PROTOCOL TITLE:

Evaluating a Novel Approach to Dispensing Methadone in Carceral Facilities

PRINCIPAL INVESTIGATOR:

Brendan Saloner
Department of Health Services, Policy, and Practice
(401)-863-2228
brendan_saloner@brown.edu

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1.0 Study Summary

Protocol Information	Description
Study Title	Evaluating a Novel Approach to Dispensing Methadone in Carceral Facilities
Study Design	Aim 1: Clinical Trial (Learning Collaborative, surveys, interview) Aims 2 & 3: Secondary data analysis
Primary Objective	The overarching goal of this project is to generate research evidence that can support the broader implementation of methadone in carceral facilities using the hospital/clinic designation.
Secondary Objective(s)	We propose a mixed-methods study that engages early adopter facilities in a learning collaborative that will blend didactic education and applied problem-solving, evaluating implementation outcomes via surveys and qualitative interviews (Aim 1). We will use 2022-2028 carceral health records from Washington, Delaware and Colorado Departments of Corrections (DOCs) to study opioid use disorder (OUD)-related outcomes during incarceration (Aim 2). We will link carceral health records from Washington DOC with post-release Washington State Medicaid data to examine post-release OUD outcomes (Aim 3).
Research Intervention(s)	Learning Collaborative activities composed of 12 didactic sessions in Aim 1.
Study Population	**Aim 1:** All human subjects are **leaders from carceral systems** participating in their professional capacity. We will work with 30 leaders from 10 carceral systems. While the exact titles of the participants will vary by system, we anticipate each system will have three participants including 1) a leader from the medical team overseeing methadone provision (addiction medicine physician, medical director, etc.) 2) a leader responsible for budgeting within the system (chief operating officer, financial officer, etc.) 3) a leader from the security team (warden, deputy warden, etc.). **Aim 2: Secondary electronic record data of incarcerated individuals from Washington, Colorado and Delaware DOCs**. Sample inclusion criteria: 1) persons aged 18 or older, 2) who have met diagnostic criteria for OUD based on the screening/assessment tools used by the DOC, 3) from the time period of January 1, 2022 to December 31, 2028, and 4) at least one other documented health condition in the health record. We will require a minimum length of stay of 60 days to allow us to measure retention in care. **Aim 3**: **Health data from Washington DOC linked with Washington Medicaid data**. To examine post-release outcomes, we will identify a cohort of individuals who 1) met Aim 2 eligibility criteria in Washington State, 2) who were

	released from incarceration from years 2022-2027 (to allow for 12 months of follow up), and 3) were enrolled in Medicaid for at least 12 months following release.
Sample Size	**Aim 1:** 30 leaders from 10 carceral systems. **Aim 2:** We estimate that 50,042 individuals will meet screening criteria for OUD across the 7-year study period across the 36 facilities in the DOCs (or 199 per facility/year). **Aim 3:** Based on an estimate of 85% Medicaid enrollment among people released from incarceration, we expect our sample size for Aim 3 to be around 14,876.The Aim 2 population that links to Medicaid claims will be used for the Aim 3 analysis.
Study Duration for individual participants	**Aim 1:** Participants in the Learning Collaborative will participate in 12 sessions, 90 minutes each, over the course of 24 months. Participants will participate in three surveys, 20 minutes each (one at enrollment, midpoint, and conclusion of the Learning Collaborative). Participants will participate in one interview lasting approximately 45 minutes during the last year of the Learning Collaborative. **1,185 minutes total (approximately 20 hours) over 24 months** Aim 2-3: N/A - Electronic records
Study Specific Abbreviations/ Definitions	AE: Adverse Events BOP: Federal Bureau of Prisons CO: Colorado DE: Delaware DEA: Drug Enforcement Administration DOC: Department of Corrections DOJ: Department of Justice FDA: Food and Drug Administration h/c: hospital/clinic HCA: Health Care Authority ICC: Intraclass correlation coefficient JCOIN: Justice Community Overdose Innovation Network JHU: Johns Hopkins University LC: Learning collaborative MOUD: Medications for opioid use disorder ONDCP: Office of National Drug Control Policy OPA: Office of Planning and Analysis OTP: Opioid treatment program OUD: Opioid use disorder PDSA: Plan-Do-Study-Act PI: Principal investigator RE-AIM: Reach, effectiveness, adoption, implementation and maintenance RRC: Research Review Committee SAMHSA: Substance Abuse and Mental Health Services Administration

	SUD: Substance use disorder UW: University of Washington WA: Washington WSIRB: Washington State IRB

2.0 Objectives

Purpose of the Study
The purpose of this study is to evaluate how carceral facilities implement the federal hospital/clinic designation to expand access to methadone for opioid use disorder (OUD), and to assess the effects of this implementation using staff feedback and administrative data.

Aim 1 – Human Subjects Component
Aim 1 involves direct interaction with human subjects. The study team will engage carceral staff participating in a Learning Collaborative and will collect qualitative and quantitative data (surveys and interviews) to understand implementation experiences, barriers, and facilitators.

Aim 2 – Secondary Analysis of Identifiable Administrative Data
Aim 2 involves analysis of identifiable administrative data provided by three Departments of Corrections (Colorado, Delaware, Washington) to evaluate pre-release initiation and retention on MOUD during implementation of the hospital/clinic designation.

Aim 3 – Secondary Analysis of Identifiable Linked Data

Aim 3 involves linking Washington Department of Corrections (DOC) administrative data with Washington State Medicaid claims to examine post-release MOUD receipt and healthcare utilization

Hypotheses to be tested

Aim 1 (Human Subjects Component)
Hypothesis: Participation in the Learning Collaborative will be associated with improved staff-reported implementation readiness, perceived barriers, and adoption of the hospital/clinic designation within participating facilities.

Aim 2 (Secondary Data – Identifiable)
Hypothesis: Facilities implementing the hospital/clinic designation will demonstrate higher initiation and retention rates of MOUD during incarceration compared to facilities not yet implementing the designation.

Aim 3 (Secondary Data – Identifiable Linked Data)
Hypothesis: The hospital/clinic designation will be associated with improved post-release MOUD engagement and healthcare utilization outcomes within one year of release.

3.0 Background

Prior experience:

The study team has extensive prior experience working with carceral systems, OUD treatment, and implementation of methadone access in correctional settings. The investigators contributed to early policy analysis and fact-finding work related to the federal hospital/clinic designation,[1,2] participated in meetings with the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Drug Enforcement Administration (DEA) officials, and organized a national convening on methadone expansion in partnership with the White House Office of National Drug Control Policy (ONDCP).[3] This background informs the development of the Learning

Collaborative and supports the study's ability to evaluate early implementation efforts.

The team also has longstanding partnerships with Departments of Corrections in multiple states through prior grants focused on MOUD implementation, standards of care, and evaluation of MOUD programs in correctional settings. These prior collaborations provide the foundation for working with participating DOCs in Aim 1 and for accessing administrative datasets for Aims 2 and 3.

