follow-up phone call for patient status.

More detailed descriptions of specific questions/categories below can be found in the Research Navigator "Specialized Forms" section. See Research Navigator.

1. Purpose

Briefly describe the purpose of the research:

This project will assess the impact of changing state capacity for First Episode Psychosis (FEP) care on care patterns and clinical event rates (e.g., Emergency Department [ED] visits or hospitalizations) in Massachusetts. In recent years there has been major growth in the evidence base supporting Coordinated Specialty Care (CSC) for FEP, and new federal/state policies to support FEP care. Despite this evolution in policy and delivery, there is limited information on which patients receive care from clinics offering FEP or CSC care, or on the real-world effects of CSC on clinical event rates during the initial years after onset.

In theory, CSC starting soon after the onset of psychotic symptoms could help many patients and families adapt to their disease and improve long-term outcomes. The evidence base supporting the use of this care for FEP patients has grown and arguably is best exemplified in the US by the results of the RAISE-ETP study. With this evidence, there also have been major changes in policy to encourage the development of FEP clinics, but is not without controversy. In 2014, the federal government required all states to allocate at least 5% of their Mental Health Block Grants (MHBGs) to FEP patients. In 2016, this FEP spending requirement increased to 10% of MHBG dollars. In Massachusetts, there now are multiple FEP clinics.

These ongoing changes, however, occur in a resource-constrained context in which the supply of mental health care has been limited and inadequate in many areas, e.g., some areas have zero psychiatrists or are far away from FEP clinics. This baseline undersupply and associated poor financing have contributed to delays in the detection and treatment of psychosis in FEP patients. The evidence base for FEP care also has controversial or uncertain areas, e.g., the optimal duration of specialized treatment, or longer-term outcome trajectories after initial CSC. Finally, there have been separate (orthogonal) changes in health insurance that limit the ability of patients to receive care from clinics or hospitals, e.g., narrow provider networks. These insurance design features also can change frequently. The net impact of these changes in this environment is unknown.

To address these knowledge gaps and support future studies, we will describe the growth of specialized FEP clinics in Massachusetts, changes in the composition of patients seen in the clinics or elsewhere, and assess potential differential access to care because of distance, timing, or insurance rules. We will then incorporate the information about differential access and exploit these mechanisms to estimate the impact of receiving care from a specialized FEP clinic. We will use the Massachusetts Case-Mix Database (2009-21), combined with supplemental data on patient and physician location, insurance networks, clinic capacity, and characteristics of the local area, to obtain detailed longitudinal information about outcomes and time-varying covariates to examine the differences in care and outcomes for patients with visits in clinic sites with CSC compared with those of patients receiving care elsewhere in Massachusetts, as the number of clinics increase.

Data resulting from this research will be used for the following.

Check all that apply.

- ☑ Publication
- ☑ Oral Presentation
- ☐ Other

Will data resulting from this research ever be submitted to the FDA?

○ Yes ◉ No

2. Study Population

Check all that apply.

☑ Patients

Describe medical condition/diagnosis to be studied:

We will be studying patients with a first episode of psychosis (e.g., patients with a new diagnosis of schizophrenia, schizophreniform disorder, schizoaffective disorder, bipolar disorder with psychotic features, major depressive disorder with psychotic features, unspecified psychosis)

☑ Healthcare Providers

Explain:

We will be studying patient outcomes as the number of coordinated specialty clinics changes. As part of this, we will examine differences in the care locations, e.g., provider characteristics, frequency of psychiatrist involvement in visits, or population density.

NOTE: Healthcare providers may be considered subjects if you are studying provider behavior or performance, or analyzing patient outcomes based on provider. In such cases, you must consider the privacy risks and privacy rights of providers and address these in the waiver of consent / authorization section.

☐ Other

Age

Check all that apply.

☑ Children (less than 18 years of age)
☑ Adults (18 years and older)
☐ Unknown

Gender

Check all that apply.

☑ Male
☑ Female
☐ Unknown

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3. Source of Health / Medical Information

Indicate:

☐ Partners Sites
☑ Non-Partners Sites

Non-Partners Sites

Check all that apply.

☐ DFCI
☐ Partners in Health
☐ Shriners Hospitals for Children
☑ Other Non-Partners Sites

Enter the other non-Partners sources of health / medical information. Enter all sites.

