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. Organiations may wish to review that document prior to submitting this Application.*

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

- Data Availability
- Fee Schedule
- Data Request Process

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

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@state.ma.us.

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

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

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

III. ORGANIZATION & INVESTIGATOR INFORMATION

Project Title:	Characterizing Care Coordination in Pulmonary Hypertension
IRBNet Number:	1723406-1
Organization Requesting Data (Recipient):	Trustees of Boston University
Organization Website:	https://www.bumc.bu.edu/busm/
Authorized Signatory for Organization:	**William Segarra, JD, MPH**
Title:	Director, Industry Contracts and Agreements
E-Mail Address:	segarra@bu.edu
Telephone Number:	617-353-4365
Address, City/Town, State, Zip Code:	25 Buick Street, Suite 200, Boston, MA 02467
Data Custodian: **(individual responsible for organizing, storing, and archiving Data)**	**Eric Jacobsen**
Title:	Director, Information Security, Information Services & Technology
E-Mail Address:	jacobsen@bu.edu
Telephone Number:	617-353-8284
Address, City/Town, State, Zip Code:	930 Commonwealth Ave Boston, MA 02215
Primary Investigator (Applicant): **(individual responsible for the research team using the Data)**	**Kari Gillmeyer, MD**
Title:	Assistant Professor, BU School of Medicine
E-Mail Address:	krgill@bu.edu
Telephone Number:	617-638-4862
Address, City/Town, State, Zip Code:	72 E. Concord Street, R-304, Boston, MA 02118
Names of Co-Investigators:	Renda Wiener, MD, MPH; Seppo Rinne, MD, PhD
E-Mail Addresses of Co-Investigators:	rwiener@bu.edu; seppo@bu.edu

IV. PROJECT INFORMATION

IMPORTANT NOTE: Organization represents that the statements made below as well as in any study or research protocol or project plan, or other documents submitted to CHIA in support of the Data Application are complete and accurate and represent the total use of the CHIA Data requested. Any and all CHIA Data released to the Organization under an approved application may ONLY be used for the express purposes identified in this section by the Organization, and for no other purposes. Use of CHIA Data for other purposes requires a separate Data Application to CHIA written request to CHIA, with approval being subject to CHIA's regulatory restrictions and approval process. Unauthorized use is a material violation of your institution's Data Use Agreement with CHIA.

1. What will be the use of the CHIA Data requested? [Check all that apply]

☐ Epidemiological	☐ Health planning/resource allocation	☐ Cost trends
☒ Longitudinal Research	☒ Quality of care assessment	☐ Rate setting
☐ Reference tool	☒ Research studies	☐ Severity index tool (or other derived input)
☐ Surveillance	☐ Student research	☐ Utilization review of resources
☐ Inclusion in a product	☐ Other (describe in box below)	

This project is an academic research study that aims to determine the current landscape of pulmonary hypertension care delivery in the state of Massachusetts and care patterns that are associated with high quality pulmonary hypertension care.

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.

Pulmonary hypertension (PH) is a serious disease of the pulmonary vasculature that carries a poor prognosis. The management of PH is complex and often requires a multidisciplinary approach to care with involvement of providers across multiple specialties.[1] Care for certain high-risk PH groups also requires timely referral from community-based settings to PH specialty care centers (SCCs),[2] referrals that often cross healthcare systems. Moreover, SCCs are often concentrated in dense urban areas with a paucity of specialty PH care in rural areas, creating access challenges.[3] While engaging specialists may increase expertise in PH management, it may also result in care fragmentation and the attendant risk of duplicative or missed tests or treatments,[4] higher costs,[5] and worse clinical outcomes.[6,7] Indeed, we have previously shown that PH patients often receive their diagnosis and treatment in discordant locations across healthcare systems.[8] Effective care coordination is key to reaping the benefits of specialist expertise while mitigating harms associated with care fragmentation.

While guidelines recommend a multidisciplinary approach to PH care,[1] they offer little guidance on how to achieve effective care coordination, particularly when patients receive care across multiple healthcare systems. Social network analysis (SNA) is an emerging tool in health care to understand how relationships between providers within a network, as measured by shared patients, may affect care quality and patient health.[9] Prior SNA studies in other disease states have revealed care patterns that are associated with improved healthcare costs,[10,11] quality of care,[12-14] and patient outcomes.[15,16] We propose to apply SNA to PH to provide unique insight into the relationship patterns that promote high-quality care coordination. Through use of these innovative methods, this research has the potential to identify modifiable individual and network characteristics that could enhance PH care coordination to improve quality of care and outcomes for patients living with PH.

Aim 1: Identify and characterize existing patient-sharing provider networks for PH. We will leverage the Massachusetts All-Payer Claims Database (APCD) to identify providers who have seen ≥ 30 patients with PH between 2014-2018 (the most recently available data). Using SNA, we will calculate a range of network statistics on the patient, provider and network level to characterize the structure and composition of the network and to identify network characteristics that signify care coordination, such as care density, a reflection of the connectedness among a patient's provider team, and clustering coefficient, a measure of the tendency for providers in a network to assemble into tightly-bound groups.[9] *Hypothesis: PH provider networks including SCCs have a higher degree of care coordination compared to community networks that do not include an SCC.*

Aim 2: Examine the impact of care coordination within a PH provider network on quality of care. We will explore the association between select PH network characteristics from Aim 1 and established metrics of PH quality of care, including prompt referral to a SCC and initiation of treatment with pulmonary vasodilators for high-risk PH subgroups,[2,17] avoidance of pulmonary vasodilators in PH groups that may be harmed by treatment,[18,19] and performance of right heart catheterization prior to initiation of therapy with pulmonary vasodilators.[2] To do so, we will build mixed effects multivariable regression models controlling for patient-level characteristics, again leveraging the APCD. *Hypothesis: Patients cared for in networks with greater degree of care coordination will receive higher quality care*.

References

1. Galiè N, Humbert M, Vachiery JL, et al. 2015 ESC/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension: The Joint Task Force for the Diagnosis and Treatment of Pulmonary Hypertension of the European Society of Cardiology (ESC) and the European Respiratory Society (ERS): Endorsed by: Association for European Paediatric and Congenital Cardiology (AEPC), International Society for Heart and Lung Transplantation (ISHLT). Eur Respir J 2015;46(4):903-75
2. Frost A, Badesch D, Gibbs JSR, et al. Diagnosis of pulmonary hypertension. Eur Respir J 2019;53(1)
3. Pulmonary Hypertension Association. Tenets of PH Care Centers. (https://phassociation.org/phcarecenters/).
4. Carico R, Zhao X, Thorpe CT, et al. Receipt of Overlapping Opioid and Benzodiazepine Prescriptions Among Veterans Dually Enrolled in Medicare Part D and the Department of Veterans Affairs: A Cross-sectional Study. Ann Intern Med 2018;169(9):593-601.
5. Frandsen BR, Joynt KE, Rebitzer JB, Jha AK. Care fragmentation, quality, and costs among chronically ill patients. Am J Manag Care 2015;21(5):355-62.

6. Tsai TC, Orav EJ, Jha AK. Care fragmentation in the postdischarge period: surgical readmissions, distance of travel, and postoperative mortality. JAMA Surg 2015;150(1):59-64.
7. Snow K, Galaviz K, Turbow S. Patient Outcomes Following Interhospital Care Fragmentation: A Systematic Review. J Gen Intern Med 2020;35(5):1550-1558.
8. Gillmeyer KR, Lee KM, Shao Q, et al. Multisystem Healthcare Use among U.S. Veterans with Pulmonary Hypertension. Ann Am Thorac Soc 2019;16(8):1072-1074.
9. DuGoff EH, Fernandes-Taylor S, Weissman GE, Huntley JH, Pollack CE. A scoping review of patient-sharing network studies using administrative data. Transl Behav Med 2018;8(4):598-625.
10. Pollack CE, Frick KD, Herbert RJ, et al. It's who you know: patient-sharing, quality, and costs of cancer survivorship care. J Cancer Surviv 2014;8(2):156-66.
11. Pollack CE, Weissman GE, Lemke KW, Hussey PS, Weiner JP. Patient sharing among physicians and costs of care: a network analytic approach to care coordination using claims data. J Gen Intern Med 2013;28(3):459-65.
12. Stein BD, Mendelsohn J, Gordon AJ, et al. Opioid analgesic and benzodiazepine prescribing among Medicaid-enrollees with opioid use disorders: The influence of provider communities. J Addict Dis 2017;36(1):14-22.
13. Pollack CE, Lemke KW, Roberts E, Weiner JP. Patient sharing and quality of care: measuring outcomes of care coordination using claims data. Med Care 2015;53(4):317-23.
14. DuGoff EH, Cho J, Si Y, Pollack CE. Geographic Variations in Physician Relationships Over Time: Implications for Care Coordination. Med Care Res Rev 2018;75(5):586-611.
15. Hussain T, Chang HY, Veenstra CM, Pollack CE. Collaboration Between Surgeons and Medical Oncologists and Outcomes for Patients With Stage III Colon Cancer. J Oncol Pract 2015;11(3):e388-97
16. Hollingsworth JM, Funk RJ, Garrison SA, et al. Association Between Physician Teamwork and Health System Outcomes After Coronary Artery Bypass Grafting. Circ Cardiovasc Qual Outcomes 2016;9(6):641-648.
17. Galiè N, Channick RN, Frantz RP, et al. Risk stratification and medical therapy of pulmonary arterial hypertension. Eur Respir J 2019;53(1)
18. Vachiéry JL, Tedford RJ, Rosenkranz S, et al. Pulmonary hypertension due to left heart disease. Eur Respir J 2019;53(1)
19. Nathan SD, Barbera JA, Gaine SP, et al. Pulmonary hypertension in chronic lung disease and hypoxia. Eur Respir J 2019;53(1)