Finally, the investigative team brings substantial expertise in linking and analyzing administrative data related to incarceration, health care utilization, and overdose outcomes. Prior Department of Justice (DOJ)-funded work demonstrated the feasibility of securely linking criminal-justice data with health claims data and underscored the importance of post-release MOUD engagement.[4,5] This experience directly supports the analytic components of Aims 2 and 3.

Gaps in current knowledge:

Incarcerated persons have a high prevalence of OUD, and risk of fatal and nonfatal overdose surges immediately following release.[6–8] Providing MOUD during and following incarceration is a proven strategy for reducing overdose risk, yet few facilities offer MOUD.[9–11] Of the three MOUDs approved by the Food and Drug Administration, methadone is particularly challenging for carceral facilities to provide because it typically can be dispensed only by federally-accredited and certified opioid treatment programs (OTPs). Very few carceral facilities have created onsite OTPs, citing the costly, time-intensive process as a barrier to uptake.[12–15] Other facilities do not provide methadone or offer limited methadone through partnerships with community-based OTPs. This is often not feasible in rural areas without OTPs, where many carceral facilities are located.[16–19] Expanding access to carceral methadone is of key public health importance, because it is the optimal treatment for some patients, particularly those with high opioid tolerance associated with use of fentanyl and its analogs.[20–22]

In 2024, the Substance Abuse and Mental Health Services Administration (SAMHSA) released updated 42 CFR Part 8 rules, which clarified that any carceral facility registered as a "hospital/clinic" with the Drug Enforcement Administration (DEA) is permitted to stock and dispense methadone for the treatment of OUD, as long as the patient is primarily being treated for another medical condition.[23] Given the high prevalence of comorbidities[24] and the opportunity to provide methadone outside of OTPs, the hospital/clinic designation could dramatically expand access to MOUD for incarcerated persons. However, implementation also requires carceral systems to engage with potentially unfamiliar processes, such as applying for the hospital/clinic designation, stocking and dispensing methadone, and initiating and maintaining methadone treatment. Through a technical assistance partnership with our team, three state departments of corrections (DOCs) – Colorado, Delaware, and Washington – are the first jurisdictions to implement the hospital/clinic designation for this purpose, each at different stages of implementation. Given the recency of the hospital/clinic designation rules, this study aims to understand how these three DOCs are implementing, how adoption affects OUD-related outcomes during and after incarceration, and the cost-effectiveness of this process, all of which can inform future adoption of this novel approach for methadone provision.

Scientific background and rationale:

Research is needed to understand the implementation and effectiveness of the hospital clinic designation. Through our previous technical assistance work, we have developed sustained relationships with the first three DOCs moving forward with methadone dispensing under the hospital/clinic designation–Colorado, Delaware and Washington State. These systems vary in their incarcerated population demographics, healthcare service structure and use of hospital/clinic methadone. There is an urgent need for research to clarify the implementation and effectiveness of this innovation. This can reduce barriers to participation for other jurisdictions by sharing practical knowledge, and speaking directly to the costs and expected outcomes of this approach.

4.0 Study Endpoints

Primary Endpoint (Aim 1 – Human Subjects Component)
Changes in staff-reported implementation readiness, perceived barriers, and adoption of the hospital/clinic designation among carceral personnel participating in the Learning Collaborative.

Secondary Endpoint (Aims 2–3 – Secondary Analysis of Identifiable Data)
Measures derived from CO/DE/WA DOC, and WA Medicaid administrative datasets, including MOUD initiation, MOUD retention, and post-release MOUD engagement and healthcare utilization. These outcomes are assessed using identifiable secondary data and do not involve direct interaction with incarcerated individuals.

5.0 Study Intervention

n/a

6.0 Procedures Involved

Aim 1 – Human Subjects Component

Johns Hopkins University (JHU) PI Dr. Sachini Bandara will oversee Aim 1 activities. Aim 1 data will be stored on JHU servers. JHU and Brown personnel will conduct Aim 1 activities. UW personnel will advise on Aim 1 activities including curriculum and survey design.

Recruitment

The three state DOCs that are data partners for Aims 2-3 have also agreed to participate in the Aim 1 Learning Collaborative. Based on our prior technical assistance work, we are aware of several carceral systems that are pursuing or considering the hospital/clinic designation. We will reach out to leadership contacts in all of these systems with a recruitment email, outlining the specifics of the LC and requirements for participation. We will also engage professional associations such as the Correctional Leaders Administration, NCCHC, and the American Jail Association.

We will reach out to leadership of those carceral systems that are pursuing or considering the hospital/clinic designation (see *Appendix 4-Template email to carceral leadership*). Leadership

will share general study information (including study contact information) with their staff. Interested staff will contact the research team directly.

Once a potential participant is identified, study staff from Brown or JHU will screen each potential participant to identify whether they meet the criteria to participate in this study (see *Appendix 4.2-LC participant screening script*).

If we enroll participants from federal prisons, we will follow Department of Justice (DOJ) regulations for research in Aim 1 activities.

Learning Collaborative

Carceral staff will participate in a voluntary Learning Collaborative (LC), consisting of 12 virtual didactic sessions (called "learning sessions" in participant-facing material) over 24 months. The sessions will be 90 minutes long and generally occur every two months, typically between 12pm and 5pm Eastern Time. The LC curriculum is described in more detail in "*Appendix 1--Learning Collaborative outline*". LC content includes educational presentations and peer discussion related to implementation of the hospital/clinic designation. Data collection procedures consist of surveys and one interview.

Survey Procedures

Approximately 30 staff will be invited to complete three 20-minute online surveys: at enrollment, midpoint, and end of the LC. Participants will receive a Redcap link via email and may complete each survey at a time that is convenient for them, including outside of work hours. Surveys will assess implementation readiness and perceptions, barriers and facilitators to the hospital/clinic designation, staffing and resource needs, and perceived effects of the LC on implementation activities. See *Appendix 2-Survey instrument*.

Surveys are completed electronically by the participant; participants may request to complete them via phone or Zoom with a study team member.

Interview Procedures

Staff will be invited via email and/or phone to participate in one semi-structured Zoom video conference interview (~45 minutes) during the final year of the LC. Interviews will be scheduled for a time that works for the participant, including outside of work hours. Interviews will focus on staff professional experiences with implementation of the hospital/clinic designation and perceptions of the LC. See *Appendix 3-Interview guid*e. With permission, interviews will be audio-recorded and professionally transcribed. Identifiers will be removed from transcripts.

Protections Against Risks (Aim 1)

The study team will not inform employers of who participates. However, employers may ascertain participation based on behaviors (e.g., if someone attends a Zoom session during work hours). We will ask participants to ensure they are in a private place (e.g., with the door closed) prior to beginning a Zoom session. Surveys and interviews collect professional opinions only. Individual responses will not be shared with employers or facility leadership. Identifiers will be removed from transcripts and survey data. Files will be stored on secure servers (Johns Hopkins OneDrive). Risks consist primarily of potential loss of confidentiality.