American Community Survey

Enter the other non-Partners sources of health / medical information. Enter all sites.

US Census

Enter the other non-Partners sources of health / medical information. Enter all sites.

Census Bureau

Enter the other non-Partners sources of health / medical information. Enter all sites.

Area Health Resource File

Enter the other non-Partners sources of health / medical information. Enter all sites.

Bureau of Labor Statistics

Enter the other non-Partners sources of health / medical information. Enter all sites.

Department of Mental Health Hospital Bed Supply

Enter the other non-Partners sources of health / medical information. Enter all sites.

Center for Medicare and Medicaid Services National Provider Identifier (NPI) dataset

Enter the other non-Partners sources of health / medical information. Enter all sites.

National provider specialty data from Doximity

Enter the other non-Partners sources of health / medical information. Enter all sites.

Massachusetts Center for Health Information Analysis Case Mix Data

Enter the other non-Partners sources of health / medical information. Enter all sites.

MA Board of Registration of Medicine licensing data

Enter the other non-Partners sources of health / medical information. Enter all sites.

Department of Mental Health data on all First Episode Psychosis clinics

Note: If the institution/entity providing the data requires you to sign a data use or other agreement, the agreement must be reviewed by Research Management. Please make sure to initiate the DUA following the directions on this page in the Navigator:
https://partnershealthcare.sharepoint.com/sites/phrmInitiate/imcdc/Pages/Data-Use-Agreements-(DUAs).aspx
PHS HIPAA policies apply to protected health information (PHI) received from non-PHS entities that is stored at Partners for research purposes.

☐ NeuroNext or Stride Network

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4. Data To Be Collected / Obtained

Check all that apply.

Administrative:

☑ Billing data
☑ Coded encounter data (diagnoses, procedures, dates)
☑ Demographic data (age, gender, vital status)

Health / Medical:

☐ Allergies
☐ Discharge Summary
☐ Doctors Orders
☐ History / Physical
☐ Immunizations
☐ Medication List
☐ Office / Clinic Notes
☐ Operative / Procedure Notes (e.g. endoscopy)
☐ Pharmacy
☐ Problem List

Health/Medical Reports/Results:

☐ Blood Bank
☐ Laboratory
☐ Pathology reports (reports only). Complete the Excess Human Material form for use of tissue/slides instead of this form.
☐ Radiology
☐ Clinical Genetic Data

Sensitive/Personal Information:

☐ HIV Status
☑ Mental Health
☐ Reproductive History (e.g., abortions)
☐ Sexual Behavior / Sexually Transmitted Diseases
☑ Substance Abuse (e.g., drug or alcohol abuse)
☐ Other potentially stigmatizing behaviors (such as illegal activities) or information

Will any sensitive/personal information listed above be collected?

◉ Yes ○ No

Explain why the sensitive/personal data checked above is needed to achieve the goals of the study:

We will capture sensitive/personal data to the extent that they are captured in the claims datasets, or could impact a first episode of psychosis or subsequent care a subject receives. We are using existing data sources only in this project. All datasets already exist. This information is critical to the success of this study as this is a study examining health outcomes, including mental health outcomes, as psychiatric resources change. We will conduct secondary data analyses of large datasets that will be de-identified as soon as feasible to protect the privacy of individuals.

Other Health/Medical Information:

☐ Other

Note: The HIPAA Privacy Rule requires Partners and its affiliated hospitals and providers to make all reasonable efforts to use or release only the "minimum necessary" identifiable health care information to achieve the intended purpose. The minimum necessary standard applies to research limited to health/medical information collected with a waiver of authorization.

Have you created a data collection form or other tool for data collection?

○ Yes ◉ No

Enter specific data variables needed to achieve the goals of your study. Enter one variable and move to the box on the right. Repeat for all variables.

Provider specialty involvement

Enter specific data variables needed to achieve the goals of your study. Enter one variable and move to the box on the right. Repeat for all variables.

Travel distances and times to and from hospitals and clinics and EDs

Enter specific data variables needed to achieve the goals of your study. Enter one variable and move to the box on the right. Repeat for all variables.

