INSTRUCTIONS:

- Complete this Protocol Template only when there is **no** existing authored protocol provided for this study.
- If you are doing a data-only study with no prospective or interventional components, use the Data Only Protocol Template instead.
- This Protocol Template is to be used in conjunction with the SMART KP IRB Core Data Form.
- Enter your responses to each question directly below the BLUE text in the fillable field.
- When completing this Protocol Template, if a section does not apply to your study then enter "N/A."

1. Protocol

Protocol Title

Healthcare Organizational Structural Conditions and the Health of People Recently Released from Prison (Structural Conditions and Health After Release from Prison [SCHARP] Study)

Principal Investigator

Stacie Daugherty, MD, MSPH

Version Date

07/10/2024

Form Author

Morgan Ford, Stacie Daugherty

2. Objectives

Describe in plain language the purpose, specific aims, or objectives and indicate the primary goal(s) of the study (e.g. safety, tolerability, effectiveness, feasibility, pilot study, etc.). State the hypotheses to be tested. State primary and any secondary study endpoints.

Societal systems of racism, segregation, and criminal justice practices are linked to high rates of imprisonment of Black, Indigenous, and other People of Color (BIPOC) and represent structural racism and discrimination (SRD). Upon release, people face further challenges influenced by SRD including unstable housing, limited employment, stigma, and poor health. Due to intersectional SRD, formerly incarcerated BIPOC may be particularly disadvantaged in avoiding poor health outcomes. Structural conditions in healthcare systems that limit access and contribute to poor health for people released from prison are further examples of SRD. Systematic investigation of these structural conditions in diverse healthcare systems has not occurred, and the extent to which structural conditions limit or perpetuate disparities in access and health outcomes among people released from prison is rarely examined.

In three different healthcare systems in the Denver/Aurora metro area, including Kaiser Permanente Colorado (KPCO), UCHealth University of Colorado Hospital, and Denver Health (DH), we will measure organizational structural conditions related to healthcare access for people released from prison. Next, leveraging a database of individuals released from Colorado state prisons, we will conduct a prospective cohort study of 400-600 people released into the metro area to measure baseline cardiovascular (CV) health and follow-up in 6 months on exposure to structural conditions in healthcare.

The study aims are as follows:

Aim 1. Measure Structural Conditions in Healthcare Organizations: Among three diverse health systems, we will analyze each system's written materials and conduct interviews with system leaders, frontline staff, as well as with representatives of community-based organizations and people with lived experience of incarceration to measure policies, practices and attitudes around healthcare access, transition programs, culture, support of social determinants of health and specialized services for people released from prison.

Aim 2. Link Exposure to Healthcare Structural Conditions to Access and Health Outcomes: We will aim to recruit 400-600 people within 2 months of prison release, but no more than 6 months since release, into a longitudinal cohort study to assess their exposure to healthcare structural conditions over approximately 6 months after release. Using the all-payer claims database, we will examine the association between exposure to structural conditions and 12-month primary outcomes of healthcare utilization (clinic visits, emergency visits, hospitalization) and secondary outcomes of CV hospitalization and all-cause mortality. Moderation by race/ethnicity and baseline CV health will be tested.

Aim 3: **Develop and Disseminate Practices to Limit Healthcare SRD:** Integrating results from Aims 1 and 2, we will develop practice recommendations to improve healthcare access and outcomes for people released from prison. Recommendations will be iteratively revised with a community advisory board and finalized using a modified Delphi panel of national experts. Final recommendations will be broadly disseminated.

Our central hypothesis is that exposure to healthcare organizational structural conditions following release can limit or facilitate access to healthcare and health outcomes. We further hypothesize that SRD will be worse for BIPOC individuals and those with poor CV health. We can respond by using this research to develop and disseminate best practices that limit healthcare SRD.

3. Background

a. Scientific Background

Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge. A list of references or bibliography must be included as part of this document or uploaded separately.

Societal structural conditions, or the formal and informal policies and practices linked to racial and ethnic disparities in incarceration are examples of structural racism and discrimination (SRD).[1,2,37] Black Americans are imprisoned in US state prisons at > 5.0 times and Latinx/Hispanic Americans at almost two times the rate of White Americans.[1,3,38] Mutually reinforcing systems of racism, segregation, poverty, and criminal justice practices (e.g. sentencing policies, like mandatory minimum sentences) foster and perpetuate racial disparities in incarceration. [1,2,9] Furthermore, upon release, people face challenges influenced by SRD including limited employment prospects, housing instability, stigma, and poor health.[2,4-9] Due to intersectional SRD, formerly incarcerated Black, Indigenous and other People of Color (BIPOC) may be particularly disadvantaged.[10] *We propose that structural conditions in healthcare systems*

that limit access and contribute to poor health for people released from prison are further examples of SRD.

Studies suggest people released from prison are at high risk for poor health outcomes, particularly from cardiovascular (CV) disease. Prior surveys show that approximately 80% of those released from prison have a chronic medical or behavioral health condition.[27] Larger scale observational data suggest that, compared to the general population, CV risk factors are more prevalent among people in or released from prison including hypertension, smoking, diabetes, obesity, and poor diet.[9,13-18] Within 2 years of release, people have an increased risk of CV hospitalizations for coronary heart disease, heart failure, stroke and all-cause death and suffer two times higher CV mortality than the general population.[6,9,11,12,14] Prisons are mandated to provide healthcare services while people are imprisoned; upon release individuals become responsible for their own healthcare. Continuity of healthcare is associated with lower healthcare costs, fewer hospitalizations, reduced emergency department use and decreased mortality.[39-41] Poor health and poor access to care after release are also associated with higher rates of recidivism.[27,39] *Access to healthcare following release from prison is key to preventing poor health outcomes in this population.*

Our group and others have shown people released from prison report barriers to accessing healthcare.[36,42,43] In qualitative and quantitative research, people released from prisons report challenges related to mistrust and discrimination in healthcare settings,[22,23,27,36,43,44] competing demands of other needs (e.g. housing, employment), the burden of medical and psychiatric comorbidities,[9,27,36] and limited knowledge and ability to navigate the system and manage their health.[9,27,36] People released from prison are generally low income and insurance coverage has been a barrier. Before passage of the Affordable Care Act in 2014, only 15-25% of those released from prison visited a physician outside of the emergency department in the first 12 months post release.[27] It is now estimated that over 80% of those released from prisons are eligible for Medicaid, which plays a key role in facilitating linkage of people released from prison to community healthcare.[21,38,39] States including Colorado have enacted policies to facilitate access including expanding Medicaid eligibility, pausing Medicaid coverage (instead of terminating) while imprisoned, and enrolling people into Medicaid prior to release from prison.[21,45,46] Despite these important efforts, observational studies conducted since 2014 suggest healthcare access following release has increased overall, yet is still primarily through more costly emergency care settings.[47,48] *Therefore, insurance coverage alone does not ensure access – structural conditions in health systems are likely playing a role in how individuals access care*.[21]

Building on models linking societal SRD with incarceration and health, we propose exposure to healthcare organizational structural conditions following release can limit or facilitate access to care and affect health

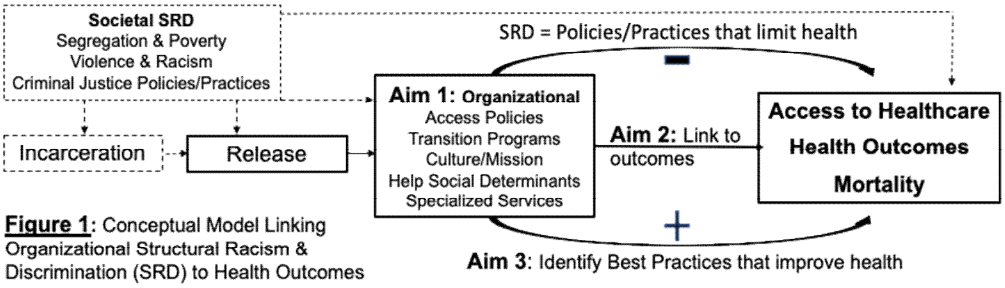

Figure 1: Conceptual Model Linking Organizational Structural Racism & Discrimination (SRD) to Health Outcomes

outcomes (Figure 1).[2,4-6,9,36] Organizational structural conditions are rarely named or measured in health equity studies.[9,32] We will systematically identify healthcare organizational structural conditions that can influence access and health following release and measure these exposures among people released from prison. These include 1) access policies and practices,[21,30,31,49] 2) transitions programs and specialized training,[21,26,27,29,50] 3) culture and mission,[22,23,26,30] 4) support of social determinants of health,[21,26,50] and 5) specialized services for mental health and substance use disorders[27,50]. These organizational conditions have not been assessed comprehensively and the ways in which they are linked to health outcomes among people released from prison is not well described.[5,9,24] Interventions to improve the health of people released from prison have largely targeted individuals or focused on specific populations (e.g. those with substance use disorders) with few targeting interventions at the health system level.[51,52] To develop an effective intervention that targets organizational SRD, the first step is understanding what health systems are currently doing (or not doing) that is influencing access and health outcomes. *We propose to enhance rigor in the field by directly measuring which healthcare system policies and practices either limit or facilitate access and health outcomes among people released from prison to inform future interventions targeting organizational SRD*.[5,9,24]

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b. Preliminary Data

Describe any relevant preliminary data.

Prior work on poor outcomes, including CV morbidity, after release from prison. In her 2007 study, Dr. Binswanger (co-I) documented that people released from Washington state prisons were at 3.5 times higher risk of death compared to similar aged individuals. CV disease was the second leading cause of death after release, two times the risk of the general population. Other studies have shown similar findings in other states and countries and highlighted the significant contribution of CV disease to the high morbidity and mortality following release from prison.

Prior work on people released from prison in Colorado. Our group has been collaborating with Colorado Medicaid and the Department of Corrections (DOC) on their efforts to evaluate healthcare access and outcomes among people released from prison. This collaboration includes ongoing receipt of data from the DOC on all individuals released from prison in Colorado who were Medicaid eligible since 2020. Among 5,701 individuals released between 4/2020-1/2021, 66% had a medical condition requiring ongoing ambulatory care. In this sample, 2,233 (~40%) were released to the Denver/Aurora Metropolitan area.

Using Colorado Medicaid data, our prior work evaluated the utilization and mortality of individuals released onto Medicaid (93%; N=15,655) between 2014-2016. The primary outcomes were time to first access, point of first access and mortality. Excluding those seeking care for behavioral health, ~40% of individuals accessed medical care within two months of release; most used acute care locations (e.g., Emergency Department) or had a pharmacy claim. Mortality >8 weeks following release was 1-2%.

4. Study Design

Describe the overall approach of the study (e.g. prospective, interventional, observational, retrospective, etc.). If your study includes more than one group, arm, or subject population, describe that here (for example, a study of both subjects and their caregivers, or a study with both a prospective interventional arm and a retrospective chart review arm).