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**: Applicantions 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.*

PH is a devastating cardiopulmonary disease that exerts a significant burden on patients and healthcare systems. Those diagnosed with the disease suffer low health-related quality of life and high mortality rates with a 5-year survival of 38-42% in population based studies.[1,2] Despite improvements in our understanding of the disease with development of novel disease-modifying therapies over the past two decades, the prognosis for patients living with PH remains poor. Recognized care delivery gaps in PH include delays in diagnosis, incomplete diagnostic evaluations leading to inaccurate classification of PH, under-utilization of advanced therapies in subgoups of PH that may benefit, and inappropriate use of

advanced therapies in subgroups that may experience harm. These care gaps are potentially mediated through care fragmentation among multidisciplinary teams and across healthcare systems. Care coordination in PH has long been recognized as critical to mitigate care fragmentation, close care gaps, and improve outcomes for patients living with PH. Yet, how to achieve care coordination in PH is not clear. This project is a foundational step to understand the landscape of PH care across Massachusetts and to determine care patterns that are associated with improved quality of care. The results of this project will inform the development and implementation of effective interventions to improve care coordination and thereby care quality for PH among teams and across healthcare systems. Thus, the results of this project will be of interest to diverse members of the public including patients, caregivers, clinicians, researchers, administrators, and policymakers.

References:

1. Wijeratne DT, Lajkosz K, Brogly SB, Lougheed MD, Jiang L, Housin A, Barber D, Johnson A, Doliszny KM, Archer SL. Increasing Incidence and Prevalence of World Health Organization Groups 1 to 4 Pulmonary Hypertension: A Population-Based Cohort Study in Ontario, Canada. Circ Cardiovasc Qual Outcomes. 2018 Feb;11(2):e003973.
2. Trammell AW, Shah AJ, Phillips LS, Michael Hart C. Mortality in US veterans with pulmonary hypertension: a retrospective analysis of survival by subtype and baseline factors. Pulm Circ. 2019 Jan-Mar;9(1):2045894019825763.

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 insured and self-insured plans. APCD data are refreshed and updated annually and made available to approved data users in Release Versions that contain five calendar years of data and three months of run-out. For more information about APCD Release Versions, including available years of data and a full list of elements in the release please refer to release layouts, data dictionaries and similar documentation included on CHIA's website.

Data requests are typically fulfilled on a one time basis, however; certain Projects may require future years of data that will become available in a subsequent release. 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 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. Select Release Version and years of data requested (Release Versions and years not listed are not available).

☐ **Release Version 7.0**	☒ **Release Version 8.0**
☐ 2013	☒ 2014
☐ 2014	☒ 2015
☐ 2015	☒ 2016
☐ 2016	☒ 2017
☐ 2017	☒ 2018

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:

We require medical claims to complete the following:

1. Identify our study cohort of patients with PH, which will be defined by at least two visits (either inpatient or outpatient) linked to an International Classification of Diseases (ICD) 9th revision (416.xx) or 10th revision (I27.x) diagnosis code.
2. Assign study subjects to World Health Organization (WHO) PH groups (necessary for identifying our outcomes) ICD code-based algorithms that we have previously developed and validated.
3. Define covariates in our models such as comorbidities and markers of healthcare utilization (e.g., counts of outpatient visits and hospitalizations)
4. Define our outcomes including 1) performance of a right heart catheterization prior to treatment with pulmonary vasodilators, 2) avoidance of pulmonary vasodilators in WHO Groups 2/3 PH, 3) time from PH diagnosis to referral to a speciality care center, and 4) time from PH diagnosis to treatment with pulmonary vasodialtors in WHO Group 1 PH

☒ Pharmacy Claims

Describe how your research objectives require Pharmacy Claims data:

We require pharmacy claims to determine whether study subjects received a prescription for a pulmonary vasodilator. This information will be used define our outcomes including 1) performance of a right heart catheterization prior to treatment with pulmonary vasodilators, 2) time from PH diagnosis to treatment with pulmonary vasodilators in WHO Group 1 PH, and 3) avoidance of pulmonary vasodilators in WHO Groups 2/3 PH

☐ 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:

We require member eligibility data to define covariates in our model including member demographics and type of health plan. These variables are potential confounders of the association between network measures and quality of care outcomes.

☒ Provider

Describe how your research objectives require Provider data:

We require provider data to construct patient-sharing provider networks, to calculate network statistics, and to define covariates in our models such as provider specialty, organizational affiliation, and PH patient panel size

☒ Product

Describe how your research objectives require Product data:

We require product data to identify insurance plan elements (e.g., annual per person or per family deductibles, enrollment in a coordinated care model) as covariates in our models assessing the association between network measures and quality of care outcomes.

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

The geographic subdivisions listed below are available for Massachusetts residents and providers only. 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:**
This project requires 5-digit zip codes for the following, which are crucial to the completion of the project:

1. We will link member 5-digit zip codes to American Community Survey data (see section IX) to determine neighborhood-level socioeconomic variables such as median household income and % living below the poverty level.
2. We will also use ZIP codes to categorize member location as urban or rural using rural-urban commuting area (RUCA) codes.These variables are key covariates required in our models assessing the effect of network metrics on quality of care outcomes

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:**
We require date resolution including month and day in order to precisely define our outcomes, including time from PH diagnosis to treatment, time from PH diagnosis to referral to a specialty care center, and performance of a right heart cateterization prior to treatment with pulmonary vasodilators

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:**
We require unencrypted NPI numbers in order to link APCD data to external publicly available data sets including the CMS National Plan and Provider Enumeration System (NPPES) and the Provider Enrollment, Chain, and Ownership System (PECOS) (see section IX) in order to determine provider specialty and organizational affiliation. These variables are key to constructing patient-sharing provider networks.

VIII. MEDICAID (MASSHEALTH) DATA

1. Please indicate whether you are seeking Medicaid Data:

☒ Yes
☐ No

2. Federal law (42 USC 1396a(a)7) restricts the use of individually identifiable data of Medicaid recipients to uses that are ***directly connected to the administration of the Medicaid program***. If you are requesting MassHealth Data, please describe, in the space below, why your use of the Data meets this requirement. *Your description should focus on how the results of your project could be used by the Executive Office of Health and Human Services in connection with the administering the MassHealth program*. Requests for MassHealth Data will be forwarded to MassHealth for a determination as to whether the proposed use of the Data is directly connected to the administration of the MassHealth program. CHIA cannot release MassHealth Data without approval from MassHealth. This may introduce significant delays in the receipt of MassHealth Data. [17-19]

This study is directly connected to the administration of the MassHealth program as a goal of this research is to improve access, coordination, and quality of pulmonary hypertension care for MassHealth enrollees. Prior work has shown that individuals with pulmonary hypertension belonging to socially disadvantaged groups including those who are Medicaid enrollees have worse clinical outcomes.[1-3] The drivers of these disparities are not fully characterized though may be mediated through disparities in access to care or coordination of care. This project aims to identify gaps in care delivery for patients with pulmonary hypertension across the state of Massachusetts. Findings from this work can be used by the Executive Office of Health and Human Services to bolster gaps in pulmonary hypertension care delivery for MassHealth enrollees and thereby improve the quality of care for these individuals.

References:
1. Parikh KS, Stackhouse KA, Hart SA, Bashore TM, Krasuski RA. Health insurance and racial disparities in pulmonary hypertension outcomes. *Am J Manag Care.* 2017;23(8):474-480.
2. Talwar A, Sahni S, Kohn N, Klinger JR. Socioeconomic status affects pulmonary hypertension disease severity at time of first evaluation. *Pulm Circ.* 2016;6(2):191-195.
3. Wu WH, Yang L, Peng FH, et al. Lower socioeconomic status is associated with worse outcomes in pulmonary arterial hypertension. *Am J Respir Crit Care Med.* 2013;187(3):303-310.