Hospitalization and ED visit information

Enter specific data variables needed to achieve the goals of your study. Enter one variable and move to the box on the right. Repeat for all variables.

Socioeconomic status

Enter specific data variables needed to achieve the goals of your study. Enter one variable and move to the box on the right. Repeat for all variables.

Insurance type and design

Enter specific data variables needed to achieve the goals of your study. Enter one variable and move to the box on the right. Repeat for all variables.

Diagnoses

Enter specific data variables needed to achieve the goals of your study. Enter one variable and move to the box on the right. Repeat for all variables.

Number of psychiatric beds

Enter specific data variables needed to achieve the goals of your study. Enter one variable and move to the box on the right. Repeat for all variables.

Hospital supply and capacity

Enter specific data variables needed to achieve the goals of your study. Enter one variable and move to the box on the right. Repeat for all variables.

Treatments

Enter specific data variables needed to achieve the goals of your study. Enter one variable and move to the box on the right. Repeat for all variables.

Prescription drugs

Enter specific data variables needed to achieve the goals of your study. Enter one variable and move to the box on the right. Repeat for all variables.

Codes for other conditions in the differential

Enter specific data variables needed to achieve the goals of your study. Enter one variable and move to the box on the right. Repeat for all variables.

Procedure codes for suspected psychosis

Enter specific data variables needed to achieve the goals of your study. Enter one variable and move to the box on the right. Repeat for all variables.

Type of care (ex. coordinated specialty care)

Enter specific data variables needed to achieve the goals of your study. Enter one variable and move to the box on the right. Repeat for all variables.

Medical spending

Enter specific data variables needed to achieve the goals of your study. Enter one variable and move to the box on the right. Repeat for all variables.

Lag time between dates of service

Enter specific data variables needed to achieve the goals of your study. Enter one variable and move to the box on the right. Repeat for all variables.

Age

Enter specific data variables needed to achieve the goals of your study. Enter one variable and move to the box on the right. Repeat for all variables.

Procedures (brain MRI, EEG)

Enter specific data variables needed to achieve the goals of your study. Enter one variable and move to the box on the right. Repeat for all variables.

Demographic information

Enter specific data variables needed to achieve the goals of your study. Enter one variable and move to the box on the right. Repeat for all variables.

Site of care

5. Data To Be Requested From The Following Time Period (Encounter Dates)

Indicate the time period of interest for your study, e.g. 01/01/2000 - 01/01/2024. Prospective reviews are allowed for most studies limited to health/medical information, usually limited to 5-7 years in the future. The end date can be extended by amendment.

From (mm/yyyy):

01/2009

To (mm/yyyy):
For future data, use anticipated project end date.

12/2021

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6. Protected (Identifiable) Health Information

PHI refers to health/medical information that is accompanied by any of the listed 18 HIPAA identifiers or by a code where the key to the code that links to the identifiers is accessible to investigators. Note that if any part of an identifier, e.g. patient initials, is included in a code number, the code number itself is then considered an identifier under HIPAA. DE-IDENTIFIED DATA (without any identifiers or codes that link back to individuals) are not considered PHI, and are not subject to HIPAA regulations.

- Names, including initials
- Social security numbers
- Medical record numbers
- Addresses by street location
- Addresses by city, county, precinct, zip code
- All elements of dates (except year) related directly to individuals including, but not limited to, dates of birth, death, admission, discharge, or any service
- All ages over 89 and all elements of dates (including year) indicative of such age
- Telephone numbers
- FAX numbers
- Electronic email addresses
- Web URLs
- Internet protocol (IP) addresses
- Account numbers
- Certificate/license numbers
- Vehicle identification numbers and serial numbers including license plates
- Medical device identifiers and serial numbers
- Biometric identifiers, including finger and voice prints
- Full face photographs and any other comparable images
- Any other unique identifying numbers, characteristics or codes including, but not limited to, globally unique identifiers (GUID) and universally unique identifiers (UUID) or equivalent

Will you be recording any of the identifiers listed above with the data or using a code to link the data to any of the identifiers? If yes, under the HIPAA Privacy Rule provisions the data cannot be considered de-identified and authorization from the subject or a waiver of authorization must be granted by the IRB. When answering this question, consider the need for recording dates or retaining direct identifiers, such as name and/or medical record number, to link data from multiple sources, to avoid duplicating records, or for QA purposes.

