HEALTH SYSTEMS INNOVATIONS FOR SUPPORTING TRANSITIONS OF CARE FOR INCARCERATED PEOPLE LIVING WITH HIV, HEPATITIS C AND SUBSTANCE USE DISORDER

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VERSION NUMBER/DATE:

REVISION HISTORY:

Revision #	Version Date	Summary of Changes	Consent Change?
V4	10.04.2022	Minor language corrections and further detail provided	Yes
V5	12.23.2022	Section 7.5 Specifics of pre vs post release fund distribution removed due to some participants returning to the community prior to accessing DOC account funds Section 5.1 and 5.4 updated to include EHR review as a source of information on SUD as it pertains to eligibility Section 13.1 updated to indicate that in the case of a participant's study phone being lost or stolen, a replacement phone will be hand delivered by the nurse case manager in the community	Yes

		Section 13.4 updated to indicate that we will collect any history of substance use from participant, not only in 3 months prior to incarceration Section 15.1: participants will be considered lost to follow up after 5 unsuccessful attempts to contact, but will not be removed from the study. Their study phone line may be turned off at that point. A study member will attempt to contact them at 3 m post-release in order to complete the end-of-study assessment Section 27: Defined all documents used in study, differentiated research tools to be attached separately from case management process tools available upon request.	
V6	02.16.2023	Eligibility criteria updated to reflect current procedure for determining eligibility, which is based on participant report at time of screening and not on COMPAS or EMR data. Updated recruitment process: sending recruitment letters to all releasees and determining eligibility based on answers to screener, wait list utilization for subset of eligible participants prior to enrollment Updated procedures for making incentive funds available to participants Procedure for phone termination were uniformized to “might be turned off” after a month of unsuccessful attempts to contact, as it may be decided to continue funding the phone line in order to attempt to collect the end-of-study assessment Removed medical information form as it is no longer in use Clarified that research baseline survey will be done EITHER by NCM or other study team member and can be done in person or over the phone Clarified NCM interaction with participants after release (weekly) and after attended outpatient appointment (minimal), and study team member will call at 3m post-release to administer end-of-study survey and possibly exit interview section 15.3 Differentiated subsequent steps after withdrawal and subsequent steps after participant declines some aspect of study activities Other forms edited: - Consent - ROI - Eligibility screener	Yes

		- Research Baseline Survey - NCM Intake Assessment	
V7	03.24.2023	DOC Facility changed from Taycheedah Correctional Institution to Wisconsin Women's Correctional System (WWCS) ROI language clarified Name of 3 Month Survey uniformized Plan for collection of modified survey questions for early participants still incarcerated stated Intended mechanism to measure Appropriateness updated	No
V8	05.03.2023	Procedures to facilitate a participant retaining their study provided cell phone number after completion of research activities have been added Procedures for waitlist vs direct enrollment updated to facilitate workflow.	No

Contents

Study Summary

Study Title	Health systems innovations for supporting transitions of care for incarcerated people living with HIV, Hepatitis C, and substance use disorder
Brief Summary	This protocol describes the second, implementation phase of a 5-year NIH-funded research project designed to evaluate post-incarceration health care utilization and outcomes for underserved people living with HIV, HCV and substance use disorder. In the first study phase, conducted from 2020-21 (UW IRB ID# 2020-0749), we analyzed Wisconsin Medicaid data to characterize the baseline level of outpatient care utilization for adults during their first 6 months after release from prison, and conducted formative research necessary to adapt an existing transitional care intervention, called C-TraC, to support individuals leaving prison. The current project aims to enroll participants in a pilot implementation study to test the feasibility and acceptability of the adapted intervention in a criminal justice setting, which we have given the name “CJC-TraC.”
Number of study sites	1
Study Design	Single Group Behavioral Intervention
Primary Objective	To evaluate the feasibility and acceptability of CJC-TraC when implemented in a state prison system.
Secondary Objective(s)	To gather preliminary evidence describing the effectiveness of CJC-TraC for improving the rate of outpatient care utilization
Research Intervention(s)/ Investigational Agent(s)	Criminal Justice Coordinated Transitional Care (CJC-TraC) Program, a multi-session transitional case management intervention bridging the pre-release and post-release period.
Drugs/devices used on study (including any IND/IDE #)	n/a
Study Population	Individuals incarcerated in Wisconsin living with HIV, Hepatitis C, or history of substance misuse preparing for release
Sample Size	220
Study Duration for individual participants	Up to 6 months (3 months before release and 3 months after release from prison)
Study Specific Abbreviations/ Definitions	NCM-Nurse Case Manager CJC-TraC- Criminal Justice Coordinated Transitional Care

Note: Include only elements relevant to this study.