The goal of Aim 1 (Measure Structural Conditions in Healthcare Organizations) is to delineate healthcare system structural conditions that influence healthcare access and care delivered to people released from prison. To our knowledge, standardized measures of structural racism in organizations do not exist. Therefore, we propose a comprehensive qualitative approach using qualitative case study methodology. Case study methodology is a well-established qualitative approach that provides in-depth understanding of complex social systems. We hypothesize that the organizations' access policies and practices, transition programs and specialized training, culture and mission, support of social determinants of health, and specialized services will be interconnected and collectively influence the care delivered to people released from prison. We will explore these conditions and their interconnectedness through multiple sources of data at each organization. These will include interviews with organizational leaders, clinicians and staff members, such as social workers, case managers, access specialists and other members of the staff responsible for facilitating access. Interviews will also be conducted with representatives from the Department of Corrections who are involved in transitions, representatives of community organizations, and individuals with lived experience of incarceration. In addition, we will conduct a structured review of key documents and policies. Using methods successfully deployed in other studies evaluating organizational policies and procedures, we will conduct a content evaluation of publicly available materials from each health system. Documents reviewed may include mission statements, financial reports, nondiscrimination policies, leadership structures, and employment policies, among others.

In Aim 2 (Link Exposure to Healthcare Structural Conditions to Access and Health Outcomes), we will prospectively enroll people recently released from prison into an observational cohort and follow their outcomes over 12-months. Participant's CV health will be measured at enrollment and then their exposure to healthcare organizational structural conditions in the 6-months since release will be assessed. The association between exposure to healthcare organizational structural conditions and 12-month access to healthcare and health outcomes will be assessed. Our primary hypothesis is exposure to healthcare SRD will be associated with limited access to ambulatory care and poor health outcomes. These effects will be worse among BIPOC and those with poor CV health.

In Aim 3 (Develop and Disseminate Recommended Practices Playbook to Limit Healthcare SRD) we will use results from Aims 1 and 2 to develop and disseminate a playbook of recommended organizational practices associated with improved access and CV outcomes for people released from prison. We will begin by integrating the analyses of the qualitative (Aim 1) and quantitative data (Aim 2) to identify instances in which the data support or enhance each other. From this, with input from a Community Advisory Board (CAB), we will then develop an initial set of recommendations. To ensure that the recommendations are grounded in the data, we will then complete a member checking process. This will involve conducting additional interviews of leaders and staff from the case studies in Aim 1. We will also interview a sample of participants from our prospective cohort study. An iterative process will be used to revise the recommendations. These recommendations will be further refined and finalized through a Modified Delphi Panel of national experts.

5. Study Population

a. Number of Subjects

State the number (or approximate number, if appropriate) of subjects you plan to include at the KP region to which this study is being submitted. If applicable, distinguish between the number of subjects who are expected to be enrolled/screened and the number of subjects needed to complete the research procedures (e.g. numbers of subjects excluding screen failures).

As appropriate, consider different populations of subjects within the same study (e.g. subject/caregiver, parent/child, patient/physician). If this is a multicenter study, indicate the total number of subjects to be accrued across all sites.

For Aim 1, at each health system we will conduct 45-minute interviews with organizational leaders and with clinicians in the Emergency/Urgent care, Behavioral Health and Primary Care. At each health system, we will additionally conduct interviews with staff members including social workers, case managers, access specialists and other members of the staff responsible for facilitating access. To understand the community context around the health systems, we will also interview individuals at the Colorado DOC involved in transitions and community organization representatives. In addition, we will interview people with lived experience of incarceration. We anticipate that we will conduct a minimum of 30 interviews in total. Aim 2 will include 400-600 people recently released from prison. In Aim 3, we will conduct additional interviews of leaders and staff from Aim 1 (5 per healthcare organization) and also interview a sample of 20 participants from our prospective cohort study.

b. Inclusion and Exclusion Criteria

- Describe the criteria that define who will be included or excluded in your final study sample.
- Describe how individuals will be screened for eligibility.
- Describe the plan for disposition of data collected during recruitment/screening in the event of a screen failure or when a potential subject is contacted but declines participation (e.g. destroyed immediately, destroyed at end of study, retained for separate analysis or so that subjects are not contacted repeatedly about participation after they have declined, etc.).

The eligibility for health system, Department of Corrections, and community leadership and staff who participate in key informant interviews during Aim 1 is broadly inclusive. We will prioritize people who also have lived experience with incarceration and people from BIPOC communities in identifying and selecting participants. We will aim to recruit participants equally across the healthcare systems and community organizations to obtain representative perspectives. We have no explicit exclusion criteria.

For the longitudinal cohort study, we will recruit individuals recently released from state or federal prison. From lists of people recently released from prison obtained from the Colorado DOC, we will specifically target releases from the women's prison to over sample women and reach our goal of ~20% women. Pregnant women will not be excluded because the study is minimal risk. Individuals of all genders and racial and ethnic categories will be eligible for inclusion.

Eligibility criteria include:
1) Released from state or federal prison into the Denver/Aurora metro area in the past 2 months, but no more than 6 months ago

2) Age 18 and older
3) Ability to understand study procedures in English or Spanish
4) No plans to leave the area for six months

Exclusion criteria include:
1) Not recently released from prison
2) On "current inmate" status*
3) Under 18 years old**
4) Doesn't speak English or Spanish
5) Plans to leave area within six months
6) Unable to consent

*Individuals on "current inmate" status (i.e., under locked confinement part of the day or night) will be excluded because they are still under correctional observation.

**Individuals under age 18 will be excluded because they are generally released from juvenile facilities and/or are involved with a different form of supervision through the juvenile justice system.

c. Vulnerable Populations

Indicate whether you will include or exclude each of the following special populations. This refers to subjects who are known members of these populations upon enrollment or at any time during the study. Justify the inclusion of any of these populations. Describe additional safeguards to protect the rights and welfare of these subjects.

- Children
- Pregnant Women
- Neonates of uncertain viability or nonviable neonates (up to 28 days post birth)
- Prisoners (NOTE: The KP IRB does not have the appropriate membership to review research involving prisoners. Consultation with KFRI will be required.)

This study falls under IRB Category I – "A study of possible causes, effects, and processes of incarceration, and criminal behavior provided that the study presents no more than minimal risk and no more than inconvenience to the subjects."

We are not enrolling prisoners, but we are studying people formerly imprisoned. Probationers and parolees are responsible for meeting their own needs for health care, in contrast to those currently incarcerated, who receive these services from the jail or prison in which they are incarcerated. Thus, people released from prison and individuals under community supervision are a high-risk group for a range of poor health outcomes and poor access to care. For these reasons, the focus of this investigation is on people recently released from prison and individuals under correctional supervision in the community. The procedures for selection of these participants will be fair and will be immune from arbitrary intervention by parole and probation departments, and the Department of Corrections.

Parole and probation boards will not be informed of participation of any individual in the study. In addition, no individually identifiable information about participants will be shared with parole and probation officers. The study's Federal Certificate of Confidentiality further ensures the confidentiality of participant data.

Pregnant women will not be excluded because the study is minimal risk. Children will be excluded.

IMPORTANT NOTE: Consider whether subjects will be in a vulnerable category at the time of data collection or during analysis. For instance, if you collect data about children who were ages 12 – 15 from years 2000 – 2002, you know that now those individuals are no longer children.

Individuals with Impaired Decision-Making Capacity

State whether individuals with impaired decision-making capacity will be included and explain the extent of cognitive impairment (complete, fluctuating, progressive, or temporary). Justify their inclusion and explain any protections to mitigate risk (such as the involvement of a caregiver or authorized representative). Describe consent/assent procedures.

Individuals with impaired decision-making capacity will be excluded.

Other Populations Targeted for Recruitment

If you are targeting a population that may be vulnerable to coercion or undue influence based on the specific circumstances of the study, describe how you will ensure that participation is voluntary and minimize any added risk. (Common examples include KP employees, students, people of low socioeconomic status, etc.)

Staff from the three health systems in which this study is taking place will participate in the interviews. To prevent a perception of coercion or undue influence, the strictly voluntary nature of the study will be clearly stated during the consent process. Prospective participants will be informed that they can withdraw from the study at any time and that they have the right to decline to answer any question without providing explanation and without penalty.

d. Setting

Describe the sites or locations where your research team will conduct the research.

If this is a multi-site study:

- Specify what procedures are being performed at this site or by this site's personnel (consider recruitment, consent process, study procedures, data analysis, etc.).
- State how each site will satisfy its IRB review requirements. Indicate if you are asking this site's IRB to rely on another IRB or if another institution would like to rely on this site's IRB and include this information in the eIRB Initial Project submission

For research conducted outside this site describe: (Community, Reservations etc.)

- Site-specific regulations or customs affecting the research at that location.
- Local scientific and ethical review structure outside this site.

To maximize generalizability, we will examine structural conditions across academic, community and safety-net health systems in the Denver/Aurora metro area of CO (i.e., within KPCO, UCHealth, and DH). Denver (~725,000) and Aurora (~375,000), the two largest cities in the state, are within 10 miles of one another and their combined metro areas cover 307 square miles and three counties. The area is diverse with 12% African American/Black, 30% Hispanic/Latinx, and 15% below the poverty level. Around 40% of people from prison are released to the Denver/Aurora Metro area. In CO, imprisonment rates are

>7 times higher in Black and >2 times higher in Hispanic or Latinx individuals compared to White individuals. Black, Hispanic or Latinx and Native Americans are 55% of the incarcerated population but only 25% of the state population.

KPCO, UCHealth University of Colorado Hospital, and DH will participate in all study aims, with KPCO serving as the coordinating site. One of the study co-investigators, Dr. Irene Blair, is affiliated with the University of Colorado, Boulder (CU-Boulder). Although CU-Boulder will not contribute data, Dr. Blair will assist with development of study documents, interpretation of findings, and manuscript preparation. We are requesting that the KP Interregional IRB serve as the IRB of record for all four sites – KPCO, UCHealth University of Colorado Hospital, DH, and CU-Boulder. (See signed IRB Authorization Agreements in the IRBNet record.)

e. Recruitment Methods

Describe how study participants will be recruited and enrolled. Indicate whether you will openly recruit using advertisements, websites, or brochures. Indicate if you plan to do targeted recruitment using existing records or referral. (Upload all recruitment materials to your submission to the IRB.)

Describe, by position/title, who will be recruiting and enrolling participants (providing the specific names of research team members is not necessary).

Describe any plans for the participants in the currently proposed study to be re-contacted or recruited for future follow-up studies. (Note that participants should be informed of this potential for re-recruitment during the current study's consent process.)

Overall Recruitment Summary

During Aim 1, we will recruit healthcare organizational leadership, frontline clinicians and staff; Department of Corrections leadership; community organization leadership and staff; and individuals with lived experience of incarceration to participate in key informant interviews to help determine structural conditions in healthcare organizations. During Aim 2, we will recruit individuals recently released from prison to assess their cardiovascular health and exposure to healthcare structural conditions. During Aim 3, we will recruit a Delphi Panel of national experts to iteratively develop best practice recommendations for improving access to health among recently released prisoners.

Aim 1: Stakeholders relevant to Healthcare

Our research team has a long record of successfully recruiting and enrolling health system leaders, clinicians and staff, and community leaders for other studies and have experience collecting qualitative data from a broad array of stakeholders.