NOTE: If you are recording medical record number or other identifiers, even if temporarily for QA purposes or to avoid duplicating records, then answer "Yes".

◉ Yes ○ No

Check the identifiers that will be recorded with or linked by code to the data.

☐ Name, including initials
☐ Social Security Number
☐ Medical record number
☐ Address by street location
☑ Address by city, county, precinct, zip code
☑ All elements of dates (except year) related directly to individuals, including, but not limited to, dates of birth, death, admission, discharge, or any service
☐ All ages over 89 and all elements of dates (including year) indicative of such age [Note: Consider substituting range, e.g., 89+, for actual age.]
☐ Telephone number
☐ Fax number
☐ Electronic email address
☐ Web URLs
☐ Internet protocol (IP) address
☐ Health plan beneficiary number
☐ Account number
☐ Certificate / license number
☐ Vehicle identification number and serial number, including license plate number
☐ Medical device identifiers and serial numbers
☐ Biometric identifiers, including finger and voice prints
☐ Full face photographic images and any other comparable images
☑ Any other unique identifying number, characteristic, or code (e.g., Pathology Accession #, Code #), including, but not limited to, globally unique identifier (GUID) and universally unique identifier (UUID) or equivalent

Explain what other identifier or combination of identifiers likely to identify the subject will be recorded:

We will be utilizing insurance claims datasets, which contain some identifiers, such as address and dates of care. We will geocode the home addresses for all subjects, then use the geocodes to supplement the dataset with other area-level variables, e.g., area-level social determinants of health, transportation, and distance.

Will identifiers be removed from the data and destroyed after all of the data has been collected, the study has been completed, or all regulatory and sponsor obligations have been met? **Note:** Federal regulations mandate that, under a Waiver of Consent/Authorization, identifiers be destroyed as early as possible. De-Identified datasets may be retained indefinitely.

For guidance, see the PHRC Recordkeeping and Record Retention Requirements.

◉ Yes ○ No

6A. Waiver of Informed Consent / Authorization

Explain why it would be impossible to conduct the research without access to and use of identifiable health / medical information. For example, the data cannot be obtained from electronic health / medical records or databases without access to identifiers or identifiers are needed for prospective data collection.

The geographic location of the subjects is vital to the study with regards to the level of first episode psychosis care and coordinated specialty care available in the subject area; geographic linkage is a key part of the study. Furthermore, dates of care are necessary to pinpoint lag time in the provision of care as well as length of stay/treatment time in the hospital, clinics, and ED.

Explain why the risk to subjects, specifically the risk to privacy, is no more than minimal risk. When addressing this question, describe the measures you have put in place to protect the privacy of subjects and confidentiality of the data; for example: (1) identifiable health information will be stored on a computer on the Partners network with password protections enabled and anti-virus software or an encrypted laptop and access to identifiable data will be limited to study staff by use of password protected files or restricted shared file areas; (2) name and/or medical record number will be replaced with a study ID or code and the key to the code stored in a password protected file; (3) direct identifiers, such as name and medical record number, will be removed once all of the data is collected and analysis performed on de-identified data.

The potential risks to subjects are minimal in this study. To minimize the risks to subjects, all data with identifiable health information will be stored on encrypted servers with storage on encrypted hard drives, both located behind Partners Research Computing firewalls; no datasets reside on laptops or other portable media. Only study staff will have access to the data. In addition, there is no direct contact with human patient subjects for this study and the study uses only existing data sources. The primary risk to patients is the potential loss of confidentiality, which will be minimal given our existing security structures, and that we only will present aggregated data in the results. We also will use de-identified analytic datasets. Further, we will not share subject-level data. In particular, when geo-coding, we will use this information to calculate address to address differences (e.g., from the address of a hospital to the centroid of each five-digit zip code), but will only report area-based results (e.g., at the county or zip code level).

Explain why the research could not practicably be carried out without the waiver of consent / authorization. When addressing this question, consider the difficulty in locating individuals who may have moved, the number of subjects and cost and use of limited resources of locating individuals and sending letters and consent forms, and the impact on the scientific validity of the study if you could use only data of individuals from whom you were able to obtain informed consent.