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

We plan to link CHIA Data to the following datasets:

1. Provider Level Data: We will link provider level data using the National Provider Identification (NPI) number to the publicly available CMS NPPES dataset to identify provider specialty and organizational affiliation. If pertinent data in NPPES are missing, we will link provider level data via the NPI number to the publicly available PECOS dataset.
2. Aggregate Data: We will link member 5-digit zip codes to the American Community Survey and rural-urban commuting area (RUCA) codes to identify neighborhood-level measures of socioeconomic status such as median income level and % living below the poverty level, and to categorize member location as rural or urban.

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.

Deterministic for each

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.

1. CMS NPPES: including National Provider Number, Entity Type Code, Provider Organization Name, Provider Practice Location, Provider Taxonomoy codes
2. PECOS (as needed if significant missing data in CMS NPPES): including National Provider Number, Organizational Provider Name, Practice Location, Provider Type
3. American Community Survey / Census data: including total population, median household income, number of persons living below the poverty level, number of persons without high school education, number of persons living in rural area
4. Rural Urban Commuting Area codes

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

Individual patient-level data will not be linked. Our study team will not attempt to identify any patients and any data shared outside of the study team (such as that used for publication) will be aggregate data with cell sizes larger than 11.

X. PUBLICATION / DISSEMINATION / RE-RELEASE

1. Do you anticipate that the results of your analysis will be published or made publically available? If so, how do you intend to disseminate the results of the study (e.g.; publication in professional journal, poster presentation, newsletter, web page, seminar, conference, statistical tabulation)? Any and all publication of CHIA Data must comply with CHIA's cell size suppression policy, as set forth in the Data Use Agreement. Please explain how you will ensure that any publications ***will not disclose a cell less than 11***, and percentages or other mathematical formulas that result in the display of a cell less than 11.

We will publish our results in high-impact peer-reviewed journals and through presentation at local, national, and international scientific conferences. As per the Data Use Agreement, we will not disclose any cell less than 11 to members outside of our study team. We will carefully review all abstracts, posters, and manuscripts prior to publication to ensure that only aggregate data meeting these requirements are included.

2. Describe your plans to use or otherwise disclose CHIA Data, or any Data derived or extracted from such Data, in any paper, report, website, statistical tabulation, seminar, or other setting that is not disseminated to the public.

N/A

3. What will be the lowest geographical level of analysis of data you expect to present for publication or presentation (e.g., state level, city/town level, zip code level, etc.)? Will maps be presented? If so, what methods will be used to ensure that individuals cannot be identified?

Our primary results will be network statistics from Aim 1 and odds ratios and hazard ratios from Aim 2. While zip codes will be used to create the networks, they will not be the primary output. Any descriptive statistics

using geographical data will be suppressed such than no cell that includes fewer than 11 individuals will be presented. We will present social network maps. Individuals cannot be identified from these maps as they do not relate to geographic regions.

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.

Kari Gillmeyer, MD, is an Assistant Professor of Medicine at Boston University School of Medicine. She has experience using claims data including Medicare data and Veterans Health Administration (VA) data. She has

developed and validated the algorithms that will be used to identify patients with pulmonary hypertension in the database, and has experience performing hierarchical modeling as will be done in Aim 2 of this proposal.

Seppo Rinne, MD, PhD, is an Assistant Professor of Medicine at Boston University School of Medicine. He has experience using claims data including Medicare and VA data, including using claims data to conduct social network analyses, as will be done within this proposal.

Renda Wiener, MD, MPH is a Professor of Medicine at Boston University School of Medicine. She is a renowned health services researcher who has extensive experience using claims data including Medicare data, VA data, the National Inpatient Sample, the California State Inpatient Database, among others.

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:	**N/A**
Company Website	Click here to enter text.
Contact Person:	Click here to enter text.
Title:	Click here to enter text.
E-mail Address:	Click here to enter text.
Address, City/Town, State, Zip Code:	Click here to enter text.
Telephone Number:	Click here to enter text.
Term of Contract:	Click here to enter text.

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

N/A

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

N/A

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

☐ Yes
☒ No

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

AGENT/CONTRACTOR #1 INFORMATION	
Company Name:	**N/A**
Company Website	Click here to enter text.
Contact Person:	Click here to enter text.
Title:	Click here to enter text.
E-mail Address:	Click here to enter text.
Address, City/Town, State, Zip Code:	Click here to enter text.
Telephone Number:	Click here to enter text.
Term of Contract:	Click here to enter text.

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

N/A

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

N/A

3. Will the agent or contractor have access to 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)	Drag signature image here or delete and physically sign
Printed Name:	**William Segaraa**
Title:	Director, Industry Contracts and Agreements
Date:	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.

Non-Government-APCD-Application-Gillmeyer_BU

Final Audit Report 2021-05-27

Created:	2021-05-27
By:	Julia Walter (jlwalter@bu.edu)
Status:	Signed
Transaction ID:	CBJCHBCAABAA7zrWf9tgnBspM2sa530QzaDSCTgXdK5u

"Non-Government-APCD-Application-Gillmeyer_BU" History

Document created by Julia Walter (jlwalter@bu.edu)
2021-05-27 - 9:54:31 PM GMT- IP address: 155.41.100.54

Document emailed to William Segarra (segarra@bu.edu) for signature
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Document e-signed by William Segarra (segarra@bu.edu)
Signature Date: 2021-05-27 - 11:10:15 PM GMT - Time Source: server- IP address: 76.28.81.16

Agreement completed.
2021-05-27 - 11:10:15 PM GMT

Study Application (Version 1.1)

1.0 General Information

***Please enter the official title of your study:**

Characterizing Care Coordination in Pulmonary Hypertension Using Social Network Analysis

***Please enter the Study Nickname you would like to use to reference the study:**

SNA for PH Care Coordination
* This field allows you to enter an abbreviated version of the Study Title to quickly identify this study.

2.0 Add Department(s)

2.1 List departments associated with this study (Note: The primary department should accurately reflect the primary Department or Section of the PI. Please verify that the primary department listed is correct (in some cases the "default" department of BU/BMC Medicine has been selected). For large departments, the PI's appropriate "section" should be listed as the primary department (e.g. if the PI is from Neurology or Infectious Disease). If the PI is from the SPH - select the appropriate department within SPH (e.g. Epidemiology) as primary.):

Primary Dept?	Department Name
⦿	**BMC/BUMC** - *MED* - Pulmonary, Allergy, Sleep and Critical Care Medicine

3.0 List of Internal (BMC/BUMC) Study Personnel. All personnel listed in this section will have access to this study (limited or full access).

3.1 * Please add a Principal Investigator for the study:
(Note: Only faculty members can serve as Principal Investigators on IRB protocols for studies at the School of Dental Medicine)

Gillmeyer, Kari Renae, MD

Select if applicable

☐ Student ☐ Resident

☐ Fellow

If the Principal Investigator is a Student, Resident, or Fellow, the name of the Supervising Principal Investigator (formerly known as Faculty Sponsor) must be supplied BOTH in Section 3.3 (Study Contact) AND in Section 3.4 (Supervising Principal Investigator) below.

3.2 If applicable, please select the Research Staff personnel. Individuals must be listed if they will have contact with research subjects or their identifiable data in the performance of any research related activities, including enrollment, consenting, collection of study data, interventions, long-term follow-up or data analysis, either as Co-Investigators in A) or as Research Support Staff in B).

A) Additional Investigators

Rinne, Seppo, MD, PhD
Co-Investigator
Wiener, Renda, MD, MPH
Co-Investigator

B) Research Support Staff

3.3 *Please add a Study Contact:

Gillmeyer, Kari Renae, MD

The Study Contact(s) will receive all important system notifications along with the Principal Investigator. The study contact(s) are typically either the Study Coordinator or the Principal Investigator. A Study Contact must also be listed in Section 3.1, 3.2, 3.4, or 3.6. If the PI is a student, resident, or fellow, the Supervising Principal Investigator MUST be entered here.

3.4 If the PI is a student, resident, or fellow, you MUST add the Supervising Principal Investigator here:

3.5 Please ONLY list the PI's Department Chair/Section Chief below. The system will automatically route for signoff to any additional "Special Routing" approvals, so please do not list those here.

Center, David, MD
Department Chair/Section Chief

**Add the name of the individual authorized to approve and sign off on this study from your Department (e.g. the Department Chair or Dean). This should be someone other than the Principal Investigator. For more information, click on the (?) Help icon.