Stakeholder Recruitment:

Recruitment of health system, Department of Corrections, and community organization staff:

Working with our healthcare systems, community partners, and community advisory board (CAB) members, we will use a snowball sampling strategy to recruit individuals from healthcare organizations (leadership, clinicians, staff), the Colorado Department of Corrections (leadership and staff), and Community organizations (leadership and staff) who focus on the health and well-being of individuals recently released from prison. All stakeholder participants will be outreached

via email from our team members. (See "Outreach Email for Health System, DOC, and Community Organization Interviews" document uploaded with this modification.)

Recruitment of individuals with lived experience of incarceration:

Individuals with lived experience of incarceration will also be recruited for key informant interviews, as they will have important insight on structural conditions within healthcare systems that influence access and quality of care delivered to people released from prison.

To recruit these interviewees, the study team will provide CAB members, community organization representatives, and other stakeholder interviewees who have contacts with lived experience of incarceration with text for an email describing the study to send to the contacts. (See Email Text for Contacts of Individuals with Lived Experience of Incarceration document uploaded with this modification.) The email will instruct those who would like more information to leave a message at our project email address or phone line requesting to be contacted by a member of the study team. The study team will reply to answer questions and assess interest in participation. The study team will also invite CAB members with lived experience of incarceration to participate in the interviews.

Compensation:

As permitted, each interviewee will receive compensation valued at approximately $25 upon completion of their interview.

Stakeholder Retention: Since no longitudinal follow-up is involved, participant retention is not an anticipated concern.

Aim 2: Individuals Released from Prison

Primary recruitment methods for Aim 2 will include (1) outreach to individuals on Colorado DOC lists of people recently released from prison, and (2) community-based recruitment.

1) DOC lists of people recently released from prison

The Colorado DOC currently provides our Denver Health team lists of people recently released from prison who have consented to share their information in post-release outreach efforts to increase access to healthcare. We have obtained provisional approval from the Colorado DOC (CDOC) research review board for this study and are in the process of setting up an agreement with CDOC that will allow CDOC to send KPCO lists of individuals recently released from prison and use the lists for study recruitment.

The study staff will mail postcards or letters to people on the DOC lists describing the study and providing the email and phone number where the study staff can be reached for more information. (See SCHARP Recruitment Postcard-Flyer.) Individuals who leave a voice message or email in response to receiving the postcard will be outreached by a member of the study team (see SCHARP Recruitment Scripts). The study staff may also contact people on the list directly if phone numbers and/or email addresses are available.

2) Community- based recruitment

Members of the research team will meet with community organizations (e.g., reentry centers, parole offices, and social service providers), including those with which study CAB members are affiliated, to introduce the study and describe the research protocol. In community organizations that agree to assist with recruitment, the research team will distribute flyers (see SCHARP Recruitment Postcard-Flyer) and give presentations that include a description of the study and our contact information. Contacts at the community organizations may also be provided with flyers to offer to clients who may be interested in participating. Individuals who leave a voice message or email in response to seeing the flyer or presentations will be outreached by a member of the study team using the recruitment scripts.

We will also schedule days for staff to be present at community sites to do walk-in recruitment. This will entail setting up a table where a staff member will be available to describe the study and provide our contact information (e.g., via the study flyer or business card). As permitted, staff may also take down the names of individuals who express interest in participating to follow up with them later to assess their interest and eligibility. We will also offer prospective participants to enroll and complete their baseline visit on site.

In addition to the DOC lists and community-based recruitment, enrolled participants will be invited to provide study information (e.g., flyers) to contacts who may also meet study eligibility criteria. Participants will be offered a small incentive ($10-$20) for referring someone else who enrolls, up to a maximum of three referrals. We may additionally post study information on the IHR website or social media outlets such as Facebook.

Potential participants who voluntarily contact study staff in response to the mailing to individuals on the DOC list, community-based recruitment, or referrals will be contacted by study staff to answer questions and confirm eligibility (See Eligibility Screening Form.) The staff member will then initiate the informed consent discussion with individuals meeting eligibility criteria who would like to participate. (See SCHARP Recruitment Scripts and Eligibility Screening Form.)

Enrollment and baseline interviews and data collection/testing will take place in-person in private spaces available in partnering community or health care organizations or Kaiser Permanente offices. Recruitment activities will continue until 400-600 eligible participants have enrolled. Participants will complete the follow up survey over the phone, or in person at a participating community site or Kaiser medical office building if requested, as close as possible to 6 months after the baseline visit.

A list of resources for assistance with employment, food assistance, healthcare, housing assistance, mental health, substance use, reentry, and other needs will be made available to participants at their baseline visit. (See Participant Resources document.)

Prospective Cohort Study Participant Retention:

Retention of study participants will be encouraged by appreciation/incentivization of their involvement and efforts, ensured confidentiality of data provided, allowance for flexible and

convenient scheduling of appointments for data collection, and maintenance of accurate and updated contact information.

Our study staff will work to establish a relationship and build trust with all participants. The NIH Certificate of Confidentiality will be described during the recruitment process to assure participants no study information can be subpoenaed. We will provide a single point of contact (study email and phone number) to ensure participants have easy access to study staff.

To ensure ongoing communications, participants will be sent a text or email after their baseline visit thanking them for their participation and providing a link to or PDF of the study consent form containing the study email address and phone number. In addition, participants will be sent "check in" texts or emails at approximately 30 days, 60 days, 90 days, and 120 days after their baseline visit containing the study email address and phone number (see Check-in texts, emails file). We may create a Facebook group for participants only.

We will also collect and maintain adequate participant contact information. During the baseline visit, participants will be asked to provide us with the phone numbers, email addresses, and postal addresses of up to three persons who can help us contact the participant if we are unable to reach them directly (see Identifying and Tracking Info Form). In addition, the texts/emails that are sent approximately 30 days and 90 days after the baseline visit will ask participants to confirm or update their contact information. (See Check-in texts, emails file). Participants who reply to the text or email will receive a small ($10-$20) incentive. If after multiple attempts we are unable to reach participants directly or via their alternate contacts, we may also collect information about participants from records available to the public (e.g., public jail and prison databases, whitepages.com) and/or check with community partners for updated participant contact information. We will send a physical letter to outreach for follow-up participants who did not have a phone number or email at enrollment but who did have a mailing address (see Physical letter for participants without a phone or email).

Finally, we will offer financial incentives for participation. Participants will receive gift cards valued at up to $75 for completion of the baseline visit (a $50 card for the baseline survey and a $25 card for the physical health measurements), and gift cards valued at $50 for completion of the follow-up survey.

Based on past study experience, and since baseline and follow-up appointments for patients will be relatively close together, we expect attrition to be low at 10%.

If we discover through regular data quality checks that questions were missed from the baseline or follow-up survey, the study staff will outreach the participant by email or phone to try to gather the missing data. (See SCHARP Scripts for Outreach for Missing Data)

Aim 3: Modified Delphi Experts

Expert Recruitment: We will identify and recruit 15-20 nationally known stakeholders with expertise in healthcare delivery, criminal justice, and health advocacy among individuals released from prison. These stakeholders will include researchers who study health care delivery to justice involved individuals; advocates for people released from prison; clinical leaders in correctional or community-based care with expertise in this population; and individuals in

relevant agencies (e.g., Medicaid, DOC). We will prioritize people who also have lived experience with incarceration and people from BIPOC communities in identifying and selecting participants. To identify experts, we will work with our CAB and consult other groups such as the *Society of General Internal Medicine,* the *American College of Physicians,* the *Academic Consortium on Criminal Health Justice*, the *Transition Clinic Network*, *Medicaid*, the *Department of Corrections*, and *Colorado Criminal Justice Reform Coalition*. All Delphi experts will be recruited verbally or via email from our team members using a snowball sampling technique. The study investigators have experience recruiting and overseeing national expert rating panels for developing consensus statements and documents.

Retention: Retention of study participants will be encouraged by selecting experts who are highly engaged and invested in studying and prioritizing healthcare delivery to people released from prison, by providing ongoing updates about how their feedback is valued and being utilized to iteratively developed best practices, and by offering a $500 incentive for completing all rounds of participation. For each round or review, participants individually will select a date/time convenient to them that they will review the materials and respond. The research team will send the materials to the participant at his/her selected day and time. This method was previously used by Dr. Morris (co-I) with a 94% participation rate.

f. Informed Consent Process

Describe how you will obtain and document consent, including:

- Where, when and how the consent process will take place.
- A process to ensure ongoing consent.
- Steps that will be taken to minimize the possibility of coercion or undue influence.
- Any steps that will be taken to ensure the subjects' understanding.
- If you will conduct screening or any other research procedures before obtaining full informed consent, describe this.

Only participants who provide informed consent will be enrolled in the study. The strictly voluntary nature of the study will be clearly stated in the consent process. All participants will have an opportunity to contact the study team with any questions. Consent processes will inform participants that they are free to withdraw from the study at any time, that all information is to be kept confidential, that their identity will not be revealed, that a code number will be used to track all their information, and that only the research investigators will have access to the data.

For interview participants, verbal consent will be performed and a waiver of documentation of consent will be obtained; because the only risks to participants relate to a potential loss of confidentiality, any breach of confidentiality will be strictly guarded against. Prospective participants who are interested in learning more about the study will be provided an informed consent document for review prior to meeting with a member of the study team to have their questions answered and provide verbal informed consent. All interviewees will receive a copy of the informed consent document after their interview. The informed consent document will be sent to interviewees either by email or mail based on their stated preference. The study team will record the names of persons participating in the interviews in order to follow up on themes or issues raised. However, all study results will be published and presented in aggregate form only, with no individual responses identified.

For the longitudinal cohort study, individual informed consent will not be required for screening the Department of Corrections database for study inclusion.

The informed consent discussion will be initiated by the study staff while describing the study as part of the initial outreach (see SCHARP Recruitment Scripts).

The discussion will address the purpose of the study, what participants are expected to do and the time commitment, the risks and benefits of participation, incentives that will be provided, and how the confidentiality of study data will be maintained. Participants will also be told that the study has a Certificate of Confidentiality from NIH, to assure them that no study information can be subpoenaed. In addition, potential participants will be informed that no individually identifiable information about participants will be shared with parole or probation officers. We will inform participants that if we are unable to reach them directly or via their alternate contacts for the 6-month follow-up survey, we may collect information about them from records available to the public and/or check with community partners for updated participant contact information.

Participants will be informed that health information collected as part of this study (e.g., blood pressure, cholesterol and glucose levels, survey responses) are purely meant for research purposes and are not meant to diagnose or guide treatment of a medical condition.

Potential participants will also be informed that information on their health care utilization and health conditions will be collected from their medical claims records (which will come from the Colorado All Payer Claims Database; health system records will not be accessed). This retrospective data extraction will collect existing data that is recorded as part of routine billing for medical services. The only risk is breach of privacy. PHI being collected includes participant name, sex, date of birth, and insurance ID # to ensure accurate linkage to the claims database. Participant identifiers will not be used in any analysis or presentation of results. The only risks of a potential loss of confidentiality will be strictly guarded against.