The large sample size of populations over decades across the datasets would make it impractical to be able to obtain individual consent for this research. In addition, the scientific validity of the study could be compromised if there is a selection bias in which patients are locatable, and which patients consent (given that more severely ill patients may be less likely to have housing stability over the past several years, and more severely ill patients may have more difficulties with anergia, concentration, energy and psychosis, all of which can impact on their willingness to provide informed consent).

NOTE: "Only in a few research studies would it be impossible to obtain informed consent; however in many studies the financial cost would be prohibitive and a potentially poor use of limited research resources." ***Ensuring Voluntary Informed Consent and Protecting Privacy and Confidentiality, National Bioethics Advisory Commission.***

Explain why the rights and welfare of the subjects will not be adversely affected by the waiver of consent / authorization. When addressing this question, consider the individual's right to privacy and the measures you have put in place to protect the privacy of subjects and confidentiality of any data and any health/medical implications for subjects; for example: (1) identifiable data will be stored securely with access limited to study staff; (2) information resulting from this study will not have any important health/medical implications for subjects.

The rights and welfare of subjects will not be adversely affected by the waiver of consent/authorization given that the risks to subjects are minimal and there are several processes in place to mitigate any risks to subjects. First, there is no direct contact with human patient subjects in this study as this study uses only existing data sources. In addition, the major risk to patients is the potential loss of confidentiality which will be mitigated given the existing security precautions (e.g., data will be kept on secure servers, only study staff will have access to data, using de-identified analytic datasets). Furthermore, the information gleaned from this study will not have any health or medical implications of subjects.

NOTE: If the research uncovers information about the subjects that has important health / medical implications for them, contact the PHRC to discuss the appropriate process for providing subjects with additional pertinent information.

Are healthcare providers also subjects of the research?

◉ Yes ○ No

Explain why it would be impossible to conduct the research without access to and use of identifiable health / medical information. For example, the data cannot be obtained from electronic health / medical records or databases without access to identifiers or identifiers are needed for prospective data collection.

We will be examining variation in coordinated specialty care for first episode psychosis and will be studying changes in psychiatric resources, which will include changes in provider supply such as the number of psychiatric hospital beds or coordinated specialty care clinics. We will only look at this in aggregate and do not plan to report on individual providers.

Explain why the risk to subjects, specifically the risk to privacy, is no more than minimal risk. When addressing this question, describe the measures you have put in place to protect the privacy of subjects and confidentiality of the data; for example: (1) identifiable health information will be stored on a computer on the Partners network with password protections enabled and anti-virus software or an encrypted laptop and access to identifiable data will be limited to study staff by use of password protected files or restricted shared file areas; (2) name and/or medical record number will be replaced with a study ID or code and the key to the code stored in a password protected file; (3) direct identifiers, such as name and medical record number, will be removed once all of the data is collected and analysis performed on de-identified data.

The potential risks to subjects are minimal in this study. To minimize the risks to subjects, all data with identifiable health information will be stored on encrypted servers with storage on encrypted hard drives, both located behind Partners Research Computing firewalls; no datasets reside on laptops or other portable media. Only study staff will have access to the data. In addition, there is no direct contact with human patient subjects for this study and the study uses only existing data sources. The primary risk to patients is the potential loss of confidentiality, which will be minimal given our existing security structures, and that we only will present aggregated data in the results. We also will use de-identified analytic datasets.

Explain why the research could not practicably be carried out without the waiver of consent / authorization. When addressing this question, consider the difficulty in locating individuals who may have moved, the number of subjects and cost and use of limited resources of locating individuals and sending letters and consent forms, and the impact on the scientific validity of the study if you could use only data of individuals from whom you were able to obtain informed consent.

We are requesting a waiver of consent because it would not be feasible to contact all subjects in these large historical datasets. First, it would be difficult to contact and locate each of these subjects, including individuals who may have moved and the cost would be prohibitive for this. Second, we do not have identifiers with which to contact subjects.

Explain why the rights and welfare of the subjects will not be adversely affected by the waiver of consent / authorization. When addressing this question, consider the individual's right to privacy and the measures you have put in place to protect the privacy of subjects and confidentiality of any data and any health/medical implications for subjects; for example: (1) identifiable data will be stored securely with access limited to study staff; (2) information resulting from this study will not have any important health/medical implications for subjects.