Aims 2-3 – Secondary Analysis of Administrative Data

Brown PI Dr. Brendan Saloner will oversee Aims 2-3 activities. Aims 2-3 data will be stored on the Brown University Stronghold environment. JHU and Brown personnel will conduct Aims 2-3 analyses. UW personnel will advise on Aims 2-3 analyses, with a focus on WA DOC data components.

Aim 2 – DOC Data

Aim 2 will analyze identifiable administrative data from the three DOC partners (CO, DE, WA) for adults with OUD from 2022–2028. Records may include: demographic characteristics, incarceration dates, health service encounters, MOUD initiation and retention indicators.

Data will be transmitted securely under DUAs and stored in Brown University's Stronghold environment. No contact with incarcerated individuals will occur.

Aim 3 – Linked DOC–Medicaid Data

For individuals released from Washington DOC, DOC will transmit identifiable data to Washington State HCA for linkage with Medicaid claims. HCA will return a linked dataset with limited identifiers to the study team. Data include: DOC administrative variables (same as in Aim 2), Medicaid outpatient, inpatient, and pharmacy claims. Data will be transmitted securely under DUAs and stored in Brown University's Stronghold environment. No participant contact occurs in Aim 3.

Protections Against Risks for Aims 2–3

Data transfers will occur via encrypted, secure protocol. Brown University's Stronghold servers ensure encryption at rest and restricted access. Identifiers will be removed at the earliest possible stage. DUAs will be executed before any transfer. Risks are limited to loss of confidentiality.

For a breakdown of data management, security, transfer, and sharing for each Aim and dataset, please see *Table 1: Data handling* below.

Table 1: Data Handling

Aims	Content		Storage		Transfer within study	Transfer outside study	
Aim 1	Over-sight	Information included	Location	Access	Process	Location	Access/ transfer
Recruitment, compensation	mPI Bandara	Identifiable information to track recruitment and send compensation	JHU Onedrive	Only team members involved in recruitment and compensation. Access will be managed by mPI Bandara	n/a	n/a. will not be shared outside of study team	n/a. will not be shared outside of study team
LC recordings		Video recordings of didactic portions of LC (if a participant is sharing, will only be recorded with that participant's consent). Discussion portion will not be recorded.	JHU Onedrive	Only team members involved in LC. Access will be managed by mPI Bandara	Recordings will be sent to LC participants by sharing the Onedrive file. Upon receipt, the participant will have to verify identity via an emailed confirmation code.	JHU Onedrive	Only recordings of presentations given by study team (no participant voices) will be shared outside of the study
Surveys		Survey answers & study ID. Identifiable information will not be collected with survey data.	JHU Redcap and Onedrive	Only team members involved in survey collection and analysis. Access will be managed by mPI Bandara	Periodically, survey data will be exported from Redcap and stored onto Onedrive for quality control and analysis.	JDC/NAH DAP	De-identified data will sent on a quarterly basis to JDC. JDC will deposit data into NAHDAP at the end of the study. Qualified researchers may access for future research.
Interviews		Audio recordings, de-identified transcripts	JHU Onedrive,	Only team members involved in interviewing, transcript cleaning, and analysis. Access will be managed by mPI Bandara	When ready to begin analysis, deidentified transcripts will be uploaded from Onedrive to Dedoose (qualitative coding software)	Syracuse qualitative data repository	De-identified data will deposited on a quarterly basis into the Syracuse repository. Qualified researchers may access for future research.

Aim 2	Over-sight	Information included	Location	Access	Process	Location	Access/ transfer
DE DOC data	mPI Brendan Saloner	DE DOC electronic health records (EHR). Limited dataset	Brown Stronghold	Only team members involved in analysis. Access will be managed by mPI Brendan Saloner	DE DOC analyst will periodically transfer data to Brown's server via a secure file transfer	n/a. will not be shared outside of study team	n/a. will not be shared outside of study team
CO DOC data		CO DOC EHR. Limited dataset	Brown Stronghold	Only team members involved in analysis. Access will be managed by mPI Brendan Saloner	CO DOC analyst will periodically transfer data to Brown's server via a secure file transfer	n/a. will not be shared outside of study team	n/a. will not be shared outside of study team
WA DOC data		WA DOC EHR. Limited dataset	Brown Stronghold	Only team members involved in analysis. Access will be managed by mPI Brendan Saloner	WA DOC analyst will periodically transfer data to Brown's server via a secure file transfer	n/a. will not be shared outside of study team	n/a. will not be shared outside of study team
Aim 3	**Over-sight**	**Information included**	**Location**	**Access**	**Process**	**Location**	**Access/ transfer**
WA DOC data	mPI Brendan Saloner	WA DOC EHR. Identifiable data including name, DOB, address (to be used for matching/linkage)	HCA secure server	Only HCA analysts involved in data linkage. Study team will not have access	WA DOC analyst will periodically transfer data to WA HCA via a secure file transfer	n/a. will not be shared outside of study team	n/a. will not be shared outside of study team
WA DOC data linked to WA HCA Medicaid data		WA DOC EHR and WA HCA Medicaid data. PHI used for linkage will be removed by HCA. LDS will be transmitted to study team.	Brown Stronghold	Only team members involved in analysis. Access will be managed by mPI Brendan Saloner	WA HCA analyst will receive identifiable data from WA DOC, perform data linkage, delete PHI used for linkage, and transfer LDS to Brown's server	n/a. will not be shared outside of study team	n/a. will not be shared outside of study team

7.0 Data and Specimen Banking

Aims 1: Survey & Interview Data

Aim 1 data will contain transcripts and recordings of qualitative interviews and survey response data. As required by the funder (NIDA—JCOIN funding mechanism), deidentified Aim 1 survey data will be shared with JCOIN Data Central (JDC), which will then deposit the data into the National Addiction & HIV Data Archive Program (NAHDAP). Deidentified qualitative data will be

shared to the Syracuse Data Repository. The data and metadata will be archived in NAHDAP and the Syracuse Data Repository, but no identifiable data will be stored in these systems. We will deposit the data into the repositories as soon as possible but no later than the completion of the funded project period for the award or upon acceptance of the data for publication, whichever is earlier. Qualified researchers may submit applications to access the data for their research, which repository staff will review. Researchers must provide IRB approval or exempt determination and sign a DUA.

Both repositories (NAHDAP and Syracuse Data Repository) are searchable on the HEAL Initiative Data Ecosystem. Aim 1 associated documentation for quantitative survey data (e.g., study protocol, survey instrument) will be made accessible on NAHDAP to facilitate interpretation of the scientific data. Associated documentation for qualitative interview data (e.g., study protocol, interview guide, codebooks) will be made accessible in the Syracuse Data Repository.

We will store the audio recordings, transcripts, and memos from interviews in a password-protected, encrypted electronic storage on secure, password protected servers at Johns Hopkins University behind the University's firewall. Identifiable information stored for recontacting purposes will be stored in a separate place as study data and destroyed at the end of the study period.

Aims 2-3: Secondary Data
Carceral and Medicaid data for **Aims 2-3** are sensitive, proprietary to each state government, and will not be shared.