1.0 Background

1.1 Describe the relevant prior experience and gaps in current knowledge.

The goal of this project is to adapt an evidence-based case management intervention that was developed in acute care hospital settings to support health care for people preparing to be released from prison. The original hospital-based program, called the Coordinated Transitions of Care (C-TraC) project, is a transitional care model created to support adults with chronic conditions who are discharging from the hospital back to the community. C-TraC uses nurse case managers who follow the patient during their hospital stay and through the discharge process, continuing care after the patient returns to the community. The Nurse Case Manager participates in daily rounds with the in-hospital health care team. After discharge, the Nurse Case Manager connects with the patient virtually to conduct medication reconciliation, review of upcoming appointments, review of 'red flags' (signs or symptoms of a potentially dangerous health event).

We have designed a mixed-methods approach based on the Replicating Effective Programs (REP) Implementation Theory Model to adapt C-TraC framework, processes, and goals to the context of correctional health care.

1.2 Describe any relevant preliminary data.

In the completed first phase of this project, we made a variety of discoveries.

In Aims 1 & 2 [*Please see IRB ID 2020-0749 & 2019-0058*] we examined individual-, area-, and system-level factors that may influence access to care following release from prison. The study cohort for Aim 1 included adults living with, or at risk of, SUD, HCV, or HIV who were enrolled in Medicaid at the time of their release from Wisconsin state prison. Preliminary results indicated that within 30-days of their release, approximately 34% of the study population has at least one outpatient visit. Women are more likely than men to have this visit as are White individuals compared to Black individuals. Receipt of prescription medication indicated for the following conditions during the 12-months before release from prison strongly increase the likelihood of an outpatient visit within 30-days: HIV, depression, diabetes, pain, Parkinson's disease, psychotic illness, osteoporosis/Paget's, and alcohol dependence. Aim 2 examined the impact of assistance with Medicaid enrollment pre-release on access to care among those with and without a history of SUD. For those with a history of SUD, we find significant increases in the likelihood of outpatient care for any cause and related to substance use disorders. However, the absolute rate of SUD-related care remains low.

AIM 3: Qualitative research done from 2019-2021 contributed directly to how the C-TraC intervention was modified to fit the present study's target population. Firstly, general challenges (e.g. access to transportation, access to cell phones) were identified by both the focus group participants as well as the interview participants. This information allowed us to consider the scope of the Nurse Case Manager's intervention and how these needs could be met while controlling the scale of the intervention to a feasible level.

Interviews conducted with formerly incarcerated adults also yielded valuable information concerning the importance of rapport and trust building with people who are incarcerated. Based on interviews with formerly incarcerated individuals, strategies have been added to the Nurse Case Manager protocol to individualize case management to prevent participants from feeling like the Nurse Case Manager is using a checklist or "just doing a job".

Interview participants were asked what they believed would be the most effective way to implement the intervention, including the number of visits with a Nurse Case Manager prior to release, how long before release meetings should be initiated, how long and how often meetings should occur following release, and the specific issues that formerly incarcerated person would likely need assistance with. Their responses were used to inform the final structure of the intervention.

1.3 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.