The study staff will then schedule the in-person baseline visit with individuals who are eligible and would like to participate. At the start of the baseline visit, the staff member will review the informed consent document, which will have been emailed/texted to the potential participant after the initial outreach call (except for participants recruited via walk-in recruitment at community sites who will receive the consent form then), and respond to any questions. Verbal informed consent will be obtained from those who agree to enroll, prior to collecting cardiovascular health measures and completing the baseline survey. Verbal informed consent will be documented in the study REDCap database.

Waiver of Informed Consent

Provide rationale and justification for the Waiver of Informed Consent for this study, including:

- Why the research could not practicably be carried out without using such information or biospecimens in an identifiable format.
- Does the proposed research present no more than minimal risk to the study participants?
- How the waiver of informed consent will not adversely affect the rights and welfare of the participants.
- Why this research cannot practically be carried out without a waiver of informed consent.

- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

N/A

Waiver of Signed Informed Consent

Provide rationale and justification for the Waiver of Signed Informed Consent by identifying which of the following conditions apply and how.

1) The research involves no more than minimal risk to participants AND involves no procedures for which written consent is normally required outside of the research context.
2) The signed consent document would be the only record linking the participants to the research, and the principal risk to participants would be potential harm resulting from a breach of confidentiality.
3) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

We are requesting a waiver of signed informed consent for the Aim 1 interviews as well as the Aim 2 prospective cohort study. Verbal consent covering all required elements of informed consent will be requested of potential participants. The main risks to participants in both Aims relate to a potential loss of confidentiality. Allowing participants to provide verbal rather than written informed consent will reduce the risk of a breach of confidentiality. The study team will record the names of persons participating in order to follow up on themes or issues raised in Aim 1 and to schedule baseline visits and follow-up surveys for Aim 2. However, all study results will be published and presented in aggregate form only, with no individual responses identified.

As noted above, we may collect information about participants from records available to the public and partner community organizations if we are unable to reach participants directly or through their alternate contacts for their 6-month follow-up survey. For individuals already enrolled in the study who we have been unable to contact for the 6-month follow-up survey, we request a waiver of informed consent to use the public databases and to consult with partner community organizations to locate them, and will reconsent them if/when they are located. Individuals enrolled after the informed consent form is updated will be informed at the baseline visit that we may collect information about them from records available to the public or from community partners.

Alteration of Informed Consent

Identify the required elements of informed consent that you wish to remove or alter. Provide justification for their removal or alteration.

N/A

Non-English-Speaking Subjects

If subjects who do not speak English will be enrolled, describe how the consent discussion will take place and indicate if translated consent forms or short forms will be used. Confirm that an interpreter will assist with the initial consent process and subsequent study visits.

Aim 1 will be limited to individuals who speak English. For Aim 2, individuals who speak either

English or Spanish will be eligible to participate. The study documents (recruitment materials, informed consent documents, scripts, interview guides) will be available in both English and Spanish. Documents will be translated into Spanish by an IHR research assistant who is a KP Certified Translator as well as using questions from existing published translations where available. The translated documents will then be checked by a second IHR KP Certified Translator. The research assistant KP Certified Translator who is fluent in Spanish will conduct recruitment activities and interviews in Spanish as needed.

Assent of Children and Parent Permission

IMPORTANT NOTE: Consent may be obtained in certain situations. For example, conducting family planning or sexually transmitted disease (STD) research. In addition, for older children ages 16 and up who participate in an adult study, the consent document can be used in place of the assent document.

Describe how you will obtain and document assent/parental permission, including:

- Describe your plan for obtaining parent permission. The permission of one parent is generally sufficient for minimal risk research, or for greater than minimal risk research if there is the potential for direct benefit to the child.
- Note that for studies involving greater than minimal risk with no prospect of direct benefit to the child, permission of both parents is required unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
- Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission.
- Indicate whether assent will be obtained and documented from all, some, or none of the children. If assent will only be obtained from some children (because of very young age, severe cognitive impairment, etc.), indicate which children will be required to assent and which will not.
- When assent of children is obtained, describe whether and how it will be documented.
- When subjects might reach the age of majority during the study, describe the plan to obtain consent from these subjects at that time using an adult consent form.

N/A

Individuals with Impaired Decision-Making Capacity Unable to Consent

Describe the consent/assent process for individuals with impaired decision-making capacity unable to consent, including:

- Describe the process to determine whether an individual is capable of consent.
- List the individuals from whom permission will be obtained in order of priority. (E.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child.
- Describe the process for assent of the subjects. Address the following:
    - Whether assent will be required of all, some, or none of the subjects. If assent will be obtained from some subjects, indicate which subjects will be required to assent and which will not.
    - If assent will not be obtained from some or all subjects, an explanation of why not.
    - When assent is obtained, describe how it will be documented.

- Describe the plan to obtain consent if subjects might regain capacity to consent during the study.

N/A

g. HIPAA Privacy Rule Authorization – if study will use or disclose Protected Health Information (PHI)

Describe the plan to obtain a signed Privacy Rule Authorization from each subject.
We will request HIPAA Privacy Rule Authorization for all study participants. For both aims, prospective participants will be asked to provide verbal authorization coinciding with their verbal informed consent. (See SCHARP Recruitment Scripts)

Partial Waiver or Alteration of HIPAA Privacy Rule Authorization

If applicable to this study (i.e., for identification and recruitment), explain your request for a Partial Waiver or Alteration of HIPAA Privacy Rule Authorization or if you want to eliminate any required language from the authorization, and provide the following rationale and justification.

- Why the research could not practicably be conducted without the waiver.
- Why access to and use of the PHI is necessary for the research.
- Why the use or disclosure of PHI for the research poses no more than minimal risk to the subjects' privacy (must have an adequate plan to protect the PHI from improper use or disclosure, a plan to destroy identifiers at the earliest opportunity consistent with the purpose of the research, and when applicable, written assurances from collaborators that PHI will not be reused or re-disclosed to any other entity).

We are requesting a partial waiver of HIPAA Privacy Rule Authorization to identify potential cohort participants from the DOC lists of people recently released from prison. This research could not be carried out without this waiver as the DOC lists will include names and contact information. In addition, we are requesting a partial waiver of HIPAA Privacy Rule Authorization to collect and record in the study REDCap database the names of individuals found to be ineligible to prevent accidentally outreaching them again, as well as to record in the study REDCap database the names and contact information of individuals who are interested in participating and need further outreach to confirm eligibility prior to obtaining verbal informed consent.

Full Waiver of HIPAA Privacy Rule Authorization

If you will not obtain a signed HIPAA Privacy Rule Authorization, provide the following rationale and justification.

- Why the research could not practicably be conducted without the waiver.
- Why access to and use of the PHI is necessary for the research.
- Why the use or disclosure of PHI for the research poses no more than minimal risk to the subjects' privacy (must have an adequate plan to protect the PHI from improper use or disclosure, a plan to destroy identifiers at the earliest opportunity consistent with the purpose of the research, and when applicable, written assurances from collaborators that PHI will not be reused or re-disclosed to any other entity).

N/A

6. Study Procedures

Describe and explain the study design, including:

- Procedures to monitor subjects for safety, including who will review the data and at what frequency for safety issues.
- Procedures performed to lessen the probability or magnitude of risks.
- All drugs and devices used in the research and the purpose of their use, and their regulatory approval status.
- The source records that will be used to collect data about subjects. (Attach all surveys, scripts, and data collection forms.)
- What data will be collected including long-term follow-up.
- The duration of an individual subject's participation in the study.
- The duration anticipated to enroll all study subjects.
- The estimated date for the investigators to complete this study (complete primary analyses)

NOTE: It should be clear exactly which procedures will be conducted for the research as opposed to procedures the subjects would undergo (in the exact manner described in the protocol) even if they were not participating in the study.

Describe procedures that will be followed when subjects withdraw from the research, including withdrawal from intervention but continued data collection.

Describe any anticipated circumstances under which subjects could be withdrawn from the research without their consent.

Describe any procedures for orderly termination.

If the study involves genetic testing or collection of genetic information, describe this.
This investigation will utilize the following methods: 1) interviews with leaders/staff, 2) review of written documents, 3) enrolled participant interviews and surveys; and 4) claims-based data queries. We will secure a Data Use Agreement with the Center for Improving Value in Health Care (CIVHC) which administers the Colorado All Payer Claims Database (CO APCD).

In addition, we will establish a multi-stakeholder community advisory board (CAB) to assist with study planning, execution, and oversight. The CAB will consist of multiple stakeholder members (community organizations, healthcare organizations, DOC officials and at least 3 people with lived experiences of incarceration and reentry in the community) that meet quarterly throughout the project. The CAB will provide input into the instruments used for the assessment of organizational structural conditions (Aims 1 and 2), recruitment assistance (Aims 1-3) and be involved throughout the life of the project to review emerging results (Aims 1 and 2), review the recommended practices playbook (Aim 3), and assist with communication and dissemination materials (Aim 3). As permitted, CAB members will be compensated $500 per year for their time.

AIM 1: Measure Structural Conditions in Healthcare Organizations

In Aim 1, a qualitative case study using multiple data collection strategies will be used. Our study team will conduct interviews, as well as review relevant documents, to delineate policies, procedures and attitudes at each site to gain a comprehensive understanding of the complex phenomena influencing care delivered to patients who have been released from prison. Interview guides, as well as document review forms will be created in collaboration with our CAB. The

domains in the guides will be informed by identified structural conditions known to influence access to health for people released from prison.

We hypothesize that the organizations' access policies and practices, transition programs and specialized training, culture and mission, support of social determinants of health, and specialized services will be interconnected and collectively influence the care delivered to people released from prison. (Table 1) We will explore these conditions and their interconnectedness through multiple sources of data at each organization.

Data collection. Rigorous case studies require multiple data collection strategies. Our study team will conduct in-person or MS Teams/Zoom interviews, as well as review relevant documents, policies, and procedures at each site to gain a comprehensive understanding of the policies, practices and attitudes influencing care delivered to people who have been released from prison. Interview guides, as well as document review forms will be reviewed by our study team and CAB. The guide will be informed by the structural conditions known to influence access to care for people released from prison. (Table 1)

Table 1: Structural Conditions Known to Influence Access and Health for People Released from Prison and Example Questions for Assessing these Conditions at the Organizational and Individual Level

Structural Conditions	Organizational Assessment (Aim 1)	Individual Exposure Since Release (Aim 2)
Access policies and practices	Does Organization: Have specific policies or practices regarding new patient primary or specialty care based on their insurance status? Offer uncompensated outpatient care? Receive reimbursement for community outreach? Have medication assistance programs?	Did the person: Experience a limit on care (e.g., were unable to book a clinic appointment) due to their insurance? Receive any form of free or price reduced care? Use or have knowledge of programs that provide financial assistance for medications or other medical supplies?
Transition specialists; specialized training of staff	Does Organization: Employ patient navigators or peer navigators that serve this population? Have Transition clinics? Provide training for employees on needs of people newly released from prison? Participate in prison in-reach (e.g., contact before release), data exchange, or coordination with parole officers?	Did the person: Receive services from patient or peer navigators? Visit a Transition clinic? Receive care from providers knowledgeable about their unique challenges? Receive info or talk with person from community healthcare system while in prison? Did their parole officer coordinate with a healthcare system? Did they receive prison medical records?
Organizational culture, mission; stigma and discrimination	Does Organization: Have mission that includes racial equity? Have devoted funding to promote racial equity programs? Have staff focused on racial equity? Include criminal justice issues in racial equity efforts? Want more or fewer patients from population (those with criminal record)? Perceive problems vs. benefits in serving population? Have respect and empathy toward population? Have positive vs. negative attitudes and beliefs about population? Have a disconnect in attitudes and beliefs between leadership and frontline clinicians and staff?	What type of organization(s) have they used? Because of their history of imprisonment OR their race OR ethnicity, did the person: Receive courteous and helpful service in healthcare organization? Experience barriers in scheduling appointment, obtaining information, or other administrative tasks in healthcare organization? Experience disrespectful or unfair treatment while attempting to obtain healthcare or during visit? Avoid obtaining care due to concerns about disrespect/mistreatment?