Metadata: Aims 2-3 statistical code, data dictionaries, summary tables, and measures will be deposited into NAHDAP.

8.0 Sharing of Results with Subjects

Survey data
Aggregated de-identified survey data will be shared with LC participants to assist LC participants in selecting topics for upcoming LC sessions.

Other resources
The following resources will be generated from this project: 1) process of care measures to track cascade of care for engagement and retention in MOUD treatment using carceral electronic health records, and 2) guidance documents and presentations resulting from the LC and dissemination efforts. These resources will be shared with study participants, as well as publicized on websites and listservs such as the National Commission on Correctional Health Care (NCCHC) and the American Correctional Association (ACA).

Additionally, in Y3-5, we will conduct four webinars disseminating study results targeting the following key stakeholder groups: LC participants, community providers and re-entry organizations in the three DOCs' jurisdictions; drug policy and criminal legal policy advocates; carceral staff interested in implementing the hospital/clinic designation; and policymakers interested in expanding access to MOUD in carceral settings.

9.0 Study Timelines

Duration of subject's participation in the study:
All participants in the LC (n = 30) will engage in 12 90-minute didactic sessions over the course of 24 months. Participants will complete a 20-minute survey during three points of the LC: one at time of enrollment, midpoint, and conclusion of the LC. Participants will complete one 45-minute interview during the final year of the LC.
In sum, a participant will spend a maximum of 1,185 minutes [(90 x 12) + (20 x 3) + 45], or approximately 20 hours actively engaged in the LC. The overall duration of the LC activities is 24 months.

Duration anticipated to enroll study subjects:
In Year 1, we will plan the initial learning collaborative activities and recruit participants. The learning collaborative will be conducted in Year 1 through Year 3 of the project. We will conduct the survey data collection and analysis at enrollment (Year 1); midpoint (Year 2) and after the conclusion of the collaborative (Year 3). We will conduct qualitative data collection during the last year of the collaborative (Year 3).

10.0 Subject Population

Aim 1

Aim 1 LC Participants – Human subjects component
Aim 1 will recruit professionals from carceral systems that are implementing or considering the hospital/clinical designation to provide methadone. The three DOCs (CO, DE, WA) that are our data partners for Aim 2 will also participate in the LC. We will recruit staff from additional carceral systems that are interested in or implementing the hospital/clinic designation. While the exact titles of the participants will vary by system, we anticipate to include the following: 1) an employee from the medical team overseeing methadone provision (addiction medicine physician, medical director, etc.) 2) an employee responsible for budgeting within the system (chief operating officer, financial officer, etc.) 3) an employee from the security team (warden, deputy warden, etc.).

Aim 1 Participant Exclusion Criteria: Individuals who meet any of the following criteria will be excluded from this study:1) under the age of 18, 2) unable to consent and complete the interviews/surveys in English, or 3) not involved in any security, medical, or budget/administrative aspects of the carceral system.

Aim 2 – Secondary data analysis
Aim 2 will involve secondary data analysis of electronic health records (EHR) from persons incarcerated in the three DOCs (CO, DE, WA) who are 1) persons aged 18 or older, (2) who have either met diagnostic criteria for OUD and/or have a record of OUD treatment prior to or during their incarceration in the DOC (3) from the time period of January 1, 2022 to December 31, 2028.

Aim 3 – Secondary data analysis of linked data
Aim 3 will focus on WA DOC data linked with WA Medicaid data. WA Health Care Authority (HCA) will link DOC records to the Medicaid records for 2022-2028. We will identify a cohort of individuals who 1) met Aim 2 eligibility criteria during incarceration, 2) who were released from incarceration from years 2022-2027 (to allow for 12 months of follow up), and 3) were enrolled in Medicaid for at least 12 months following release.

Aims 2-3 Dataset Parameters:
Aims 2-3 are secondary administrative data, records that are not included will be based on dataset availability of the following parameters: 1) have a minimum incarceration length of stay of 60 days 2) have one other non-OUD documented health condition in the health record 3) records from January 1, 2022 to December 31, 2028.

Inclusion/exclusion of special populations

- Individuals who are not yet adults
    - All Aims: Excluded
- Adults unable to consent
    - Aim 1: Excluded
    - Aims 2-3: Secondary data may include data of individuals unable to consent due to mental or neurodevelopmental conditions. However, they are not a target population.
- Pregnant women
    - All Aims: May include pregnant women. However, they are not a target population. The condition of their pregnancy is neither relative to a research aim or will it be affected by their participation/inclusion.
- Prisoners
    - Aim 1: Excluded
    - Aims 2-3: Target population. However, these individuals will not be contacted or enrolled as Aims2-3 are secondary data.

11.0 Vulnerable Populations

Prisoners

The following information from “HRP 415-Checklist-Prisoners” apply to this study:

- This research focuses on a condition particularly affecting prisoners as a class (i.e., opioid use disorder).
- This study is considered minimal risk under Subpart C, since prisoner involvement is limited to secondary analysis only, and does not involve interactions with prisoners.
- Prisoners are not recruited or contacted,
- There are no interventions with prisoners in this study.
- The only risk is loss of confidentiality with protections in place against this risk, see Section 17.0 Data Management and Confidentiality.

12.0 Local Number of Subjects

Aim 1 LC participants

This is a multi-site study with a total study-wide accrual goal of 30 participants for the LC activities (sessions, surveys, interviews). Study-team members at Brown and JHU will work

together to screen and enroll participants. We expect the accrual will be split between Brown (around 15 participants) and Johns Hopkins (around 15 participants) study team members. UW personnel will advise on Aim 1 activities but will not enroll participants.

Aim 2-3 Secondary data – N/A

13.0 Recruitment Methods

Aim 1 Participant Recruitment & Methods

Source of subjects

Aim 1 will recruit approximately 30 professionals from ~10 carceral systems to participate in the Learning Collaborative (LC). Carceral systems will be invited to participate based on their current implementation, imminent implementation, or consideration of methadone provision via the hospital/clinic designation. The three DOCs (CO, DE, WA) that are our data partners for Aim 2 will also participate in the LC. We will recruit staff from additional carceral systems that are interested in or implementing the hospital/clinic designation. If we enroll participants from federal prisons, we will follow Department of Justice (DOJ) regulations for research in Aim 1 activities.

Our goal is to recruit seven additional carceral systems as sources for LC participants. Based on our prior technical assistance work, we are aware of several carceral systems that are pursuing or considering the hospital/clinic designation. We will reach out to leadership contacts in all of these systems with a recruitment email, outlining the specifics of the LC and requirements for participation. We will also engage professional associations such as the Correctional Leaders Administration, NCCHC, and the American Jail Association. Our study team will not recruit participants from additional carceral systems for LC participation until all required approvals (per each carceral system's policies) are in place. For example, some systems may require the study team to submit a research request form to internal leadership for staff to participate in the study.

We will take the first 7 carceral systems that accept on a rolling basis with an option to expand to additional systems if capacity allows.