Human Immunodeficiency Virus (HIV), Hepatitis C virus (HCV) infection, and substance use disorders (SUD) represent interdependent epidemics of enormous public health significance. In the past decade, HCV surpassed HIV/AIDS as the leading cause of infectious death among U.S. adults, while opioid overdose overtook motor vehicle accidents as the number one injury-related cause of death. Evidence-based strategies to effectively prevent and manage these conditions exist, yet recent outbreaks of HCV and HIV among people who inject opioid in socioeconomically disadvantaged communities in the U.S. illustrate the failure to deliver such services in the settings where they are most urgently needed. Criminal justice system involvement is highly prevalent among people who inject drugs, and incarcerated populations have a disproportionately high burden of HIV, HCV, and opioid use disorders. Further, their transitions back into the community are plagued by poor coordination, including poor access to treatment and a resulting high risk of death after release.

This project represents an innovative adaptation of a low-cost transitional care intervention [*Aim 3 of the parent study IRB ID 2020-0749*] to the context of criminal justice-related health systems that is feasible, effective, and sustainable.

2.0 Study Objectives and Endpoints

2.1 Describe the purpose, specific aims, or objectives. An objective is the purpose for performing the study in terms of the scientific question to be answered. Express each objective as a statement of purpose (e.g., to assess, to determine, to compare, to evaluate) and include the general purpose (e.g., effectiveness, safety) and/or specific purpose (e.g., effect of an intervention on health behavior, utility of an assessment method).

The main objective of this project is to adapt and evaluate the feasibility and acceptability of a low cost, evidence based transitional care program, called C-TraC, for increasing use of outpatient medical care for incarcerated people with HIV, HCV and/or opioid use disorder.

We have designed a mixed-methods approach based on the Replicating Effective Programs (REP) Implementation Theory Model to adapt C-TraC processes and goals to the context of correctional health care. Formative research conducted during the first phase of this study in 2020-2021 [*UW IRB ID: 2020-0749 and WIDOC RRC Application ID: Westergaard 1912*] identified they key processes necessary for successfully supporting patients with complex medical and behavioral health challenges as they navigate outpatient health services. Focus groups, interviews, and informal discussions with Wisconsin Department of Corrections (WIDOC) staff also informed the operational details for successful implementation of the pilot protocol at two WIDOC institutions which are described in this protocol. After completion of the pilot trial, we will have gained experience about successful implementation strategies as well as unanticipated challenges and will have collected preliminary data about the effectiveness of the CJC-TraC intervention for improving post-incarceration health outcomes that will be used for planning future studies designed to formally test the effectiveness and cost effectiveness of CJC-TraC.

State the hypotheses to be tested.

The main hypothesis to be tested in this pilot study is that the CJC-TraC protocol developed in collaboration with WIDOC partners will be successfully implemented in a way that is deemed acceptable to WIDOC staff and incarcerated patients. We will consider implementation to be successful if (1) we enroll a substantial number of eligible participants (e.g. at least 50% of the targeted sample size of 220), and (2) Participants complete post-incarceration study activities with a reasonable rate of retention (e.g. fewer than 50% of participants being lost to follow-up after

release). We will assess acceptability by systematically querying study participants and WIDOC staff about their experience with CJC-TraC using validated questionnaires, as described below.

A secondary hypothesis is that individuals who participate in the CJC-TraC pilot will have a higher rate of using non-emergency, outpatient health services (e.g. primary care clinic appointment) after incarceration, in comparison to contemporaneous rates of health service utilization by individuals with comparable levels of comorbidities and demographic characteristics.

2.2 Define the primary and secondary study endpoints. A study endpoint is a specific measurement or observation to assess the effect of the study variable (study intervention). Study endpoints should be prioritized and should correspond to the study objectives and hypotheses being tested.

In this pilot study we will assess endpoints related to feasibility, acceptability, and effectiveness, as described above:

Primary Endpoints: Feasibility

- The number of participants who are enrolled and complete the baseline study assessment per month, at each of two institutions;
- The number of pre-release CJC-TraC intervention sessions completed with the nurse case manager for each participant, at each institution;
- The number of post-release telephone contacts between the CJC-TraC nurse case manager and study participants;
- The proportion of study participants who are retained in follow-up for three months and complete the end-of-study assessment.

Primary Endpoints: Acceptability

- The proportion of study participants who rated specific aspects of the intervention useful and encounter volumes appropriate, collected on 3 month survey.
- The subjective experience in the program regarding prison-to-community transition support and healthcare support, collected by participant interview.
- The proportion of DOC staff who rated the intervention acceptable, useful, or appropriate, collected by DOC staff survey.