3.6 If applicable, please select the Administrative Assistant(s):

List here anyone performing administrative tasks only (not engaged in research and having no contact with subjects or identifiable data; where training and COI disclosure are not required) An Administrative Assistant can also be a Study Contact.

4.0 Review Path Determination

4.1 Review Path Determination

- ○ This project meets the definition of Not Human Subject Research (NHSR). Examples are non-research Quality Improvement/Quality Assurance projects; studies that involve obtaining anonymous data /tissues or coded data; or BMC/BU Medical Campus is not 'engaged' in human subjects research.
- ○ BMC/BU Medical Campus (the Relying Institution) cedes IRB review to another institution (the Reviewing Institution) under an Authorization Agreement.
- ○ The only research activities in this study involve chart reviews.
- ○ This study fits into one or more of the federal Exempt categories or the study does not have external funding and fits into one or more of the Equivalent Protections Exempt categories.
- ◉ None of the above. This study requires Expedited review or the review of the Full Board.

4.2 Emergency Use Report

Is this a report of an Emergency Use of an Investigational Drug or Device that has already occurred? For more information, click **here**.

○ Yes ◉ No

4.3 Individual Patient IND

Is this application for an FDA approved Individual patient (single use) IND under **21 CFR 312.310**?

○ Yes ◉ No

4.4 Humanitarian Use Device

Is this application for an FDA approved Humanitarian Use Device under **21 CFR 814**?

○ Yes ◉ No

5.0 Required Training and Conflict of Interest

5.1 BMC/BU Medical Campus Institutional Requirements for training

☑ The PI confirms the following:

- All individuals at Boston Medical Center or Boston University Medical Campus who will have contact with subjects or their identifiable data have been listed on this application in Section 3.0 (including those who will obtain informed consent, analyze identifiable data, perform study interventions, recruit subjects, etc.)
- All individuals listed in Section 3.0 have completed their INSPIR profile or have been asked to do so.
- All individuals listed in Sections 3.1, 3.2, and 3.4 are up to date with human subjects training and with GCP training if required. For more information, click **here**.

5.2 Conflict of Interest Disclosure

I confirm that **all** those responsible for the design, conduct, or reporting of the proposed program, including at minimum, all Senior/key personnel in the grant application, will, before this application is submitted, have completed the required financial interest disclosure through **COI Smart** for **Boston Medical Center** or through the **Financial Interest Disclosure form** for **Boston University**. NOTE: The IRB considers any missing financial interest disclosures to be noncompliance by the Principal Investigator.

☑ I confirm

Of the financial interest disclosure forms that will be completed, will any significant financial interests that are related to the research be disclosed?

○ Yes ◉ No

6.0 Funding Source

6.1 Funding Source

What is the source of your research funding? If you have multiple sources of funding (including sub-awards), check all that apply.

- ☐ Student/Resident/Fellow Research with no External Funding (choose if the PI is a student/resident/Fellow and the study is student/resident/Fellow research)
- ☐ Department/Internally Funded (choose if the PI is not a student/resident/Fellow and the study has no specific funding)
- ☐ Government
- ☐ Industry
- ☑ Foundation/Other
- ☐ Training Grant (e.g. T32, K-award)

6.2 Study Type

This study is:

- ◉ Initiated by the BMC/BU Medical Campus PI
- ○ Other

Does this study meet the definition of a clinical trial as defined by the International Committee of Medical Journal Editors? (See help for definition)

- ○ Yes
- ◉ No

NOTES:

- Studies that meet the ICMJE definition will **not** receive final IRB approval until the IRB is provided with the NCT number from **clinicaltrials.gov**. The responsibility for registering falls to the PI or Sponsor of the trial. For more information, click **here**.
- Clinical trials that are also initiated by the BMC/BU Medical Campus PI are **required** to consult with the **CRRO** prior to submission. Note that this pre-review consultation requirement is not satisfied by a consultation about registering with clinicaltrials.gov.
- All **BMC** and **BU Medical Campus** investigators or research team members that need assistance with **ClinicalTrials.gov** should contact ***Karla Damus*** *in the CRRO (**damusk@bu.edu**, (617) 358-7382)* . Examples of help include: registration of a clinical study to obtain the **NCT identifier** required by the IRB for all clinical trials, accessing/becoming a ClinicalTrials.gov user, resetting a forgotten password, and updating or reporting results for registered studies.

If this trial has been registered, please enter the 8 digit NCT number in the box, below:

6.3 Funding Details

For instructions on how to complete this section, click on the Help icon.

View Details	Sponsor Name	Sponsor Type	Contract Type:	BU SAP Grant Number or BMC AU Number	Award Number
⊟	Parker B. Francis Fellowship	Foundation - Non-profit	Grant	Pending	Pending

Sponsor Name:	Parker B. Francis Fellowship
Sponsor Type:	Foundation - Non-profit
Sponsor Role:	Payor;
Grant/Contract Number:	
Project Period:	From:07/01/2021 to:06/30/2024
Is Institution the Primary Grant Holder:	Yes
Contract Type:	Grant
BU SAP Grant Number or BMC AU Number:	Pending
Award Number:	Pending
Grant Title:	Characterizing Care Coordination in Pulmonary Hypertension: A Mixed Methods Study
PI Name: (If PI is not the same as identified on the study.)	

6.4 Grants Office

In the check boxes below, please indicate which grants office is handling your award/ sub-award.

- [x] BU Office of Sponsored Programs (OSP-med)
- [ ] BMC Research Finance (RF)
- [ ] BMC Clinical Trial Office (CTO)
- [ ] Charles River Campus Office of Sponsored Programs (OSP-CRC)
- [ ] Other (must list below)

Funding Notifications:

- [x] I have received a Notification of Award (NoA)
- [ ] I have received a Just In Time notice (JIT)
- [ ] I have received a fundable score for this study.

7.0 Study Summary

7.1 Provide a brief summary of the project in terms understandable to a non scientist (in 500 words or less). Do NOT copy from a grant application.

Pulmonary hypertension (PH) is a severe disease affecting the blood vessels within the lungs. People living with PH tend to have many providers involved in their care including primary care providers, cardiologists

or pulmonologists *without* specific expertise in PH, cardiologists or pulmonologists *with* expertise in PH, and sometimes other specialists. These providers may see patients in different clinics, hospitals, and healthcare systems. While seeing many providers can improve access to experts, it can also cause gaps in care and lead to fragmented care including repeating important tests or treatment by different providers or missing important tests or treatments altogether. These gaps often worsen the quality of care for people and increase healthcare costs. Coordinating care between providers is vital to prevent those gaps. We do not yet know how to best do this for PH. For this proposal, we will measure how well PH care is coordinated in the state of Massachusetts using a method called network science. We will then determine the degree to which care coordination can improve the quality of PH care, like getting the right tests and treatments at the right time for people with PH. This research has the potential to improve care coordination and quality of care for people with PH.

8.0 Navigation Menu

Please note: Questions in the Navigation Menu section determine which subsequent sections will be displayed and which ones will be hidden. If later you make any change to the Navigation Menu section, you will need to click on the "Save and Continue to Next Section" button throughout the whole application to display any new required section or hide any sections that are no longer required.

8.1 Separate Protocol

Is this a new submission with a separate protocol? This protocol must be from the sponsor or cooperative group or be based on the **protocol template** found on the IRB website, and must include the purpose, inclusion/exclusion criteria, design/procedure, and data safety and monitoring plan. A separate protocol is REQUIRED for all initial submissions of medical or surgical clinical trials. Depending on the complexity of the study, the IRB Director or Chair may require a separate protocol for other types of initial submissions. Please contact **medirb@bu.edu** if you have questions about whether a separate protocol is needed.. A GRANT APPLICATION IS NOT A PROTOCOL.

- ○ Yes
- ◉ No
- ○ Not applicable, this is not a new submission

8.2 International Research

Are any BU/BMC investigators involved in any way in research activities at non-US sites, including oversight of international research activities?

○ Yes ◉ No

8.3 Subjects Recruitment

Is the PI/study staff recruiting subjects for this study?

- ○ Yes
- ◉ No

8.4 Subjects Consent

Will informed consent be obtained from any of the subjects?

- ○ Yes
- ◉ No

8.5

Genetics

Does this research involve genetic testing, gene therapy, or collection of genetic information?

○ Yes ◉ No

8.6 Biological Samples Collection

Does this study involve collecting biological samples for research purposes?

○ Yes ◉ No

8.7 Drugs/Biological Agents

Does this study involve administering drugs or biological agents?

○ Yes ◉ No

8.8 Devices

Does this study involve the use of one or more device (as **defined** by the FDA) other than for routine measurements or monitoring (e.g., an EKG machine)?