Assessment and support of social determinants of health (SDOH)	Does Organization: Provide any housing assistance? Employment of formerly incarcerated or people with prior conviction? Assess SDOH? Provide referrals for SDOH needs identified? Have a community benefit program? Have financial assistance programs? Do these programs support organizations that serve people releasing from prisons? How?	Was the person ever asked about their housing, employment, food security or financial stability when visiting a healthcare system? Did the person receive housing, food, or employment assistant from any healthcare Organization?
Specialized services	Does Organization: Have mental health or substance use disorder treatment for people who are released from prison?	Was the person offered or did they receive mental health or substance use disorder services from a healthcare organization?

Interviews: At each health system we will conduct 45-minute interviews with organizational leaders and with clinicians in the Emergency/Urgent care, Behavioral Health and Primary Care. At each health system, we will additionally conduct interviews with staff members including social workers, case managers, access specialists and other members of the staff responsible for facilitating access. To understand the community context around the health systems, we will also interview individuals at the Colorado DOC involved in transitions and with community organization representatives. In addition, we will interview people with lived experience of incarceration.

Document Review: We will conduct a structured review of key documents and policies. Researchers will ask leaders, clinicians and staff members at the health system to guide them through the process of a patient accessing care in the clinic and emergency settings. The team will record field notes and collect relevant published materials as appropriate. Using methods successfully deployed in other studies evaluating organizational policies and procedures, we will conduct a content evaluation of publicly available materials from each health system. Our preliminary review of our target health systems' websites suggests the following information is readily available including: mission statements, annual financial reports (e.g. % Medicaid, % uncompensated care), Community Health Needs Assessments and Implementation Plans (required by IRS for all tax-exempt organizations), nondiscrimination policies, leadership structures (e.g. diversity among leadership, health equity/diversity leadership role in the organization), and specialized services (e.g. specialized transition clinics, services for substance use disorders, services for behavioral health). In addition, we are interested in any available materials on employment policies (e.g. those that exclude or support people with incarceration histories, or the use of background checks), employee training materials (e.g. training on bias, discrimination, cultural competency), advocacy work, community partnerships (e.g. collaboration with community groups focused on criminal justice involved individuals), specialized programs relevant to access (e.g. participation in state Medicaid value-based care programs), internal funding/awards for staff working with criminal justice populations, and any highlighted news, public relations stories or commissioned reports about people released from prison. If this information is not available or listed on their websites, we will work with our health system contacts to obtain a copy of these materials (if they exist). The field notes and documents will serve as the data sources that will be coded and analyzed along with the interview transcripts.

AIM 2: Link Exposure to Healthcare Structural Conditions to Access and Health Outcomes

In Aim 2, we will recruit people recently released from prison. The DOC currently provides our Denver Health team a list of all recently released individuals in the state who are enrolled in Colorado Medicaid and who have consented to share their information for support in accessing healthcare. (see Preliminary data) We are in the process of setting up an agreement with DOC which would allow the DOC to send KPCO lists of individuals recently released from prison and use the lists for study recruitment. The lists would include names, mailing addresses, phone numbers and county of release. Potential participants from the DOC lists will be sent a postcard or letter with study details and contact information. We will also reach out to potential participants on the DOC lists by phone and email should that information be available. We will also use community-based outreach methods including flyers, walk-in recruitment, and presentations at re-entry centers, correctional facilities, parole, social service providers, and by word of mouth. We may post study information on social media outlets such as Facebook.

At enrollment (baseline visit), verbal informed consent will be obtained, cardiovascular (CV) health measured, and the baseline survey administered. Enrollment activities will take place in private spaces available in partnering community or health care organizations or at Kaiser Permanente offices. Baseline surveys include questions on sociodemographics, burden of social determinants of health, prior healthcare experience, and medical and psychiatric health conditions. Baseline CV health will be measured using Life's Essential 8 criteria which includes 1) body mass index, 2) blood pressure, 3) lipids, and 4) blood glucose as well as assessments of 5) smoking, 6) diet, 7) physical activity, and 8) sleep via short surveys.[17] Non-fasting lipid and glucose measures will be obtained using point-of-care testing systems approved by the Food and Drug Administration. Devices will be calibrated according to manufactured instructions and specimens will be properly disposed of immediately after results obtained.

The BMI, blood pressure, lipid (cholesterol), and blood glucose readings will be provided to participants (see POC Testing Results for Participants) under CLIA waiver. Participants with blood pressure and glucose readings outside of the normal range will be advised to seek health care, and Drs. Binswanger and Daugherty will also be on call to assist these individuals as needed.

We will also ask about **exposures to different health system conditions** since release from prison (Table 1). These exposures and questions will be refined with our learnings from aim 1 and input from our CAB. Example questions include:

1) Access policies and practices - Were you unable to make a doctor's appointment or schedule procedures due to your type of insurance or lack of insurance? Have you received free or price-reduced healthcare?

2) Transitional services and staff training – Have you worked with a patient navigator or other person who helped you get access to healthcare? If yes, did this person also have a history of being imprisoned?

3) Organization culture/discrimination in healthcare due to prison history or race/ethnicity – Because of your history of imprisonment OR your race/ethnicity: Have you been treated disrespectfully or unfairly by anyone in a clinic or hospital? (If "yes", describe); did anyone in the clinic or hospital act like they were afraid or didn't trust you?

4) Support of Social Determinants of Health – Were you asked about your housing, employment, food security or financial stability when visiting a healthcare system? If yes, did you receive any support?

5) Specialized services – Have you received mental health or other services from a healthcare system?

6-Month Follow up - Participants will complete follow up surveys over the phone or in person at a participating community site or Kaiser Permanente medical office building, if requested, as close as possible to 6 months after the baseline visit. The same questions about exposures to health system factors since release from prison will be asked. Individuals who are reincarcerated and then released after the baseline enrollment will be interviewed upon their subsequent release. Individuals who are not re-released will not be eligible for follow up.

PRIMARY OUTCOMES – Our primary outcomes over 12 months since release will be the number of: 1) Outpatient clinic visits, 2) Emergency or Urgent care visits, and 3) Hospitalizations. Utilization will be primarily assessed using the Colorado All Payer Claims Data (CO APCD). The CO APCD is a comprehensive database of payer claims representing most covered lives (~65%) in Colorado across commercial healthcare plans, Medicare and Medicaid. The CO APCD includes 100% of individuals enrolled in Medicaid. Since >90% of individuals released from CO state prisons are eligible for Medicaid (see prelim data), we anticipate linkage to claims in >90% of those enrolled in the study. Claims are available within 3 months of the service. Enrolled participants will be linked to the CO-APCD using their name, date of birth, sex, and, as available, insurance ID number.

In secondary analysis, we will use participant self-reported use of healthcare at 6 months as an outcome. Self-reported utilization will be assessed using the National Health Interview Survey Adult Access to Health Care & Utilization Module. The 10 questions capture when medical care was last sought, usual place of care, the purpose of care (e.g. wellness visit or emergency care), frequency of getting medical care and reasons for not getting medical care (e.g. cost). We will revise the time intervals to reflect the study timeline (e.g., in the past 6 months since being released, how many times have you gone to the hospital emergency room). Prior studies have demonstrated self-reported and claims data regarding healthcare utilization among adults released from prison is highly correlated (Kappa 0.69).

Additional secondary outcomes to be assessed at 6 (self-report or APCD) or 12 (APCD) months since release include:

CV hospitalizations - the primary discharge diagnosis indicates CV-related hospitalization using Healthcare Cost and Utilization Project categories.

Regular source of health care - More claims for clinic visits than emergency/urgent care visits. Answer to place they usually go if sick and need health care is a “doctor’s office or health center”.

Mortality – The CO APCD links mortality data from the CO Department of Public Health.

Pharmacy Claims – The CO APCD includes pharmacy claims for all medication fills.

Reincarceration - We will ask participants about reincarceration including short stays for arrests and longer stays including transfers to the state prison. We will collect data on recidivism through participants' reports and publicly available data portals.

CV Health - Participants will be asked whether a doctor has told them since they were released that they had CV disease (e.g., a heart attack, heart failure) or specific risk factors including hypertension, diabetes, elevated cholesterol, obesity. They will also be asked about their smoking, dietary and exercise habits. We will query outpatient claims for ICD-10 codes for risk factors including hypertension, diabetes, hyperlipidemia, peripheral artery disease, coronary artery disease, smoking and obesity.

PARTICIPANT LEVEL COVARIATES

Social Determinants of Health (SDOH): The burden of SDOH among those released from prison is high; >75% are unemployed, 25% are homeless and 20% have food insecurity. We will use the Center for Medicaid and Medicare Services Health-Related 26 question Social Needs Screening Tool to assess for housing instability, food insecurity, transportation problems, utility help needs, interpersonal safety, financial strain, employment stability, family and community support, education needs, physical activity, substance use, mental health and disabilities. Participants will also be asked about their lifetime experiences of discrimination using the questions recommended in the PhenX SDOH toolkit.

Prior Healthcare Experiences: To assess past healthcare experiences at baseline, we will ask whether participants were sent to the ED or hospitalized during their most recent incarceration. We will ask about locations where they received healthcare before incarceration. Given variability in the prison discharge process, we will ask participants whether they had been assigned a pre-release specialist or given discharge medications or access to their medical records before release. Finally, we will ask them about healthcare utilization and hospital admission in the time between their release from prison and before study enrollment.

Medical and Psychiatric Conditions: In addition to assessing CV health conditions, participants will be asked whether they've ever been told they have any of the following chronic medical conditions: arthritis, asthma or chronic obstructive pulmonary disease, cancer, chronic pain, depression, hepatitis B or C, HIV/AIDS, posttraumatic stress disorder, renal disease or renal failure, schizophrenia, seizure disorder, or stroke. Participants will also be asked if they are currently taking medications for these or other conditions.

MODERATORS

Participant Race/Ethnicity: Our primary moderator of interest is participants' self-reported race and ethnicity collected according to US census categories and current data standards. Participant race and ethnicity represent social constructs that, due to societal SRD, may moderate associations between healthcare organizational SRD and health outcomes.