We will reach out to leadership of those carceral systems that are pursuing or considering the hospital/clinic designation (see *Appendix 4-Template email to carceral leadership*). Leadership will share general study information (including study contact information) with their staff. Interested staff will contact the research team directly. We will not request or receive lists of staff selected by leadership. Leadership will not track who participates. For emails to potential participants, see *Appendix 4.1-Template email to potential participan*ts.

Recruitment outreach & materials

Once a potential participant is identified, study staff from Brown or JHU will screen each potential participant to identify whether they meet the criteria to participate in this study (see *Appendix 4.2-LC participant screening script*). A recruitment log will be maintained with facility/system names, potential participant names/roles, and contact information to keep track of those who declined participation, requested access to LC didactic session recordings, and/or enrolled in the study. This log will inform the team in ongoing recruiting efforts and follow-up.

The information in the recruitment log will be destroyed at the end of the study period and will not be shared outside of the study team.

For each data collection event in Aim 1, we will send an initial email requesting their participation in the data collection event. The email will explain that the survey or interview will focus purely on leaders' professional experiences and opinions regarding implementation of the hospital/clinic designation and the LC, and reiterate the voluntary nature of the data collection event. We will then send weekly email reminders up to three times, after which we will call and/or text participants up to two times.

All data collection outreach and interviews will be conducted by study team members who are not part of the LC activities.

Aims 2-4 Participant Recruitment & Methods – Secondary data analysis only; N/A

Amount, method, and timing of payments to subjects

Aim 1

Each participant will be offered $50 for each survey/interview. We recognize that some organizations prohibit outside compensation, and in those circumstances participants may not be able to accept this compensation. Some organizations have policies that apply universally to payments for outside activities that may be related to their job. For those allowed to receive outside compensation: participants will receive $50 compensation per completed survey (i.e., a total amount of $150 if all three surveys are completed), and $50 if they participate in an interview ($200 maximum compensation total). The study team will not inform participants' employers of who participates or who receives compensation from this study. Attending didactic LC sessions will not be compensated. All compensation will be through prepaid debit cards purchased by the JHU team. JHU team members will send a prepaid debit card within one week after survey and interview completion. Prepaid debit cards will be sent out via email or mail depending on the participant's preference. Incomplete interviews or surveys (e.g., skipped questions) will not affect payment of the full amount.

Aims 2-4 – Secondary data analysis only; N/A

14.0 Withdrawal of Subjects

If the study team becomes aware that a participant has left their place of employment, or changed positions so that they are no longer involved in security, medical, or budget/administrative operations of their carceral system, they would no longer continue Aim 1 activities.

If a participant would like to discontinue participation in the LC, the study team will give the option to view recordings of subsequent LC sessions that do not include participant voices (i.e., recordings of study staff only) after the participant has withdrawn from the study.

Any reasons for participant discontinuation or withdrawal from the study will be recorded in the recruitment tracking spreadsheet. Unless the participant requests otherwise, their data will remain in the dataset.

15.0 Risks to Subjects

Aim 1: LC Foreseeable Risks

Aim 1 activities pose minimal psychological and social risks.

Risks related to recruitment & participation

During recruitment outreach, the study team will stress that participation in all research activities is voluntary and confidential. The study team will not inform participants' employer of their enrollment or involvement in this study. However, based on individual research activities, employers may be able to infer that a participant is involved in the study. Employers will not have access to participants' interview or survey data. Study team members will give assurance to participants that the study team will not share their decision to participate, or not participate, and any information shared during surveys and interviews will be kept confidential, so as to not affect their employment. We expect the probability of this risk occurring to be low.

During LC activities, it may be revealed that a carceral system requires their employees to participate in this study and/or is providing care in a matter that does not align with established guidelines. See "*Appendix 5 – Adverse event (AE) reporting protocol*" and "*Appendix 5.1—AE reporting table*" for more details on how this and other events will be assessed and addressed. We expect the probability of this risk occurring to be low. In addressing adverse events, we will adhere to policies of the carceral system that is involved in the event.

Participants will be aware of other participants in the LC due to the group format of didactic sessions. The study team will ask participants to maintain confidentiality of the other participants.

Risks related to surveys and interviews

<u>Confidentiality</u>

The primary risk associated with survey and interview data is loss of confidentiality. Where possible data will be de-identified, and will be kept in a separate folder away from identifiable participant information. Interview recordings will retained for the duration of the study to enable cross-checking potential transcription mistakes and unclear audio passages. They will be stored in an encrypted JHU Onedrive folder, accessible only to those involved in transcript cleaning and qualitative coding (as potential transcript mistakes may be spotted during the coding process). Interview audio will be destroyed at the end of the study period, or after planned manuscripts have been accepted. Survey results will be reported in aggregate form only. Interview data will be reported in a way that protects from inadvertent identification of participants (e.g., redacting specific details that could identify the speaker). Please see "*Appendix 5 – Adverse event reporting protocol*" for more information regarding reporting breaches of confidentiality. Due to these protections, we expect the probability of this risk to be low.

<u>Psychological distress</u>

Interview questions focus on professional procedures and experiences therefore likelihood of questions causing discomfort and distress is low. However, participants will be informed that they may skip any questions they would like in the interview and stop the interview at any time. If the participant experiences distress during an interview, the study team will refer them to 988, the federal mental health hotline, and check in on them one to two weeks after the event. As the surveys and interviews focus on participants' professional duties and processes and LC activities, we expect the probability of this risk to be low.

Aims 2-3: Potential risks

Aims 2-3 involve secondary data analysis only, and is considered minimal risk research under Subpart C.

The main risk of these secondary data Aims is loss of confidentiality. The data are of currently and formerly incarcerated individuals with OUD, who could face societal stigma in the event of a data security breach. Study staff will only access limited identifiable data and will take steps to protect against this risk with data security measures described in Section 17.0. Should there be any actual or potential loss of confidentiality of individuals in Aims 2-3 datasets, we will follow the AE reporting steps based on the AE reporting protocol.

Unforeseeable risks

Unforeseeable risks may arise from Aim 1: LC activities. Study team members will follow reporting *Appendix 5-Adverse event reporting protocol* to categorize, respond, and (if necessary) report adverse events.

16.0 Potential Benefits to Subjects

The information and participation in the Aim 1 LC may inform efforts to increase methadone access using the hospital/clinic designation in the participant's carceral facility/system.

There may not be benefits to individual study participants. The potential benefits of the LC are applicable to the participant's carceral facility/system rather than the participant themselves.

17.0 Data Management and Confidentiality

Data Management Overview: JHU will be responsible for data stewardship for Aim 1; Aim 1 data will be stored on JHU's Onedrive. Brown will be responsible for Aims 2-3; Aims 2-3 data will be stored on Brown Stronghold. Study team members from both institutions will be involved in analysis on all Aims.

Primary data analysis plan: Aim 1

Survey Analysis

Design. The 20-minute survey will assess the quality of implementation of the hospital clinic designation. We will administer surveys at 3 points: enrollment into the LC, midpoint, and upon conclusion.