○ Yes ◉ No

8.9 Radiation

As part of this study, will subjects be exposed to any procedures involving ionizing radiation for research purposes only?

○ Yes
◉ No

8.10 Samples or Data Retained for Extra Use

Will you be collecting samples or data that will be retained for extra use by yourself or other investigators? Extra use means any analysis that is in addition to that required for the study endpoints. Please also answer Yes if this study has been submitted solely to establish a repository.

○ Yes ◉ No

8.11 StudyFinder Listing

Do you agree to have the study title, summary, and PI name and e-mail address listed on StudyFinder, a publicly viewable medical campus website for general publicity and collaboration purposes? (If you also want to use StudyFinder to recruit subjects, there is another question to answer in the Recruitment section.)

◉ Yes ○ No

9.0 Study Site Information

9.1 Select one:

- (•) Single site research - conducted by BMC/BU Medical Campus investigator(s)
- ( ) Multi-site research project - BMC/BU Medical Campus is a research site but is NOT the main study site
- ( ) Multi-site research - BMC/BU Medical Campus is the main research site and/or the BMC/BU Medical Campus Principal Investigator is the overall PI of the entire study or the FDA sponsor

9.2 IRB Authorization Agreement – BMC/BU Medical Campus is the Reviewing Institution

Does this study have or require an Authorization Agreement for External (non-BMC/BU Medical Campus) investigators who will rely on BMC/BU Medical Campus IRB review? ***

( ) Yes (•) No

***If this study has or will require an IRB Authorization Agreement where BMC/BU Medical Campus investigators will rely on IRB review by another institution, do not check YES here, but instead, go to Section 4.1 and check the 2nd option, "BMC/BU Medical Campus (the Relying Institution) cedes IRB review to another institution (the Reviewing Institution) under an Authorization Agreement.".

10.0 Purpose

10.1 Background/Rationale/Purpose

Provide background information, study rationale, and purpose / study objective(s) and/or hypotheses for this study.

The diagnosis and management of pulmonary hypertension (PH) is challenging, often involving multiple providers and referrals to PH specialty care centers, referrals that often cross health systems. Effective care coordination is critical to capitalize on PH specialist expertise while mitigating harms associated with care fragmentation. Yet, how to achieve this important goal in PH is unclear. Social network analysis (SNA) is an innovative tool that may provide new insight into PH care coordination patterns. The goal of the proposed research is to identify and characterize opportunities for improvement in PH care coordination, which will inform development and testing of an intervention to promote care coordination for PH in a subsequent study. We will achieve this goal through the following aims:

Aim 1: Identify and characterize existing patient-sharing provider networks for PH in Massachusetts.
Aim 2: Examine the impact of care coordination within a PH provider network on quality of care.

11.0 Subjects

11.1 Inclusion Criteria

Include age ranges and sex. If study involves different criteria for different cohorts, please list separately.

Order Number	Criteria
	We will identify study subjects within the Massachusetts All-Payer Claims Database (APCD) who meet the following inclusion criteria: **Patients** 1. Adults age ≥ 18 years 2. Diagnosed with PH defined by at least two visits (either inpatient or outpatient) linked to an International Classification of Diseases diagnosis code between 2014-2018

1	3. At least one face-to-face visit with a provider in Massachusetts **Providers** 1. Have seen ≥30 PH patients between 2014-2018 2. Specialty that commonly cares for PH patients including primary care providers, pulmonologists, cardiologists, thoracic surgeons, rheumatologists, and palliative care providers 3. Practice in a zip code in Massachusetts

11.2 Exclusion Criteria

Include age ranges and sex. If study involves different criteria for different cohorts, please list separately. Do NOT duplicate inclusion criteria; if no additional criteria, indicate "None."

Order Number	Criteria
1	No study subjects will be excluded based on race, religion, ethnicity, or sex.

11.3 Race / Ethnicity

Will the expected demographic breakdown of the study population reflect either the Boston population or BMC population?

- ○ Yes
- ◉ No

If you answered "No", please explain why below:

As the primary data source for this study (the Massachusetts APCD) includes medical claims across the state of Massachusetts, the expected demographic breakdown of the study population will mirror that of Massachusetts and will likely differ from the demographic breakdown of Boston and the BMC population.

11.5 Special Populations (for more information, click on the (?) Help icon)

Please indicate if ANY (even one) of the following populations will be recruited (Note: Enrollment from any of these categories requires prior IRB approval):

- ☐ Minors who are wards of the State**
- ☐ Cognitively impaired subjects (will require use of an LAR, and assessment of ability to consent)**
- ☐ Employees, students, or trainees under the direct supervision of the PI**
- ☐ Minors**
- ☐ Minors independently making their own healthcare decisions**
- ☐ Non-English speaking subjects**
- ☐ Pregnant Women**
- ☐ Prisoners**
- ☐ Women of child-bearing potential
- ☐ Individuals whose HIV testing status is provided to the study team prior to consent being obtained (e.g., for recruitment)
- ☐ Individuals identified as a patient of a federally-assisted substance use disorder clinic (Project RESPECT, Office-Based Addiction Clinic, CATALYST Clinic, or others - see (?) Help Icon for full list)

Please indicate if any of the following populations will be targeted by your research:

- ☐ BMC Residents or Fellows
- ☐ BU Dental Students
- ☐ BU Medical Students and/or Graduate Medical Sciences Students
- ☐ BU School of Public Health Students
- ☐ Homeless**
- ☐ Individuals with psychiatric disorders**
- ☐ Terminally ill patients**

**designated as vulnerable

12.0 Design/Procedure

12.1 Design and Procedure

Describe in detail the experimental design, including all materials and all procedures to be performed. Do NOT copy from a grant application – your application will be returned to you for revision if you do so.

Please include a clear timeline of the procedures to be performed. Clarify which procedures /test articles are investigational and which are part of standard clinical care. This description may include:

1. methods
2. specific information concerning experimental interventions, such as dose and frequency of drug (and placebo) administration, or deception/debriefing process for social behavioral studies
3. number, frequency and duration of subject contacts (visits, telephone calls, mail outs, emails)
4. entire duration of participation for a single subject
5. any additional requirements of the subject (post treatment follow-up, diary cards, questionnaires, etc.)
6. If any nursing staff (other than research nurses) are expected to interact with subjects, include a brief description of the plan for inservice training of nursing staff.

   (Note: For multiple sites, indicate which of the procedures will be done at any other sites other than BMC/BU Medical Campus (see Study Site Information). Attach, in the Study Attachments section, copies of any surveys, questionnaires, and other data collection instruments.)

Methods
Aim 1: Identify and characterize existing patient-sharing provider networks for PH in Massachusetts.
Data sources and study sample: To complete this aim, we will leverage the Massachusetts APCD, the most comprehensive source of health claims data in Massachusetts that includes claims from all commercial payers, self-insured employers, Medicaid, and Medicare and captures more than 90% of the state's population. This database provides comprehensive patient information including demographics, socioeconomic variables, medications, comorbidities, procedures, and healthcare utilization; and provider information including geographic location and national provider identification (NPI) numbers. We will additionally link the APCD data to NPI-level datasets such as the CMS National Plan and Provider Enumeration System (NPPES) and the Provider Enrollment, Chain, and Ownership System (PECOS), which are freely-accessible, publicly-available provider datasets, to obtain provider specialty and organization-level characteristics. Within the APCD, we will identify all adults (age ≥ 18 years) diagnosed with PH, defined by at least two visits (either inpatient or outpatient) linked to an International Classification of Diseases (ICD) 9th revision (416.xx) or 10th revision (I27.x) diagnosis code between 2014-2018 (the

most recently available data). We will limit the sample to patients who have had at least one face-to-face visit with a provider included in the network. We will limit providers to those who commonly care for PH patients such as primary care providers, cardiologists, pulmonologists, rheumatologists, or thoracic surgeons with a ZIP code in Massachusetts.

Construction of patient-sharing networks and network statistics: We will construct provider patient-sharing networks with providers representing "nodes" and connections or "edges" representing shared patients between providers. To fully summarize and characterize the networks, we will calculate a range of network statistics on the patient, provider, and network level that capture structural and compositional characteristics of the network and that assess measures of care coordination including care density and clustering coefficient. We will additionally create visual representations of the networks using open-source network software tools.

Aim 2: Examine the impact of care coordination within a PH provider network on quality of care.
Data sources: Massachusetts APCD, as described in Aim 1. Additionally, we will merge zip code-level patient data from the APCD with data from the American Community Survey conducted by the U.S. Census Bureau to assess zip code-level socioeconomic status characteristics, and with publicly-available Rural-Urban Commuting Area (RUCA) codes to determine level of rurality. The U.S. Census Bureau makes aggregate level data freely available to the public.