CV health: Given the high prevalence of CV risk among people released from prison, we will evaluate how CV health at enrollment influences health outcomes. We will measure Life's Essential 8 criteria which includes 1) body mass index (BMI), 2) blood pressure, 3) lipids, and 4) blood glucose as well as assessments of 5) smoking, 6) diet, 7) physical activity, and 8) sleep via

short surveys. LS8 has a graded relationship with CV disease incidence and all-cause mortality across racial groups and has been shown to be associated with many chronic illnesses. LS8 scores are lower (worse CV health) among racial/ethnic minority groups, including among people released from prison.

Non-fasting lipid and glucose measures will be obtained using point-of-care testing systems approved by the Food and Drug Administration (FDA). BMI will be calculated based on height and weight measured by a digital scale and stadiometer. Research assistants will be trained to obtain point-of-care blood samples (i.e., finger sticks), blood pressure and height and weight samples according to established clinical guidelines.

LE8 scores will be generated for each measure using American Heart Association categories of poor (1 point), intermediate (2 points), and ideal (3 points). Scores will be summed across the eight domains to yield a total cardiovascular health score ranging from poor, to intermediate, to ideal. Based on prior work in a similar population, we anticipate mean LE8 to indicate intermediate CV health.

SURVEY PRETESTING

We will pre-test drafts of the baseline survey with members of the IHR staff and study CAB. Pre-testing will entail having a study team member verbally administer the survey to the IHR staff/CAB member via Microsoft Teams. Pre-testing will focus on assessment of survey organization, question wording, readability/understandability, skip patterns, and respondent fatigue/survey length. Pre-testing with members of the CAB with lived experience of incarceration will additionally focus on identification of problems that individuals recently released from prison might encounter when completing the survey. We will ask IHR staff/CAB members to answer the survey questions as pretend study participants, rather than based on their personal experiences. CAB members who assist with the pre-testing will be offered a $25 gift card in compensation for their time.

AIM 3: Develop and Disseminate Recommended Practices Playbook to Limit Healthcare SRD

Based on results from Aims 1 and 2, **in Aim 3** we will develop and disseminate a playbook of recommended organizational practices associated with improved access and CV outcomes for people released from prison. We will begin by integrating the analyses of the qualitative (Aim 1) and quantitative data (Aim 2) to identify instances in which the data support or enhance each other. From this, with input from our CAB, we will then develop an initial set of recommendations. To ensure that the recommendations are grounded in the data, we will then complete a member checking process. This will involve conducting additional interviews of leaders and staff from the case studies in Aim 1. We will also interview a sample of participants from our prospective cohort study. During the interviews, the participants will have an opportunity to provide feedback on the integrated findings, as well as the initial recommendations. An iterative process will be used to revise the recommendations. These recommendations will be further refined and finalized through a Modified Delphi Panel of national experts. Once we have identified the recommendations, we will disseminate the recommendations in a manner that correspond with the guidelines.

Member checking interviews. Using the qualitative methods described in Aim 1, we will conduct 5 interviews per healthcare organization and 20 interviews with participants from Aim 2. The health system interviews will include leaders and staff from each of the case study sites in Aim 1. During the interview, the research assistant will present the findings from the qualitative case studies and the participant cohort study, as well as preliminary recommendations. They will elicit feedback to ensure that the analyses and recommendations are grounded in the experiences of the participants. Data analysis will be conducted in a similar manner as described in Aim 1. The revised recommendations will then be reviewed and finalized during the Delphi Panel.

Modified Delphi Panel. A modified Delphi Panel engages experts in an iterative process involving multiple rounds for the purpose of building consensus on a set of items, position statements, etc. The identity of the panel members is kept confidential to minimize the risk of bias or dominance of opinion in a group setting. A Delphi panel allows for context variation and thus enhanced generalizability of outcome through a heterogeneous mix of panel experts. Questions of clarification are allowed and incorporated into feedback.

Modified Delphi Panel procedures. We will conduct up to 3 rounds of approximately 5-7 weeks each – 2-3 weeks for the panel to complete their tasks and 3-4 weeks for the research team to compile feedback. We plan to keep the process moving so as not to lose any panel members, while preserving sufficient time for analysis between rounds. The panel will be conducted asynchronously online through REDCap. For each round, each participant will select a date/time that they will review the materials and respond. The research team will send the materials to the participant at their selected day and time. This method was previously used by Dr. Morris (co-I) with a 94% participation rate. Following each round, the research team will compile and summarize all quantitative and qualitative responses using Excel. We will create an anonymous summary document that will be sent to all panel members at the start of the next round. Each round will take approximately 1-2 hours to complete.

Round 1. We will present the developed recommendations and elicit open response feedback from the participants. *Round 2:* We will present summaries of the responses in Round 1 as well as adaptations and modifications of the recommendations. Participants will have an opportunity to rank the recommendations to identify the top or key recommendations. They will also provide additional open-ended responses and will have the opportunity to revise their opinions on any of the topics. *Round 3.* We will present a review of feedback from Round 2 with the goal of reaching consensus on all remaining components from Rounds 1 and 2.

Process for developing the playbook. To go beyond providing recommendations, our study team will develop a playbook that accompanies the recommendations. This guide will be modeled off prior work and provide practical steps, tips, and advice on how to implement practices and policies to aid those released from prison. The playbook will provide suggestions on how to implement the recommendations, as there is likely no single “correct” way and each health system will face unique challenges. To develop the playbook, the research team will begin with the findings from the qualitative case studies in Aim 1. From the case studies, we will identify real-world examples of implementation of the different policies and practices. If there are no examples from the case studies on how to implement one of the recommendations, we will

engage our CAB and relevant stakeholders to provide input, examples, and guidance. We will package the refined best practices with instructions on how to use them; examples of how healthcare systems have implemented them; FAQ, in the form of a "Recommended Practices Playbook" for healthcare systems.

Dissemination plan: There will be two aspects to our dissemination plan for our best practices playbook: 1) ***stakeholder engagement*** via our CAB throughout the study with a focus on eventual use in diverse settings, and 2) ***diverse dissemination mediums*** for our target audiences.

Stakeholder Engagement - The first aspect of our plan will employ ***stakeholder engagement*** throughout the study to guide our efforts. Significant and ongoing consumer involvement facilitates methods for including the perspective of adopting settings and leaders in charge of policy decisions. As previously discussed, we will establish a **CAB** at the beginning of the study which will include relevant decision-makers and disseminators (e.g., health system leaders, DOC leaders, community groups focused on transitions from prison, people with lived experiences). We will work with the CAB to iteratively develop communication and dissemination materials. All dissemination materials will feature vignettes by our various stakeholders (e.g., health system leaders, participant stories) and include testimonials, experiences using the practices, and lessons learned.

Diverse Dissemination Mediums - The second aspect of our plan will use diverse dissemination mediums to reach our target audiences -healthcare systems, researchers, and policy makers. We will work with our CAB to identify modes of dissemination among their respective ***healthcare organizations***. Example mediums include presentations at clinical leadership meetings, individual meetings with health system leaders, presentations/workshops at national meetings (e.g., the Academic and Health Policy Conference on Correctional Health Conference), and publications in journals, on websites and on social media.

Dissemination to ***researchers*** will be conducted by transparently reporting our protocol in *clincicaltrials.gov* and relevant publications. In addition to these traditional academic dissemination activities, we will conduct workshops and symposia at meetings of key professional societies that showcase our playbook and how it can be employed. We will use social media to feature the playbook on multiple research and health system websites, Twitter, and other social media.

In addition, ***policy makers*** such as state Medicaid organizations have shown a strong interest in improving healthcare for people released from prison, and are hungry for tools, processes, and evidence to help incentivize and facilitate quality improvement in healthcare systems for this vulnerable population. Our research team has been collaborating with CO Medicaid to assemble some of the preliminary data which informs this proposal. We are increasingly interfacing with additional regulatory agencies and policy-oriented groups. Dr. Daugherty is the Colorado representative on the American College of Cardiology Carrier Advisory Committee that provides input to Medicare on coverage and policy decisions. Dr. Hanratty is the principal investigator on a grant that supports a payer-partner collaboration with Colorado Medicaid on definitions of high-risk patients that has implications for payment models and care management requirements. We

will continuously monitor our dissemination activities and adapt them based on results, using principles of implementation and improvement science.

a. Data Analysis

Describe the data analysis plan, including:

- Statistical procedures.
- When applicable, the power analysis.
- Any procedures that will be used for quality control of collected data.

Aim 1

All interviews will be professionally transcribed verbatim and entered into Atlas.ti for data management. The transcripts and documents will be reviewed by multiple team members who will familiarize themselves with the data. The team will engage in a multi-stage coding process to inductively develop a codebook. Once a final codebook is agreed upon, two or more members will code and reconcile the remainder of the transcripts and documents. Any discrepancies in coding will be reconciled through consensus. According to case study methodology, all data will be analyzed within and across cases to describe the factors within each of the identified structured conditions that contribute to the quality of care delivered to people released from prison.

We will use multiple approaches to ensure rigor and trustworthiness of our data collection, analysis, and findings. Throughout the study, we will engage our multidisciplinary research team and will have targeted conversations about team members' biases and assumptions. Team members will be encouraged to practice self-reflexivity. Team-based coding will assure confirmability, maintaining the reliability of coding processes needed to ensure a close connection between the data and the representation of the data through codes and categories. During the analysis phase, we will keep an audit trail and analytic memos to record all team decisions. Dialogue with the larger team and CAB about preliminary findings will confirm, question, or deepen team analysis.

Aim 2

Descriptive statistics will be computed for participant characteristics and outcomes, initially reporting on differences in eligible participants who enrolled vs. did not enroll, participants who followed up vs. were lost to follow up. The primary analysis will assess the association of the described exposure variables with the outcomes of interest. Participant-level covariates will be screened in bivariable analyses (e.g., chi-squared, t-tests) and included in multivariable models if related to the outcome at $p<0.2$, associated with loss to follow up, or have been identified a priori to be confounders. Separate multivariable generalized linear models will be used to assess the association of hypothesized predictors with outcomes adjusted for potential confounders, with a link function chosen based on the distribution of the outcome. Specifically, for the primary count outcomes (clinic visits, ED/urgent care visits, hospitalizations) we will use Poisson regression models, and for the secondary binary outcomes we will use logistic regression models. Bonferroni correction (alpha=0.05/3=0.0167) will be used to adjust for multiple testing of our three primary outcomes. Moderation analysis will be performed by including and assessing the effect of an interaction term between covariates and the described moderator variables (e.g.,

race, CV health) in multivariable models. Goodness-of-fit tests and model-fitting diagnostics will be performed to identify influential points and outliers, and to evaluate alternative model specifications. All hypothesis tests will be two-sided with alpha=0.05, unless otherwise indicated, with p-values and confidence intervals reported. Analyses will be conducted using R or SAS version 9.4.

Missing Data: Missingness of self-reported exposures at 6-months will be minimized by ensuring confidentiality of data provided, using follow up phone visits, maintaining accurate contact information, providing incentives and personal contact with the study team. With these strategies prior studies have achieved >90% retention of those who are available for follow up (not reimprisoned). Missing outcome claims data is anticipated to be rare as >90% of those released from prison are Medicaid eligible and the CO APCD has 100% of Medicaid enrollees. Due to the possibility of missing outcomes and exposure variables, we will examine the data to assess patterns of missingness by comparing those with missing data to those with full data on sociodemographic and clinical covariates. We will utilize all available data in analyses and adjust for covariates that are found to be associated with missingness. Sensitivity analyses will be carried out using multiple imputation approaches.