Analysis. The primary outcomes of interest will be an adaptation of the Implementation Outcomes scales by Weiner et. al[1], which measures quality of implementation using 12 items

each measured on a 5 pt Likert scale, for a total of 60 possible points. We will compare midpoint and ending scores to the baseline score separately using paired t tests.

Power. With 30 participants we calculate that we have 80% power to detect a minimum 2-point change in score with a 4-point SD_{Δ} in outcome change (Δ) over time, using a 2-sided test with $\alpha = 0.05$.

Data management and security for quantitative survey data
We will use JHU REDCap for data management of all survey data collected from participants. Brown study team members involved in survey data collection and analysis will be given access to the JHU REDCap project. REDCap is a secure, password protected, web-based application for building and managing online surveys/databases and all data corrections get automatically logged in data audit trails. Data will be extracted from REDCap periodically and stored in a password-protected, access-controlled Onedrive folder managed by JHU mPI Bandara.

Qualitative Interview

Overview of qualitative analysis. The goal of the semi-structured interviews is to gather data on professional opinions about the implementation of the hospital/clinic designation in their system- including implementation quality and facilitators and barriers to implementation. The guide will be based on our research questions, a literature review, and conceptual framework. The guide for each interview will open with an overview of the study and an opportunity to ask questions, followed by innocuous and grand tour questions to establish rapport, and finally by researcher-driven questions. Interviews will be conducted via videoconference by study staff. We will use standard procedures for qualitative data collection. After each interview, we will create notes identifying preliminary themes. These notes, along with the interview guide, will contribute to the development of a codebook. Using a randomly selected sub-sample of transcripts, two team members will pilot the codebook. It will then be further refined and finalized, with full study team input. Text segments will be organized in QSR NVivo v12 or a similar qualitative analysis software and analyzed according to themes and sub-themes. An audit trail will document all methodological decisions. Brown and JHU team members will conduct qualitative analysis.

Data management and security plan

All audio recordings and subsequent transcripts will be stored digitally in a study specific folder in the Hopkins OneDrive, a HIPAA compliant secured cloud-based storage environment for securely sharing content with authorized investigators. Transcripts and written notes will be de-identified, with any identifying information redacted, and labeled with a unique identification number. The crosswalk linking the names of participants to the identification numbers will be stored on a separate OneDrive folder in a password protected file accessible only to Drs. Bandara and Saloner and those responsible for sending prepaid debit cards. Audio recordings will retained for the duration of the study to enable cross-checking potential transcription mistakes and unclear audio passages. They will be accessible only to those involved in transcript cleaning and qualitative coding. Interview audio will be destroyed at the end of the study period, or after planned manuscripts have been accepted.

Secondary data analysis: Aims 2-3

Statistical design

Aim 2 Overview. Using data from carceral electronic records from Washington, Colorado and Delaware DOC**,** we will use a trial emulation methodological approach to identify the effect of a facility adopting the hospital/clinic designation on medication for opioid use disorder initiation and retention during incarceration.

Aim 3 Overview. Using a dataset linking carceral health records with Medicaid claims data, we will use a regression adjustment approach known as "trial emulation" to identify the effect of a facility adopting the hospital/clinic designation on MOUD initiation and retention in the 12 months after release from incarceration.

Analysis

Aim 2. We will use propensity score models to examine the differences between people who were versus were not able to access methadone using the hospital/clinic pathway:

Aim 3. We will follow the same inverse probability of treatment weight estimation methodology outlined in Aim 2. We will extend the Aim 2 outcomes model to examine post-release outcomes measured repeatedly over time. To examine the moderating effect of community context, we will conduct stratified analysis by reentry community characteristics.

Power

Our study is powered to detect small changes in our primary outcomes under conservative assumptions. As shown in our *planned enrollment tables*, we estimate that 50,042 individuals will meet screening criteria for OUD across the 7-year study period across the 36 facilities in the three state DOCs (or 199 per facility/year). Using an NIH sample size calculator for a group randomized trial with multiple measurement occasions (our target trial design), and assuming an alpha level of 0.05, 80% power, and an intraclass correlation coefficient (ICC) of 0.10, for a binary outcome (e.g., use of MOUD during or after incarceration) with a mean of 0.50, our study would be powered to detect an absolute change of 0.10 with as few as 4 clusters (facilities) per condition. Numerous other factors could also improve power beyond these assumptions, including propensity score weighting or covariate adjustment to reduce variation.

For a breakdown of data management, security, transfer, and sharing for each Aim and dataset, please see *Table 1 – Data handling earlier in this protocol*.

Data management and security for Aim 1 primary data

Aim 1 data will be stored at and managed by JHU. Files will be stored on JHU Onedrive, in folders with access limited to study team members actively involved in this Aim. Surveys will be conducted on JHU Redcap. Interviews will be transcribed by a service that is compliant with relevant data protections (e.g., TranscribeMe!) and analyzed on Dedoose. mPI Bandara (JHU) will be responsible for oversight of data management for Aim 1. JHU and Brown study team members involved in data collection and analysis will have access to Aim 1 data.

Data management and security for Aims 2-3 secondary data

mPI Saloner (Brown) will be responsible for oversight of data management for Aims 2-3. Data will be stored on Brown Stronghold servers. JHU and Brown study team members involved in data analysis will have access to Aims 2-3 data on Stronghold.

For Aim 2, a limited dataset will be provided by all three DOCs. Data will include all incarceration dates and healthcare encounter data and will be extracted at least once annually and transmitted by secure file transfer protocol to the Brown University Stronghold server, so that the dataset can be refreshed on an ongoing basis. The Stronghold Research Environment is maintained at a high-security level in accordance with federal and Rhode Island regulations governing secure computer systems. Access to data housed on the Stronghold servers for this study will be limited to approved team members.

For Aim 3, Washington DOC's electronic records will be linked to Washington Medicaid claims data by Washington Health Care Authority (HCA) analysts. Under a data use agreement, analysts at Washington DOC will transmit unique identifiers for all individuals who meet inclusion criteria for the Aim 2 analysis to counterparts at HCA. With a combination of unique identifiers, analysts at HCA will use a probabilistic matching approach to link carceral records to Medicaid records. After matching has been completed HCA analysts will drop unique identifiers and append a study identifier. This limited dataset will be provided to the study team and also stored on the Brown Stronghold server. HCA will retain the crosswalk between these records for subsequent linkage but will only share deidentified records with our study team.

Secondary data are proprietary and will not be shared with outside researchers or deposited into data repositories. Secondary data will be destroyed once all planned publications are accepted, or the end of the study period, whichever comes first. All study staff have completed CITI trainings relevant to this project: human subjects research, responsible conduct of research, HIPAA/information privacy security, and good clinical practice.