Primary exposures of interest and covariates: Our primary exposures of interest are SNA measures of care coordination as described in Aim 1, including care density and clustering coefficient. We will additionally explore other key patient-level drivers of quality of care such as demographics, zip-code level measures of socioeconomic status, insurance type, urban versus rural location, Elixhauser comorbidity score, and healthcare utilization; and provider-level variables such as specialty, PH patient panel size, and organizational affiliation.

12.2 Outcomes

Describe anticipated primary outcome and any secondary outcomes and how they will be measured:

We will use previously validated ICD-based algorithms to assign patients to World Health Organization PH Groups, and then assess quality of care using four established metrics. Each outcome will be measured using ICD codes and prescription data available within the Massachusetts APCD.
Primary outcome: Performance of right heart catheterization (RHC) prior to initiating pulmonary vasodilators for any PH patient
Secondary outcomes: 1) Time from PH diagnosis to speciality care center referral in Group 1 PH patients, 2) Time from PH diagnosis to treatment with pulmonary vasodilators for Group 1 PH patients, 3) Avoidance of pulmonary vasodilators in Groups 2/3 PH patients.

12.3 Data Analysis

Provide a description of your plan for data analysis. State the types of comparisons you plan (e.g. comparison of means, comparison of proportions, regressions, analysis of variance). Which is the PRIMARY comparison/analysis? How will the analyses proposed relate to the primary purposes of your study? If you are doing qualitative research please state how comparisons will be made.

Primary analysis:
The unit of analysis will be the patient. For network statistics at the provider level, we will assign patients to providers using an algorithm that matches the patient to the provider who delivered the plurality of PH care (defined by visits linked to an ICD PH code) over the study period. For time-to-event outcomes, we will build Cox-proportional hazards models with provider-specific random effects to account for clustering of characteristics. For dichotomous outcomes, we will construct mixed effect logistic regression models.

Sensitivity analyses:
To assess the stability of our results, we will perform several sensitivity analyses. First, we will examine patient-sharing among a more limited set of providers we hypothesize may be more important for care coordination and outcomes, including primary care physicians, pulmonologists, and cardiologists. Second, because coordination may be more challenging across health systems, we will estimate effects after controlling for whether patients received PH care in one or multiple healthcare systems. Finally, to assess

for residual confounding in the models, we will calculate an E-value to determine the minimum strength of association with the exposure and the outcome that an unmeasured confounder would need to have to nullify the results.

12.4 Sample Size/Specimens

How many subjects (or records, or specimens, or charts) will be enrolled in this study? Be sure to include all subjects who will be consented - even those who will be disqualified following consent because they did not meet the enrollment criteria.

Subjects under BMC/BU Medical Center PI
5000

Sample Size Justification

Describe how you will have access to a population that will allow recruitment of the necessary number of subjects. Indicate why you chose the sample size proposed. Provide your sample size calculations. If this is a pilot study, this justification does not necessarily require a formal sample size calculation, but should provide a rationale for choosing the sample size proposed (e.g. to estimate a mean to a certain accuracy, to determine if the response rate is above a certain percentage, etc.) Note: Once the IRB approves a certain study sample size then you may not enroll beyond that sample size without first obtaining approval from the IRB. Explain how many evaluable subjects you will need to end up with to answer your study question and how many subjects you will need to enroll and consent to achieve this number.

As this study is using secondary data collected through billing activities, the sample size will include all patients diagnosed with PH in the state of Massachusetts over the study period of 2014-2018.

Considering our primary outcome of performance of a RHC prior to initiating treatment with pulmonary vasodilators, prior population studies have shown the prevalence of this to range from 42-48%. Assuming a conservative difference of RHC being performed in 45% of patients cared for in networks with high degree of care coordination compared to 40% of patients cared for in networks with low degree of care coordination, with 80% power and alpha of 0.05, we would require a sample size of 3,068. At Boston Medical Center alone, 2,780 patients would meet the study inclusion criteria. Thus, we expect a much larger state-wide sample drawn from the Massachusetts APCD which will adequately power the study to detect differences in our outcome.

12.5 Study Attachments

You must attach to this application all surveys, interviews, questionnaires, focus group outlines, etc. that will be used in this study. The IRB must review these materials. If these items are included as part of the attached protocol they do not have to be submitted again. Failure to provide this information could result in a delay in IRB review. If some of the materials are not finalized- submit the DRAFT versions. The final versions will need to be approved by the IRB via an amendment PRIOR to use.

Version	Sponsor Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document
No Document(s) have been attached to this form.							

13.0 Risks & Benefits & Justification for Approval

13.1 Potential Risk/Discomforts

List the reasonably foreseeable risks or discomforts to subjects as a result of their participation in the research. Be sure to include physical harms, discomforts, hazards, inconveniences as well as the potential for any social harms (e.g. loss of job or insurability due to breach in confidentiality). For each risk listed be sure to describe the magnitude (seriousness) of the risk, the probability of occurrence, and the potential duration.

Data collection will be retrospectively obtained from the Massachusetts APCD, an administrative database managed by the Center for Health Information Analysis (CHIA) which contains health claims data from public and private payers providing insurance to MA residents and employees. There will be no direct contact with patients or providers, and no patient interventions performed during the proposal. We will collect patient information including demographics, comorbidities, social factors, prescriptions, procedures, and healthcare utilization. We will collect provider information including specialty, geographic location of practice, and organization affiliation. For patient-level data, we will receive a limited dataset from CHIA without direct patient identifiers. For provider-level data, we will request that National Provider Identification (NPI) numbers be included in the dataset. Provider NPI numbers will be linked to unique identifiers to create a coded dataset and will be stored on an encrypted, password-protected server behind a secure firewall maintained by Boston University. Only the PI will have access to the link between unique identifiers and provider NPI numbers. Given the nature of the study design, there will be no physical, psychological, social, cultural, financial or legal risks imposed on any of the study subjects. The only potential risks to study subjects are loss of privacy or confidentiality. We will take steps to mitigate these risks as outlined below.

Provide a description of how risks will be minimized including, if appropriate, the availability of medical or psychosocial resources that subjects might need as a consequence of the research.

To mitigate risk of loss of study subject privacy or confidentiality, we will store all data on an encrypted, password-protected platform behind Boston University's secure firewall on the BUMC Network Y Drive. We will link provider NPI numbers with a unique identifier to create provider coded data. The provider coded data and master key will be stored in separate, password-protected folders. Only the PI will have access to this link. Other members of the study team will have access to aggregate, de-identified data with cell sizes larger than 11 as per the data use agreement set forth by CHIA. We will not attempt to identify any individual provider or patient within the dataset.

13.2 Potential Benefits

Describe potential benefit(s) to be gained by the individual subject as a result of participating in the research. (Payments to subjects should not be included in this section.) If there are no direct benefits to individual subjects, you must include a societal benefit that may result from this study.

The results from this research will be foundational in developing and implementing interventions to improve care coordination, and thereby care quality, for patients living with PH. Through these mechanisms, this research has the potential to improve clinical outcomes for patients with PH, including those directly involved in this study and others not involved in the study.

13.3 Risk to Benefit Ratio

Describe how risks to subjects are reasonable in relation to anticipated benefits:

The anticipated benefits of this project to future patient care and health systems, as outlined above, far outweigh the small risks.

14.0 Data & Safety Monitoring

A data and safety monitoring plan (DSMP) is meant to assure that each clinical investigation has a system for oversight and monitoring of the conduct of the clinical investigation. This oversight is intended to ensure the safety of the participants and the validity and integrity of the data. A DSMP should be commensurate with the risks.

A DSMP can be as simple as the investigator reporting Unanticipated Problems, Adverse Events, and Protocol Deviations to the IRB. A DSMP can be as complex as having a Data and Safety Monitoring Board.

A DSMP can include clinical trial monitoring. Clinical trial monitoring refers to the methods used to oversee the conduct of, and reporting of data from, clinical investigations including appropriate clinical investigator supervision of study site staff. Monitoring activities include communication with the investigator and the study site staff; review of the study site's processes, procedures, and records; and verification of the accuracy of the data.

14.1 For more than minimal risk research, your application needs to include a separate Data and Safety Monitoring Plan. For more information, click here. Please check-off one of the options below:

- [x] This study is not greater than minimal risk. Unanticipated Problems, Adverse Events, and protocol deviations will be reported to the IRB as required by IRB policies.
- [ ] A DSMP is attached in a detailed protocol (provide page number in textbox below).
- [ ] A DSMP is attached in the Study Attachments section below.