The rights and welfare of subjects will not be adversely affected by the waiver of consent/authorization given that the risks to subjects are minimal and there are several processes in place to mitigate any risks to subjects. First, there is no direct contact with human patient subjects in this study as this study uses only existing data sources. In addition, the major risk to patients is the potential loss of confidentiality which will be mitigated given the existing security precautions (e.g., data will be kept on secure servers, only study staff will have access to data, using de-identified analytic datasets). Furthermore, we will only look at this in aggregate and do not plan to report on individual providers.

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7. Research Data

How will research data be recorded and stored?

☑ Electronically

Electronic Research Data

What type of device will the research data be accessed and stored on?

Check all that apply.

☐ Cloud (e.g., OneDrive, Dropbox, Amazon S3, Azure, etc.)
☐ Desktop computer
☐ Portable device i.e., Laptop, Netbook, Tablet, iPod computer, Cell/Smart phone
☐ USB Flash/Thumb, External Hard Drive
☑ Other device

Describe other device:

All data will remain on Partners Research Computing servers. There is minimal access to this facility and it is secured by guards 24/7. The data will remain on the servers at all time, and will not be transferred to any personal computers, laptops, or removable devices.

Portable devices can include cell phone/smart phones, laptops, iPad/tablet computers, iPods or any other electronic device that can communicate wirelessly. For information on portable device security, refer to the Partners Portable Device Security Handbook (PHS Internal only link)

Where is the primary storage location of the device(s)? For example, the desktop computer is located in the PI's locked office on White 1; the laptop is stored in office 123 of White 1 and is secured to a desk with a laptop lock; the hard drive is stored in a locked cabinet in office 123 on White 1 and access is limited to study staff only, etc.

All data will remain on Partners Research Computing servers. There is minimal access to this facility and it is secured by guards 24/7. The data will remain on the servers at all time, and will not be transferred to any personal computers, laptops, or removable devices.

Who will have access to the electronic research data stored at PHS? For example, PI, PHS study staff, non-PHS research collaborators who will access data onsite or remotely. There are both IRB and institutional policies regarding how non-PHS collaborators can access PHS electronic systems, whether clinical or research. Describe in detail if requesting non-PHS, research collaborator access to electronic data stored on PHS systems.

Note: For more information, see PHRC guidance regarding Non-BWH/Non-MGH Employees as Co-Investigators/Study Staff and Collaborators.

Only study staff will have access to the data.

NOTE:

- **All computers and portable devices must have password protections enabled;**
- **All computers must have active anti-virus software;**
- **Laptops, tablet, netbook computers, and USB Flash/Thumb drives must be full disk encrypted;**
- **If data will be transmitted outside the Partners firewall, data must be encrypted during transit with the use of SSL/https.**

Will data be uploaded to a website/server?

○ Yes ◉ No

☐ Paper

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8. Sending Health / Medical Information to Collaborators Outside Partners

Will any health / medical information be sent to collaborators outside Partners?

○ Yes ◉ No

HIPAA and Limited Data Sets/Tracking Disclosures of Identifiable Health Information (PHI)

1. Tracking is NOT required for disclosure of LIMITED DATA SETS under a DATA USE AGREEMENT. For more information about LIMITED DATA SETS and DATA USE AGREEMENTS, refer to Partners policy "Limited Data Sets Policy/Data Use Agreements" (PHS Intranet link).

2. Disclosures of PHI to persons or entities outside Partners without the written authorization of the subject must be tracked in accordance with Partners policy "Accounting of Disclosures" (PHS Intranet link). You may use the HIPAA Tracking Tool. NOTE: A code derived from the subject's name is considered identifiable, for example, a code that contains subject initials.

NOTE: Partners (PHS) is the HIPAA covered entity. PHS includes BWH, BWFH, MEE, MGH, NWH, NSMC, McLean, PCHI and SRH, among others. PHS does not include other Harvard affiliated hospitals, such as BIDMC, DFCI, HSPH, or CHB. Therefore, when PHS investigators send identifiable information to investigators at BIDMC, DFCI, HSPH, CHB or any other institution outside Partners, it is considered a disclosure of protected health information.