Stronghold produces automated reports for each PI's environment on:

- Security groups and members of these groups
- Last logins of users accessing the environment
- Date and time of transfers in and out of the environment

Quality control of primary data

Aim 1 surveys

Dr. Bandara will actively manage data and monitor data quality by implementing statistical process control strategies, i.e., building range checks and data completion flags into the REDCap database, running routine reports on run charts and outlier detection scripts. These reports will be sent back to the data collection team for immediate action and timely reports will be provided to Dr. Saloner to remedy any systematic concerns. Systematic issues identified will be addressed by the investigative team through training enhancement and/or protocol amendment.

Aim 1 interviews

We will use standard procedures for qualitative data collection. Each interviewer will be trained in qualitative interview techniques and the study-specific interview guide. Interviewers will complete mock interviews with a senior member of the study team. The first 1-2 interviews with participants may be observed by a senior member of the study team to ensure quality of interview data collection. The study team will convene regularly to discuss emerging themes and potential edits to the interview guide. An audit trail will document all methodological decisions. Edits to the interview guide will be submitted to the IRB for review prior to implementing the changes.

18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

N/A. This study does not involve more than minimal risk.

19.0 Provisions to Protect the Privacy Interests of Subjects

Aim 1: LC participants – Privacy protections

To protect participants' privacy interests, study staff from Brown and JHU will inform participants that their participation in the research activities are voluntary and that they may skip any questions or stop the survey/interview at any time. The study data collected is protected by a certificate of confidentiality. Study information will be used only for research purposes. Study team members will ensure that participants are in a private place prior to starting a survey or interview. Survey results will be reported in aggregate form and will be de-identified of participant names and organizations. When reporting interview quotes, identifying information such as names and organizations will not be tied to quotes. If specific details are shared during an interview that could potentially identify the speaker, the study team will not report those details.

Audio-recordings, memos, raw survey responses and de-identified data files will be stored on secure, password protected servers at Johns Hopkins behind the University's firewall. Individual computers are encrypted and password protected. Only the study principal investigators and analysts will have access to the files.

Procedures

During the consent process, study team members will inform participants that they may skip any questions and discontinue the LC sessions, surveys, or interview at any time. Before the interview begins, study team members will confirm that the participant is in a safe, private space, and not in proximity to carceral leaders and staff. Study team members will confirm if the participant agrees with being audio recorded anonymously during interviews.

For didactic sessions, if a participant is sharing during the first section of the session, the study team will confirm if the participant agrees with being recorded and will be reassured that this recording will be shared with participants only. Participants will be reminded that recordings will be stopped at the end of the presentation/sharing section and will not include discussion sections. Participants will be aware of other participants in the LC due to the group format of didactic sessions. The study team will ask participants to maintain confidentiality of the other participants.

During any of the research activities, study team members will monitor for any signs of discomfort and will remind participants of their rights as needed. If a participant expresses psychological discomfort or distress during any LC activities, we will refer them to 988, the federal mental health hotline, and check in on them one to two weeks after the event. Please see *Appendix 5-Adverse events reporting protocol* for more details.

Access to sources of information

Aim 1

Study team members from Brown and JHU will not access private information about participants outside of information gathered during the LC sessions, surveys, interviews and identifying information gathered to send prepaid debit cards. Any identifiers gathered for prepaid debit card purposes will be kept in a separate folder than study data.

Currently, we do not have any BOP (federal prison) facility staff enrolled in the LC. If any BOP staff are enrolled: All research staff with access to identifiable data will complete data security training and sign a confidentiality statement consistent with the DOJ standards.

Aims 2-3

The study team will follow approval processes required by each DOC and by WA HCA. See Section 24.0 for more details. DUAs will be executed with each data owner prior to receiving datasets.

20.0 Compensation for Research-Related Injury

We do not foresee risks of research-related injury. Aim 1 involves didactic sessions and data collection with professionals in the context of their employment. Aims 2-3 involve secondary data analysis only.

21.0 Economic Burden to Subjects

Aim 1
There is no cost to Aim 1 participants. Didactic sessions and data collection will occur virtually.

Aims 2-3
These are secondary data analyses, with no costs to the individuals that are part of the datasets.

22.0 Consent Process

Aim 1 – Obtaining informed consent

Participation in each Aim 1 activity is voluntary and employers will not be informed of who consents. We will be following *HRP-090 - SOP - Informed Consent Process for Research* for our Aim 1 activities. Once a potential LC participant has been identified, study staff will schedule a 15 to 20-minute Zoom call with them to tell them more about the study and complete an informed consent online. The participant will be sent a copy of the consent form (*Appendix 6-Informed consent-Learning collaborative*) to review prior to the call. During the call, the study

team member will review the consent form and answer any questions the participant has. The participant may choose to consent to participating in certain LC activities and not others:

- Didactic sessions
    - Audio recording of peer sharing (if they elect to share)
- Surveys
- Interview
    - Audio recording

If someone does not want to engage in the research component (i.e., surveys and interview), they will be permitted to consent solely for the didactic sessions and attend or view recordings of the didactic portion of the LC and use generalizable tools used by LC participants. Audio recording of interviews and participant peer sharing sections (if they share during a didactic session) are optional.

Consent forms will describe research and study activities, including LC sessions, surveys, qualitative interview data collection, and audio recordings. For those who consent to surveys and/or interviews, study staff will review *Appendix 6.1-Consent addendum: Data repository*. This will have a checkbox to allow data sharing for surveys, and a checkbox to allow data sharing for interview data. Consent forms will also include contact information of the study team and IRB who will be available to answer questions about the consent. Participants will check a box for components to which they would like to consent. Electronic signatures of the participant will be obtained on Redcap during the consent Zoom call.

Our study does will not enroll individuals who are under the age of 18, unable to consent, or unable to complete the interviews/surveys in English.

Aims 2-3

Waiver of HIPAA Authorization for Aims 2-3 secondary data

We ask that a waiver of HIPAA authorization be granted for the use of secondary data for Aims 2-3, as it would not be feasible to obtain individual patient consent from all patients in the WA/DE/CO DOC EHR, and WA HCA datasets, due to the large size of the datasets.

A waiver of HIPAA Authorization is being requested for the use of disclosure of PHI in the conduct of research without the expressed authorization of the individual patients. The use of PHI involves no more than minimal risk to the privacy of individuals and PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study. The primary risk involves the potential for breach of privacy and loss of patient confidentiality. This part of the study presents no more than minimal risk to privacy since the data will be stored in a HIPAA-compliant manner, and only IRB-approved study site personnel will have access to the identifiable data. It is not possible to seek the participants' authorization because this part of the study is retrospective in nature. The volume of records being reviewed make obtaining authorization infeasible for the conduct of this study. This part of the study will not affect the participants' medical care.

Many of the patients in the DOC datasets have been released and the contact information on file for many of these patients may not be current. The rights and welfare of the participants will not adversely be affected since the study does not include direct participant contact and does not affect participants' medical care.

PHI included in the limited datasets received by the study team are: incarceration dates, age or date of birth, health service encounter dates, geographic location such as census block/tract. These data elements are necessary to assess the impact of individual, treatment, and contextual-level factors on patient outcomes. Secondary data are proprietary and will not be shared with outside researchers or deposited into data repositories. Secondary data will be destroyed once all planned publications are accepted, or the end of the study period, whichever comes first. The PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study.