14.2 Who will monitor the research for safety of the participants? (check all that apply)

- [x] The Principal Investigator at Boston Medical Center or BU Medical Campus who will report all adverse events and Unanticipated Problems to the IRB in compliance with IRB policy, Federal/State regulations, and sponsor requirements (as applicable).
- [ ] An independent Data Safety Monitoring Board/Data Monitoring Committee
- [ ] The Sponsor or Funding Agency
- [ ] Other:

14.3 DSMP Attachments

Here you can attach any Data and Safety Monitoring Plan documents including your DSMP, Data Safety Monitoring Board charter, and any other related documents.

Version	Sponsor Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document
No Document(s) have been attached to this form.							

15.0 Consent Procedures

15.3 Waiver or Alteration of Informed Consent Process

Does the study meet the criteria for a Waiver or Alteration of Consent Process?

○ No
◉ Yes

In the text box below, please provide study-specific reasons that justify how the study meets each of the following five criteria for Waiver or alteration of Consent. For more information, click **here**

1. the study is not greater than minimal risk; AND
2. that waiving the requirements for informed consent will not adversely affect the rights and welfare of study subjects; AND
3. that the research cannot be practicably carried out without the waiver of informed consent or alteration of the consent process; AND
4. If the research involves using identifiable private information or identifiable biospecimens, the research cannot practicably be carried out without using such information or biospecimens in an identifiable format (for research that is submitted for initial approval on or after July 1, 2017); AND
5. that (if applicable) there is a plan to disseminate pertinent information to study subjects or legally authorized representatives after the study is completed.

1. This study is minimal risk since the only risk is related to loss of confidentiality; however, there are protections in place to prevent a breach of confidentiality from happening including secure transfer and storage. These protections adhere to the requirements set forth by CHIA.
2. The rights and welfare of the subjects are not adversely affected as this project has sufficient protections in place to protect the data and the sharing of the data is consistent with CHIA & BU policies.
3. The research could not be practicably carried out without the waiver since it would be nearly impossible to recontact all subjects within the claims dataset to consent given that subjects' contact information may be out of date, people may have moved, or passed away. Given the sample size of this study, it would be impracticable to attempt to obtain consent for this secondary use.
4. For patients, direct identifiers (including name, address, DoB) will not be in the data set provided to us by CHIA and the study will never have access to the mastercode. Providers' NPI numbers, which is identifiable, will be coded in the analytic data and the mastercode will be kept securely in a separate location from the coded analytic dataset.
5. The results from this study will be investigational only and won't be clinically actionable. Therefore, it's appropriate to not provide subjects with any additional pertinent information.

15.5 Consent by Substituted Judgment

Do you intend to obtain consent from a Legally Authorized Representative (LAR) for cognitively impaired/decisionally impaired adult subjects?? For more information, click **here**.

○ Yes
◉ No

15.6 Non-English Language Consent Forms:

Will you obtain consent from subjects who are not fluent in English? For more information, click **here**.

○ Yes ◉ No

16.0 Privacy and Confidentiality

16.1 Privacy (Privacy refers to an individual's control over who has access to him/herself)

Please check one:

☑ The following measures will be used to protect the privacy of subjects and potential subjects:

- The information that will be obtained from and/or about subjects and potential subjects is the minimum necessary to conduct the study; and
- If any interventions and interactions occur with subjects and potential subjects, they will take place in private settings.

☐ Other appropriate measures will be used to protect the privacy of subjects and potential subjects (describe):

16.2 Confidentiality of the Data

In the section below indicate how the study will ensure subject confidentiality and privacy on all study data/results, documents, CRFs, and other documents/files:

☑ Study data/results, documents, CRFs, and other documents/files will be identified with a unique study ID #. The study ID # will be linked to a master-code list that contains all study ID #s and direct subject identifiers (i.e. name, address, DOB, MRN, etc). The master-code list will be maintained separately from study files and access limited to the researchers.

☐ All study data, documents, CRFs, and other documents/files will be recorded as anonymous. There is NO master-code. There will be no reasonable way to link study data and documents to individual subjects, even temporarily AND subject identities cannot be reasonable ascertained via deductive disclosure.

☐ There is an alternate plan for how subject will be identified in study data, documents, CRFs, and other documents/files. Please specify in text box below.

You have indicated above that Study data/results, documents, CRFs, and other documents /files will be identified with a unique study ID #. Please select one of the options below:

○ Study data/results, CRFs, and other documents/files for subjects who have been assigned a study ID # may also contain subject identifiers that by themselves or when combined with other identifiers, could result in identifying a subject (ex. maintaining paper medical records that contains a subject's name and MRN in a participant's research file.)

◉ Study data, documents, CRFs, and other documents/files for subjects who have been assigned a study ID # will NOT contain any subject identifiers that by themselves or when combined with others identifiers, could result in identifying a subject.

- **Please describe in the text box below how you will secure the data (e.g. how the master-code will be stored relative to the study data).**
- **If the dataset contains protected health information (PHI) or Personal Information (as defined under Massachusetts law) and is being stored electronically, please provide explicit confirmation that it will be stored according to BMC and/or BU policy for secure storage of such data. Please see the (?) Help Icon to the right for the definitions of PHI and Personal Information and for the appropriate storage options for BMC and BU and specify which will be used.**

For patient-level data, we will receive a limited dataset with all direct patient identifiers removed by CHIA. The only remaining potential identifiers that will be included in the limited data set are zip codes and dates of service.

For provider-level data, NPI numbers will be included in the dataset and will be merged with publically available NPI-level data such as NPPES and PECOS databases to obtain provider specialty and organization-level characteristics.

To mitigate risk of loss of study subject privacy or confidentiality, we will store all data on an encrypted, password-protected platform behind Boston University's secure firewall on the BUMC Network Y Drive. We will link provider NPI numbers with a unique identifier to create provider coded data. The provider coded data and master key will be stored in separate, password-protected folders. Only the PI will have access to this link. Other study team members will have access to aggregate, de-identified data with cell sizes larger than 11. We will not attempt to identify any individual provider or patient within the dataset.

Do you plan to share data with a third-party vendor or software application or program? Some examples include transcription services and smartphone apps. Note: sponsors are not considered third parties. Please contact the IRB @ medirb@bu.edu if you have questions about whether this applies to your study.

- ○ Yes
- ◉ No

16.3 Release of identifiable data.

Is identifiable data being released outside of BMC/BU Medical Campus? (e.g. to sponsors, because of mandated reporting, etc).

- ○ Yes
- ◉ No

Pertinent findings (related to the aims of the study) and incidental findings (unrelated to the aims of the study): Does the research (including screening) involve any test or procedure done for research purposes only that may yield findings that are of potential health or reproductive importance to the individual subjects (e.g., disease risk, abnormal lab values, imaging abnormalities, genetic results)?

- ○ Yes
- ◉ No
- ○ Not Applicable - no additional research results will be collected for this study.

16.4 Destruction of Identifiers

If the data are identifiable and/or if a master-code exists, when and how will the data be de-identified or the master-code be destroyed?

All data including de-identified data, identifiable data, coded data, and master key will be destroyed upon completion of the study per the data use agreement set forth by CHIA. BUMC IT will certify the destruction of data stored on central resouces under their control.

16.5 Certificate of Confidentiality from the NIH

Please check one option below. For more information, click **here**.

- ○ This study IS funded by the NIH or CDC; therefore, the study automatically has a Certificate of Confidentiality

(•) This study is NOT funded by the NIH or CDC

Please select one of the following options:

(•) A Certificate of Confidentiality is NOT needed, because the identifiable study data does not include potentially damaging information that needs protection from compelled disclosure

( ) A Certificate of Confidentiality IS needed to protect identifiable study information from compelled disclosure - the PI is responsible for applying to NIH for the Certificate of Confidentiality after IRB conditional approval

Note: Consent forms must be consistent with the above information. For consent form templates that show confidentiality language, click **here**.

17.0 HIPAA Compliance

17.1 Do you need access to protected health information (PHI) without signed authorization from the individual whose information you need?

(•) Yes
( ) No

17.2 Do you need PHI (without authorization) *only* to identify subjects for recruitment?

( ) Yes
(•) No

17.3 Note: All questions below only pertain to data that you are requesting to access without signed HIPAA Authorization from research participants. Do not include information below on data that you will collect AFTER obtaining signed HIPAA Authorization from the participants.

Please indicate your selection criteria for the records: (e.g. all Type 2 diabetics prescribed metformin, all men aged 50-75 with diagnosis of BPH)

All adults age >= 18 with a diagnosis of pulmonary hypertension, defined as at least two visits (either inpatient or outpatient) linked to an ICD-9 (416.x) or ICD-10 (I27.0) code for pulmonary hypertension in the state of Massachusetts between 2014-2018 who had at least one face-to-face visit with a provider in Massachusetts.