Sample Size: We plan to recruit a total of 600 people released from prison, over 30 months (~20 people/month). Approximately 400 people are released from prison each month and 20% are released to the Denver/ Aurora metro area (based on our preliminary work using DOC database). In prior work we recruited 200 people released from prison over 14 months (~14 per month) with one research assistant. Therefore 20 people a month plus follow up with two research assistants is feasible.

Power calculation: Power calculations for our primary and secondary outcomes are presented in Table 2 using two analytic sample sizes: one of 510 (15% unable to follow-up) or 450 (25% unable to follow-up). For the primary and secondary outcomes of interest, we present detectable rate ratios (for count outcomes) or difference in proportions (for binary outcomes) between two groups. Specifically, we calculate the minimum detectable effect size at 80% power for the association between each outcome and a binary exposure variable with prevalence of 20% (e.g., use of a peer navigator) or 50% (e.g., exposure to healthcare discrimination).

Table 2: Detectable effect sizes for primary and secondary outcomes with 80% power by different exposure variable prevalence and sample sizes

	Type	Referent rate or proportion	Alpha	Effect size by prevalence of:		Effect size by prevalence of:	
				20%	50%	20%	50%
Primary outcomes				(N=510)		(N=450)	
Clinic visits[29,47]	Count	2.5*	0.0167	1.28	1.22	1.30	1.24
Emergency visits[47,50]	Count	1.14*	0.0167	1.44	1.34	1.47	1.37
Hospitalizations[47,50]	Count	0.81*	0.0167	1.53	1.42	1.57	1.45
Secondary outcomes							
Primary source clinic[48]	Binary	0.48*	0.05	0.171	0.138	0.182	0.146
30-day mortality[12]	Binary	0.0032	0.05	0.048	0.043	0.053	0.048
90-day mortality[12]	Binary	0.0089	0.05	0.058	0.050	0.064	0.055
Pharmacy claim	Binary	0.31+	0.05	0.166	0.134	0.177	0.143
Reincarceration[29]	Binary	0.53*	0.05	0.169	0.136	0.179	0.144

*Based on prior studies over 12 months; +Based on preliminary data of first point of contact post release

Our reference group proportions and rates are based on prior work among populations released from prison or those with criminal justice involvement. We assume the analytic approach is a multivariable regression model in which 20% of the variability in the dependent variable is explained by other predictors. The alpha is adjusted using a Bonferroni correction for the number of primary outcomes (0.05/3=0.0167).

As an example, we describe the power calculation for one primary count outcome and one secondary binary outcome. Assuming a final sample size of 510 and a binary exposure variable prevalence of 20% (e.g., use of a peer navigator), according to Table 4, those with no use of a peer navigator (the referent group) have 2.5 clinic visits per year. With 80% power (two-sided, alpha=0.0167) we can detect a rate ratio of 1.28, or a rate of 3.2 clinic visits per year for those with a peer navigator vs. 2.5 clinic visits per year for those with no peer navigator. Using the same sample size and exposure prevalence, we would have 80% power (two-sided, alpha=0.05) to detect an absolute increase of 16.6% in the proportion of those with a pharmacy claim as their first point of healthcare contact (i.e., 31.0% of those that indicate no use of a peer navigator to 47.6% that indicate use of a peer navigator).

Aim 3

Delphi Panel analysis. With our goal of developing recommendations for improving access and health among people released from prison, we want to be confident that we have support from more than a simple majority of experts. Therefore, we will define consensus as agreement among ≥66% of the panel. For any Round 1 topics that do not achieve consensus, we will compile and summarize feedback, and distribute it to the panel for consideration in Round 2. This feedback will be organized thematically by topic, including both quantitative and qualitative data. For example, we will describe the mean and median ranking and rating for each of the recommendations, along with any notes the panel members provided explaining their reasoning. For the qualitative responses, we will emphasize varying opinions and perspectives that emerge, as well as descriptions of the decision-making process itself. The analysis of Rounds 2 and 3 will be conducted in a similar manner. Where consensus has *not* been achieved, we will again compile the panel's feedback thematically and redistribute it for further consideration. At the conclusion of the entire Delphi process, we will write and circulate a final synopsis summarizing the panel's work.

b. Sharing of Results with Subjects

Describe whether results (study results or individual subject results, such as results of standard or research lab tests and genetic tests) will be shared with subjects or their providers.

If the study carries a risk of incidental findings, describe your plan for evaluating these and determining whether and how subjects or their providers will be given this information.

If laboratory results will be shared with subjects or their healthcare providers, verify that the laboratory conducting the test is Clinical Laboratory Improvement Amendments (CLIA) certified.

Preliminary quantitative and qualitative study data will be shared with Delphi panel members as part of the process to develop recommendations around practices to limit healthcare SRD. Preliminary findings will also be shared with CAB members who will review emerging results,

review the recommended practices playbook, and assist with communication and dissemination materials. Final results will be disseminated to various stakeholders, including individuals who participate in the interviews. Results will not be shared directly with participants in the longitudinal cohort study or their providers.

c. Data and/or Specimen Banking

Indicate if specimens may be used for future research and whether that may include genetic research.

State if data or specimens will be sent to a separate repository. If data or specimens will be banked in a repository for future use as part of this protocol submission address the following questions:

- What will be banked and what identifiers will be associated with the data or specimens?
- Where and how will the data or specimens be stored?
- For what purpose will the data or specimens be used?
- How will the data or specimens be accessed, and who will have access?
- Describe the procedures to release data or specimens, including the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.

Data will be stored in a folder on the KPCO server for future research in the form of a limited dataset. The data will not be sent to a separate repository.

7. Privacy, Confidentiality and Data Security

Describe the steps that will be taken to protect subjects' privacy during recruitment, consent and study procedures.

To minimize the risk of loss of confidentiality, study staff will be thoroughly trained regarding confidentiality. Signed consent forms will be kept separate from all other study documentation so that a link between the name and signature of the participant with the data obtained from the interviews and surveys cannot be made. Study data will be stored on the secure server and will be accessed only by members of the study team authorized to view these data. Individuals' decisions about whether or not to participate will not be reported to anyone outside the study team.

Each participant will be assigned a unique Study ID signaling the participant is enrolled. This Study ID will be the subject's assigned ID number for the remainder of the study. The Study ID will be captured in the REDCap tracking system. A protected sheet linking the identities of participants and their Study ID will be stored in a password protected folder on a secure server.

Any hard copies of study documents or recordings of interviews will be kept in a locked file cabinet that only the study staff and investigators will have access to. If documents are misplaced, the Steering Committee and Data Safety Monitor will be issued a written notice immediately. Notices will be tracked and monitored. All investigators and research staff will complete local courses on HIPAA and human subjects research.

Describe the plan for storage of data and/or specimens.

- Who will have access and how.
- Where the data/materials will be stored and for how long.

- What identifiers will be included.
- Any other steps that will be taken to ensure security (e.g., training of staff, authorization of access, password protection, encryption, physical security, and separation of identifiers from data and specimens, certificates of confidentiality).
- Describe the plan to destroy/archive or retain data at the end of the study.

The primary database management system to be used for this study is REDcap (Nashville, TN, USA). REDCap is a password protected database software package created by Vanderbilt University and supported by the REDCap Consortium of worldwide partners to facilitate Institutional Review Board (IRB)-approved clinical and basic research. The authorization matrix in REDCap allows 'super users' to set different levels of access to individual data entry forms and can control access to several data management modules built within the program, including the data export module. REDCap allows for a full audit trail, recording all operations on the data, including viewing and exporting. The audit log records operation, date and time, and the user performing the operation. All study data will be entered into REDCap including study tracking for participation, survey data, transcripts from interviews, field notes, and data collected in written material analysis. The REDCap database will be accessible to all site PIs, analysts, research assistants, and the project managers who require access for recruitment and tracking, completion of questionnaires, and/or data entry.

Data will also be extracted from the Colorado All Payers Claims database and merged with study records from REDCap to create the study analytic database. The analytic database will be stored on the KP server. Direct access to the database will be limited to Drs. Daugherty and Binswanger and the KPCO analysts.

Collection of data from subjects electronically

If you will collect any data from participants electronically (including email, website, etc.), explain:

- How the data will be collected.
- How the information will be secured (encryption, password protection, etc.; may require consultation with IT department).
- Any risks to the participants' privacy posed by using these methods (describe in consent, as applicable).
- How you will verify the participant's identity.

Interviews and meetings of the Delphi panel and CAB will be conducted either in-person or using ITS-approved videoconferencing technology meeting HIPAA requirements (e.g., MS Teams, Zoom).

Does this study involve the disclosure of PHI to a collaborator?

If any data will be sent outside of this site, list each recipient (may list by role or category if the information is the same for several different entities). For each recipient, describe:

- What will be sent.
- Whether the information will be fully identifiable (PHI, if health information), a Limited Data Set, de-identified, or aggregate.
- How the data/materials will be transferred securely (for instance, Secure File Transfer).

This study does not involve disclosure of PHI to collaborators outside of the sites participating in this study. PHI will come from the DOC list of individuals recently released from prison, participants themselves, or CO APCD. No health system collected PHI will be included.

8. Provisions to Monitor Data to Ensure the Safety of Subjects

This is required when research involves more than Minimal Risk to subjects.

The plan might include establishing a data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor.
Describe:

- Who will monitor the study data for safety?
- The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe.
- What data are reviewed, including safety data, untoward events, and efficacy data.
- How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).
- The frequency of data collection, including when safety data collection starts.
- The frequency or periodicity of review of cumulative data.
- Criteria for taking action on monitoring findings (for instance, stopping rules, immediate suspension, reporting, protocol changes, changes to monitoring frequency or plan).
- For studies monitored by a DSMB/C, describe the committee membership and structure, meeting format, and quorum requirements. Upload the board/committee charter, if one exists.

Data Safety Monitor

Dr. Daugherty will have overall responsibility for participant safety monitoring. The risks for this study are minimal. Although adverse events are not anticipated, should any occur they will be reported to the sponsor and the IRB according to guidelines described below.

Oversight for data safety and monitoring of the study will be conducted by a faculty member (Dr. Pamela Peterson) who will not be directly involved with the proposed research study. In this capacity, the Data Safety Monitor (DSM) will provide independent observation and verification of protocol compliance, recruitment and study progress, and data completeness. This will be done through correspondence with the steering committee and by reviewing draft annual reports on parameters provided by the study team. The DSM will also monitor the study for adverse events, and the study team's response to these events, should any occur. A letter summarizing the DSM's findings will be included in the finalized annual project reports. Though adverse events are not anticipated, should any occur they will be reported to the IRB at the time of the event, and copies of all correspondence regarding the event with the IRB and to NHLBI will be shared with the DSM.