23.0 Process to Document Consent in Writing

Aim 1

We will be following *HRP-091 - SOP - Written Documentation of Consent for* Aim 1 research activities to consent and enroll participants. Study staff will reach out to participants to complete a documented informed consent process online together. Electronic signatures of the participant will be recorded on Redcap.

24.0 Setting

Study-wide

This is a multi-site study. Brown will be the sIRB, with the following pSites: JHU & University of Washington (UW). Site PIs at each pSite (Drs. Bandara and Jack, respectively) will submit Brown IRB-approved materials to their institution's IRB to request reliance. For more information, see Section 26.0: Multi-site Research.

Aim 1

JHU and Brown will be involved in consenting and enrolling participants for Aim 1. Aim 1 research activities and procedures will be conducted remotely:

- Consent: Zoom
- LC sessions: Zoom
- Surveys: Self-administered online with option to complete with a study team member on Zoom or phone
- Interview: Zoom

UW study personnel will advise on the LC curriculum and survey measures. There will be no community advisory board for this study, though the study team will engage with the three DOCs (WA, CO, DE) and other Aim 1 participants to inform the content of the LC.

Aim 2

Aim 2 secondary data analyses will involve data extraction and transfer from the three DOCs' electronic records system to Brown University Stronghold server. Please see section 17.0 Data

Management and Confidentiality for more details on data storage location, access and data transfer process.

The process of receiving data from DE and CO DOCS include submitting an application for research that will be reviewed and approved by the state DOC data teams and leadership; signing a letter of agreement between study PI and the DOCs for data sharing; providing proof of Brown's IRB approval and providing study publications to the DOC.

Aims 2-3: Washington State agencies

Washington State requires the following steps for any research involving their agencies (applicable to this study: WA DOC, WA HCA).

1. Review and approval by the WA DOC Research Review Committee (RRC)
2. Review and approval by the Washington State IRB
3. Execution of a contract detailing research activities

Please see *Table 1 -Data handling* for more information on linking WA DOC data to WA HCA Medicaid data. After linkage is performed, a limited dataset will be transferred to Brown University Stronghold server. Aims-2-3 analyses will be performed primarily by Brown personnel, with assistance from UW and JHU personnel.

25.0 Resources Available

Feasibility & Time

Aim 1

We anticipate recruitment and data collection to be conducted approximately during Y1-Y3. We will recruit 30 participants for the LC, which we believe is feasible. The 3 carceral systems (WA, DE, and CO DOCs) who are our data partners for Aim 2, are already implementing/pursuing the h/c designation and have agreed to participate in the LC activities. In addition, we expect to recruit 7 additional systems into the LC (approximately three participants from each carceral system).

Aim 2

We anticipate Aim 2 will have data extraction in three waves during approximately Y2-Y4, and analysis ending in Y5. DE, CO, and WA DOCs will contribute limited datasets from their electronic records system to support this aim.

Aim 3

We anticipate Aim 3 will have approximately two waves of data extraction and linkage and end analyses in Y5. WA DOC will transfer data to WA HCA for linkage, and WA HCA will transfer a limited dataset of linked data to the study team.

Facilities & Personnel

Study-wide

All study team members engaged in human subjects research will have recently completed all appropriate training: human subjects research, HIPAA, responsible conduct of research, and good clinical practice.

Brown

mPI Dr. Brendan Saloner will lead data management and analysis for Aims 2-3 and hold primary responsibility for ensuring study protocols are followed. Ms. Minna Song will provide study-wide administrative support, liaise with the IRB, and support Aim 1 surveys and interviews, Ms. Kristianny Ruelas-Vargas will provide administrative support and assist with Aim 1 data collection, Ms. Allison O'Rourke will provide quantitative expertise and support analysis of all aims, Dr. Rebecca Hubbard will provide methodological expertise for Aims 2-3.

JHU

mPI Dr. Sachini Bandara will lead data management and collection for Aim 1, JHU research assistant TBD will provide study-wide administrative support and support for Aim 1, Dr. Joseph Levy will support methods and analysis for secondary data aims.

Consultant

Dr. Kelly Ramsey will lead Aim 1's LC and support dissemination and implementation more broadly. She is a consultant hired by Johns Hopkins University, and will be listed on JHU's pSite application as key personnel.

UW

Dr. Helen Jack will provide content expertise for Aim 1's LC (e.g., on LC curriculum and survey measures) and analysis and interpretation of Aim 2-3 results (e.g., WA DOC data elements and measures of methadone implementation).

Psychological resources for participants

We are not interacting with patients and do not foresee participants experiencing medical or psychological needs arising from participation. If a participant expresses psychological discomfort during any LC activities, we will refer them to the federal mental health hotline and check in on them after the event. Please see *Appendix 5-Adverse Events reporting protocol* for more details.

Study management

Brown team members will be responsible for sIRB submissions, amendments, and communication of changes to pSites. The study team will meet on a biweekly basis to discuss ongoing work, with additional Aim-specific subgroup meetings as needed. mPI Sachini Bandara will manage Aim 1 LC activities with consultant Kelly Ramsey. mPI Brendan Saloner will manage Aims 2-3 activities including data management.

26.0 Multi-Site Research

Study-wide recruitment methods

<u>Aim 1</u>

Participant accrual
We plan to accrue 30 total participants across JHU and Brown. There is no predetermined number of participants to be recruited by each site, though we expect accrual to be approximately evenly split between JHU and Brown (15 participants each). UW personnel will advise on Aim 1 activities but will not be involved in recruiting or consenting participants.

Recruitment
Recruitment methods and methods to identify potential subjects are described in detail in Section 13.0, and will not vary between JHU and Brown. We will use the following materials to recruit participants (these materials are attached to the IRB application for review):

1. *Appendix 4-Template email to carceral leaders*
2. *Appendix 4.1-Template email to potential participants*

Data security

Aims 2-3
Local review and approval policies are described for each data provider in Section 24.0.
All engaged participating sites and data providers will safeguard data, including secure transmission of data, as required by local information security policies.
All local site investigators will conduct the study in accordance with applicable federal regulations and local laws.
All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.

Communication among collaborating institutions (pSites)
Study-wide
"HRP-830 Communication and responsibilities worksheet" will be submitted for each pSite during the pSite addition process. These worksheets will generally reflect that Brown IRB will be responsible for reviewing IRB materials, HIPAA waiver, modifications, progress reports, and potential problems/reportable events (including complaints and protocol deviations), and the final study closure report.
Brown study team members will communicate IRB-approved materials including modifications with pSites, and will gather information needed to submit annual IRB reports.

All sites will have the most current version of the protocol, consent document, and HIPAA waiver. All modifications will be communicated to sites and approved by the site's IRB and Brown's IRB before the modification is implemented. All engaged participating sites will safeguard data, including secure transmission of data, as required by local information security policies. All local site investigators will conduct the study in accordance with applicable federal regulations and local laws. All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.

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