17.4 Indicate what date range is needed for the records: (e.g. 11/14/98-12/1/13)

1/1/2014 to 12/31/2018

17.5 Please list all data variables that are needed from the medical record or attach the file containing the data variables below. NOTE: If you are using the CDW to provide some or all of the data, the variables you list here will be utilized as your official data request by the CDW:

Patient variables
International Classification of Disease diagnosis codes (ICD-9 416.x, ICD-10 I27.x) linked to inpatient and outpatient visits
Demographics such as age, sex, race, and ethnicity
Insurance type
Medicaid enrollment
Healthcare utilization variables such as number of outpatient visits, emergency department visits, hospitalizations

Procedure codes
Prescription data for pulmonary vasodilators including type of medication, dose, date of prescription
5-digit zip code
Dates (in YYYMMDD format) of service

Provider variables
National Provider ID number
Provider DOB (year only)
CMS Provider type (individual or non-individual)

Version	Sponsor Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document
No Document(s) have been attached to this form.							

17.6 Will you be using the Clinical Data Warehouse (CDW) or will study staff be accessing the records?

- ○ CDW
- ◉ Study staff will access records
- ○ Both

17.7 Does your research require access to any of the HIPAA identifiers?

- ◉ Yes
- ○ No

What identifiers will you be accessing? Check all that apply, and provide detail where necessary:

Zip codes

Dates of service

No other protected health information will be included in the datasets

(The read-only answer displayed above is from the previous version of the Study Application. If you need to make any changes to the list of HIPAA identifiers in that read-only text box, please do this by fully checking off all of the HIPAA identifiers you need to access in the checkboxes below)

- ☐ The HIPAA identifiers are listed in the read-only text box above and it is still accurate (Otherwise, select the correct HIPAA identifiers in the list below)
- ☐ Names
- ☑ All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent geocodes, except for the initial three digits of the ZIP code if, according to the current publicly available data from the Bureau of the Census:
    - The geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people; and
    - The initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people is changed to 000

What geographic data will you access/record?

5-digit zip codes

- ☑ All elements of dates (except year) for dates that are directly related to an individual, including birth

date, admission date, discharge date, death date, and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older

Which dates will you access/record?

Dates of service (in YYYYMMDD format) including pulmonary hypertension-linked visits, hospitalizations, emergency department visits; dates of prescriptions for pulmonary vasodilators; dates of procedures such as right heart catheterizations

- ☐ Telephone numbers
- ☐ Fax numbers
- ☐ Email addresses
- ☐ Social security numbers
- ☐ Medical record numbers
- ☐ Health plan beneficiary numbers
- ☐ Account numbers
- ☐ Certificate/license numbers
- ☐ Vehicle identifiers and serial numbers, including license plate numbers
- ☐ Device identifiers and serial numbers
- ☐ Web Universal Resource Locators (URLs)
- ☐ Internet Protocol (IP) addresses
- ☐ Biometric identifiers, including finger and voice prints
- ☐ Full-face photographs and any comparable images
- ☐ Any other unique identifying number, characteristic, or code, including any code that includes or is derived from any of the identifiers on this list.

17.8 Please describe why the research cannot be conducted without access to protected health information:

Constructing patient-sharing provider networks using social network analysis, and mapping those networks geographically requires use of zip codes.

Identification of our outcomes including time to treatment with pulmonary vasodilators and time to referral to a specialty care center requires determination of dates of services.

This study cannot be completed without the above information.

17.9 Why is it not practicable to carry out the research if authorization must be obtained from the participants?

We expect our study sample to include thousands, and potentially tens of thousands of patients. Contacting this many patients to obtain authorization to review previously collected medical records would be overly burdensome and would be intrusive to the patients. Additionally, we will only receive a limited dataset from CHIA and will not have access to direct patient identifiers. Therefore, it would be impracticable to obtain authorization as we will not have access to patient identities or contact information.

17.10 What is your plan to protect any identifiable information from use and disclosure by unauthorized parties?

All datasets will be stored on an encrypted, password-protected server behind Boston University's firewall. Only study team members will have access to the data. Any data shared outside of the study team (such as that used for publication) will be aggregate, de-identified data with cell sizes larger than 11 as per the data use agreement set forth by CHIA. We will not attempt to identify any individual provider or patient within the dataset.

17.11 When and how will you destroy any identifiers linked to the data?

(Please note: identifiers should be destroyed at the earliest opportunity as consistent with the design of the research study)

All data including de-identified data, identifiable data, coded data, and the master code will be destroyed upon completion of the study per the data use agreement set forth by CHIA. BUMC IT will certify the destruction of data stored on central resouces under their control.

17.12 Please affirm the items below:

- [x] I agree that the protected health information will not be re-used or disclosed to any other person or entity, except as required by law, for the authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by the Privacy Regulation (45 CFR 164.512)
- [x] I declare that the requested information constitutes the minimum necessary data to accomplish the goals of the research.

18.0 Cost/Payment

18.1 Cost

Please describe the costs of research visits and procedures and who (the sponsor, the subject's insurance, or the subject) will be responsible for these costs. If any research costs will be billable to insurance, the costs to the subjects will include deductibles and co-payments. Costs of travel and/or parking should be included if the study requires additional visits beyond what would be required for standard clinical care.

As the data being used for this study is previously collected medical records, no costs for research visits or procedures will be incurred.

18.2 Payment

Will the subject be reimbursed for participating in this study? (e.g. money, gift certificates, coupons, etc.)

- ○ Yes
- ◉ No

19.0 Study Attachments

19.1 Attach here any remaining study documents that you have not attached in previous sections.

Version	Sponsor Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document
No Document(s) have been attached to this form.							

Institutional Review Board
72 E. Concord St., Robinson 4 – Suite 414
Boston, Massachusetts 02118-2307
Tel: 617-358-5372

Title of Study: Characterizing Care Coordination in Pulmonary Hypertension Using Social Network Analysis
IRB Number: H-41419

RE: Initial Review Submission Form
Review Type: Expedited
Action: Approved

Date of Approval: 03/31/2021
Expiration or Status Check-In Due Date: 02/29/2024

Funding Source: Parker B. Francis Fellowship
Award #: Pending

March 31, 2021

Dear Kari Renae Gillmeyer, MD,

A qualified member of the Institutional Review Board (IRB) has reviewed the above referenced submission and has determined that the study meets the requirements set forth by the IRB and is hereby approved. This submission was approved by the expedited review process in accordance with the policies and procedures of the Human Research Protection Program (http://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#10.2.2).

This approval is valid through the expiration or status check-in due date indicated above.

This approval corresponds with the versions of the application and attachments in the electronic system most recently approved as of the date of this letter.

Protocol Specific Determinations and Findings

- Not Greater than Minimal Risk under 45 CFR 46 / 21 CFR 56
- Limited Data Set under HIPAA Privacy Rule
    - The BUMC IRB acknowledges the PI will receive a HIPAA Limited Data Set from CHIA. Although the data set will not be housed under a covered entity, it will be secured using storage methods appropriate for the storage of PHI at Boston University.
- Waiver of informed consent approved under 46.116(f)

Approved HIPAA Data Sets:

Records Selection Criteria:
All adults age >= 18 with a diagnosis of pulmonary hypertension, defined as at least two visits (either inpatient or outpatient) linked to an ICD-9 (416.x) or ICD-10 (I27.0) code for pulmonary hypertension in the state of Massachusetts between 2014-2018 who had at least one face-to-face visit with a provider in Massachusetts.

Records Date Range:
1/1/2014 to 12/31/2018

HIPAA Identifiers:

- 5-digit zip codes
- Dates of service (in YYYYMMDD format) including pulmonary hypertension-linked visits, hospitalizations, emergency department visits; dates of prescriptions for pulmonary vasodilators; dates of procedures such as right heart catheterizations

Records Data Fields List:
Patient variables
International Classification of Disease diagnosis codes (ICD-9 416.x, ICD-10 I27.x) linked to inpatient and outpatient visits
Demographics such as age, sex, race, and ethnicity
Insurance type
Medicaid enrollment
Healthcare utilization variables such as number of outpatient visits, emergency department visits, hospitalizations
Procedure codes
Prescription data for pulmonary vasodilators including type of medication, dose, date of prescription
5-digit zip code
Dates (in YYYMMDD format) of service

Provider variables
National Provider ID number
Provider DOB (year only)
CMS Provider type (individual or non-individual)

As a principal investigator, you are reminded that you must comply with the responsibilities listed here <http://www.bumc.bu.edu/irb/maintaining-irb-approval/responsibilities-of-the-principal-investigator/>.

Sincerely yours,

Carolyn Swain, IRB Analyst