Adverse Event and Unanticipated Problem Reporting*:* The study is felt to pose low risk to participants as we are conducting an observational study with no intervention or treatment. Our outcomes of interest include medical visits and hospitalizations. Participants will be asked about these events during their 6-month follow up study call. The research staff will ask the participant about details of the reported event. A log of all potentially adverse events will be kept and shared with the DSM at each review. After the 6-month follow up, participants will not be contacted again by study staff. At the end of the study, additional clinical events will be collected by linkage to claims data. For purposes of this study, each potentially adverse event (AE) and Unanticipated Problem (UP) will be reported according to standard NIH and IRB procedures regarding severity and causality from study participation.

Defining and Reporting of Serious Adverse Events (SAEs): We will follow the KP guidelines that require investigators to promptly notify the IRB (within 5 days of the initial receipt of information) when SAEs occur. SAEs will be defined as death, prolongation of hospitalization, and persistent/significant disability. All suspected serious adverse events (SAE's) will be reported to the DSM within 24 hours of initial receipt of information. SAEs that are unrelated to study participation do not have to be reported to the IRB (however, we will report these to the monitoring entity and NIH). Risks that are described in the protocol and consent form do not have to be reported as SAEs, unless the expected SAE occurs more frequently or is more serious than expected. One exception to this rule is in the case of death. All deaths must be reported, whether or not the death was related to the research. In addition to following the requirements above, we anticipate that the DSM will define study-specific SAEs.

9. Risks and Benefits

a. Risks to Subjects

List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects' participation in the research. Describe the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks.

- If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.
- If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant.
- If applicable, describe risks to others who are not subjects and risks to Kaiser Permanente

Minimal risks to human subjects are anticipated for this study. The study involves completion of interviews and surveys. This is an observational study, and no intervention or medical care is being delivered. There is little risk of physical or psychological harm that would exceed that which would normally be encountered in a medical or psychological evaluation of a healthy individual. The anticipated risks include a loss of confidentiality and psychological discomfort. In addition, we will obtain finger stick blood samples from cohort study participants to measure point of care cholesterol and glucose. Pain from the finger stick or erroneous results are possible. All of these risks are uncommon. It is possible that within the data collection procedures, an interview question or survey question could make a participant uncomfortable. If that happens, participants can decline to answer any question that makes them uncomfortable or can discontinue program participation at any time without penalty. To protect our research staff and participants, a participant will be discontinued if they threaten study staff or make threatening comments towards any other individual during study activities. We are not specifically asking about suicidal ideation in this study. However, a system of referral will be in place for any participant who expresses suicidal thoughts, intention, or plan. Similarly, we will not ask about physical or sexual abuse, but if we were to learn about someone who has harmed or intends to harm another individual, we will need to report it. Participants who express that they have been sexually or physically abused or are homeless will be provided with our participant resource list which contains names and contact information of organizations who can provide supportive services or referrals.

b. Potential Benefits to Subjects

Describe the potential benefits that individual subjects may experience from taking part in the research. Include as may be useful for the IRB's consideration, the probability, magnitude, and duration of the potential benefits. Indicate if there is no direct benefit. Do not include benefits to society or others.

The risks to the participant include a loss of confidentiality and psychological discomfort due to being asked about their health issues. However, we believe these risks are outweighed by the potential benefit to the participant of being given the opportunity to help in the development of best practices to improve their access to health care services. If this research results in knowledge or changes in policies to improve access to health services for people released from prison, the participant may benefit from those changes.

10. Economic Burden to Subjects

Describe any costs that subjects may be responsible for because of participation in the research study (for example, co-pays; paying for treatment, therapies, or other interventions, or the delivery of these) and how you will inform participants of these costs prior to their enrollment in this study.

We do not anticipate any costs associated with participation in this study. Interviews and meetings of the Delphi panel and CAB may take place via telephone/web conference, or, if desired and given COVID-19, in locations convenient to participants. Interviews and baseline visits may be arranged to take place outside of normal work hours, as needed, to accommodate participant schedules.

11. Compensation to Participants

Describe any compensation provided to participants, for example, for time inconvenience, discomfort, travel, or in the event of research related injury. If applicable, describe how you will inform participants of this prior to their enrollment in the study, including if payment will be prorated if the subject withdraws early from the study.

NOTE: payment may not be withheld as an incentive for participants to complete the study.

As permitted, Aim 1 interview participants will receive compensation valued at approximately $25 upon completion of their interview. For the longitudinal cohort study (Aim 2), participants will receive up to $75 in gift cards for the baseline visit (a $50 card for completing the baseline survey and a $25 card for completing the physical measurements), and another $50 in gift cards for completing the follow-up survey. Participants will also be offered a small incentive ($10-$20) for referring someone else who enrolls, up to a maximum of three referrals. Delphi Panel members will receive $500 upon participation completion.

12. Resources Available

Describe any special resources or expertise required to conduct the study.

Our multidisciplinary team has an established record of collaboration and success. Dr. Daugherty (PI, KPCO, CU) is Professor of Medicine at the University of Colorado (CU), a cardiologist at Kaiser Permanente Colorado (KPCO) and a health services researcher at the Institute for Health Research (IHR) with expertise leading NIH-funded studies focused on health equity. Our team has collaborated on multiple prior projects focused on disparities, discrimination and bias. Dr. Daugherty, with Drs. Hanratty (DH) and Blair (CU) (Co-Is), recently completed a NHLBI-funded multicenter trial that recruited 960 patients testing an intervention on the negative effects of racial

discrimination. Dr. Binswanger (KPCO, IHR) is a general internist, addiction medicine physician and health services researcher with expertise in the health of individuals in the criminal justice system. Dr. Blair is a social psychologist with expertise in discrimination and stigma, including implicit racial and ethnic bias in healthcare. Dr. Blair also collaborated on a study demonstrating bias among physicians towards patients with Medicaid. Dr. Hanratty is a general internist at Denver Health and medical director of Internal Medicine with experience implementing studies in ambulatory care. Dr. Hanratty oversaw the creation of a Corrections Transition Clinic at Denver Health and has worked closely with CO Medicaid to incorporate DOC release information into data systems at Denver Health. Dr. Morris (CU) is a qualitative and mixed methods expert with a focus in disability disparities and leads two current grants with Dr. Daugherty as co-I. Dr. Morris has extensive qualitative expertise, including leading studies addressing sensitive topics such as racism and ableism in healthcare and education. Our team also has experience leading Delphi panels to develop consensus. Dr. Suresh (CU) is a biostatistician with extensive experience with analysis and complex study designs. Dr. Tate was a project manager of our earlier intervention work in healthcare and recently completed her PhD in Health and Behavioral Sciences focused on structural racism in end-of-life transitions. She has expertise in community engagement and runs an advisory panel of community members that offers perspectives on research, healthcare and inequity. Our research team includes researchers in fields underrepresented by women and BIPOC individuals.

13. Prior Approvals

Describe any approvals that will be obtained prior to commencing the research. (e.g., school, external site. funding agency, laboratory, radiation safety, or biosafety approval.)

The NIH Notice of Award was issued September 7, 2022. IRB Authorization Agreements have been executed for the University of Colorado, Denver, DHHA, and the University of Colorado, Boulder as of 12/7/22, 12/9/22, and1/4/23, respectively.

14. Drugs or Devices

NOTE: see the ICH-GCP guidance for a summary of investigator and sponsor responsibilities in clinical trials.

a. Drug Studies

If the research involves drugs and is investigator-initiated, indicate whether there is any possibility that the results will be reported to FDA (e.g. as part of a new drug application [NDA]).

- If the drug is investigational (has an IND), confirm that you will comply with all applicable FDA requirements for investigators.
- Confirm that you will follow applicable KP pharmacy policies and procedures.
- Describe your plan for drug storage, handling, and accountability, including distribution, return, and destruction of the drug(s).

N/A

b. Device Studies:

If this is a device study and you think the device is Non-Significant Risk, include justification here or upload it as a separate document along with any available device information (instructions for use, etc.).

If the research involves devices and is investigator-initiated, indicate whether there is any possibility that the results will be reported to FDA (e.g. as part of a premarket approval application [PMA]).

- If the device has an IDE or a claim of abbreviated IDE (Non-Significant Risk device), confirm that you will comply with all applicable FDA requirements for investigators.
- Describe the device, the manufacturing process, and the device labeling, including safety instructions or warnings. If available, this may be addressed in separately uploaded device information (such as instructions for use).
- Describe device storage, handling, and accountability, including how access to the device will be limited to appropriate personnel and how you will ensure the device will be used only for appropriate study subjects.

N/A

15. Multi-Site Research

a. If this is a multi-site study and you are the lead investigator or this site will be the coordinating center for any activity, describe the processes to ensure communication among sites, such as:
   - All sites have the most current version of the protocol, consent document, and HIPAA authorization.
   - All required approvals have been obtained at each site (including approval by the site's IRB of record).
   - All modifications have been communicated to sites, and approved (including approval by the site's IRB of record) before the modification is implemented.
   - All engaged participating sites will safeguard data as required by local information security policies.
   - All local site investigators conduct the study appropriately.

b. Describe the method for communicating to engaged participating sites the following:
   - Problems.
   - Interim results.
   - The closure of a study.

c. Describe any special resources or expertise required to conduct the study.

KPCO will serve as the lead (coordinating) site with Dr. Stacie Daugherty as the PI. The KPCO team will meet at least twice a month to discuss study goals, progress, interim results, and any problems that may arise. In addition, KPCO will coordinate regular meetings with the DH and CU teams.

Each site is fully operational. Our offices are currently open but all of our research investigators and staff are allowed to work from home, if desired, and have all necessary office equipment and communication tools (web conferencing) to conduct work virtually. At KPCO we have been

conducting qualitative interviews and recruitment virtually in several CDC- and NIH-funded studies.

The KPCO IRB-approved protocol, recruitment materials, consent and HIPAA documents, interview scripts, and other documents will be shared with the DH and CU teams. The KPCO team will be responsible for ensuring that DH and CU have the most up-to-date study documents for submission to COMIRB.

Study data collection, management, and analysis will be led by KPCO. As needed, KPCO will lead preparation of data use agreements to share study data with DH and CU.

16. Community-Based Participatory Research

Describe involvement of the community in the design and conduct of the research.

Describe your plan for ensuring that community research partners are appropriately trained in human subjects' protection.

NOTE: "Community-based Participatory Research" is a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. Community-based Participatory Research begins with a research topic of importance to the community, has the aim of combining knowledge with action and achieving social change to improve health outcomes and eliminate health disparities.

We will establish a multi-stakeholder CAB to assist with study planning, execution, and oversight. The CAB will consist of multiple stakeholder members (community organizations, healthcare organizations, DOC officials and at least 3 people with lived experiences of incarceration and reentry in the community) that meet quarterly throughout the project. The CAB will provide input into the instruments used for the assessment of organizational structural conditions (Aims 1 and 2), recruitment assistance (Aims 1-3) and be involved throughout the life of the project to review emerging results (Aims 1 and 2), review the recommended practices playbook (Aim 3), and assist with communication and dissemination materials (Aim 3).

As needed, the KPCO research team will be responsible for facilitating CAB members' completion of human subjects' protection training prior to their participation in the CAB.