The referred to questions assess attitudes regarding appropriateness and acceptability of the CJC-TraC intervention, and do not include questions about respondents themselves. Pilot intervention participants and WIDOC staff involved with the CJC-TraC pilot program at Wisconsin Women's Correctional System (WWCS) and Oakhill Correctional Institutions will be asked questions to capture perceptions about the intervention itself at the conclusion of the pilot intervention. WIDOC staff are not considered research subjects as a result of being asked these questions as they are not being asked to share data about themselves, but rather professionally assess the intervention. In addition to assessing the acceptability and appropriateness of CJC-TraC, pilot intervention participants provide additional identifiable and personal data throughout the lifespan of the study and are therefore considered research participants.

Secondary Endpoints: Effectiveness

- The number of non-emergency outpatient visits observed within 3-months following release.
- The number days until the first non-emergency outpatient visit following release.

3.0 Number of Participants

Primary Objective: We plan to enroll 220 individuals over the course of two years to participate in the pilot intervention, with approximately equal numbers of men and women

Secondary Objective: We will obtain administrative records for approximately 20,000 individuals who are released from prison between 1/1/2020 – 12/31/2023 to characterize trends in non-emergency outpatient health care use for the overall population of incarcerated persons in Wisconsin.

3.1 *If applicable, distinguish between the number of participants who are expected to be enrolled and screened and the number of participants needed to complete the research procedures (i.e., numbers of participants excluding screen failures).*

4.0 Feasibility & Acceptability

Primary Objective:

We estimate based on analyses completed in Phase 1 that approximately 70% of people incarcerated at the two participating institutions meet eligibility criteria. We plan to meet and discuss the study with every eligible individual, as described below, and anticipate that approximately 70% of eligible individuals will agree to participate. Taking this into consideration, we assume 50% of all people who are being released from the institutions will enroll in the study.

We will strive to enroll the 220 participants in the two-year study period or about 9 people per month. We will be enrolling men from Oakhill Correctional Institute (OCI) and women from Wisconsin Women's Correctional System (WWCS).

Due to high volume of potentially eligible individuals, and feasibility of resources for the Nurse Case Manager, potential participants who have anticipated releases to Dane or Milwaukee County will be prioritized in recruitment.

Participants will be considered enrolled after signing the consent form. Active participation in the study will continue until the end-of-study assessment, which will be scheduled to occur 3 months after the date of release from prison. Participants may voluntarily withdraw from the study at any time.

We anticipate that the recruitment goals will be feasible to achieve, based on the annual number of individuals released from the two participating institutions, as shown below.

Eligibility			
	Oakhill	**REECC**	**Total**
Total Yearly Average Releases (2019-2022)	316	327	643
Total Released to Dane and Milwaukee Counties	112	65	177
Total Released to Rock, Racine, Kenosha, and Waukesha Counties	62	64	126
Assumed enrollment of eligible individuals (50%)	87	64	151
Monthly Enrollment Possible	**7**	**5**	**12**
Total Recruitment Possible (24 months)	**168**	**120**	**288**

Secondary Objective: Preliminary assessment of effectiveness

We will conduct a descriptive analysis of concurrent trends in outpatient health care use among formerly incarcerated adults, focusing on those with a history of a substance use disorder, HCV or HIV. Each year, approximately 9,000 individuals >=18 years are released from Wisconsin state correctional facilities. Based on our prior work, we expect that 70% of these individuals will have one or more of these three conditions. Thus, we expect the population-based analysis will include approximately 20,000 individuals who were released between 1/1/2020-12/31/2023.

5.0 Inclusion and Exclusion Criteria

5.1 *Describe how individuals will be screened for eligibility. If you plan to retain screening data collected by phone or other methods for people who decline to participate, describe this, including the rationale for retaining the information.*

People who will be included in the study sample for the pilot intervention is as follows:

- Adults 18 years of age or older,
- Able to understand and speak in English,
- Plans to reside in Wisconsin after release,
- Eligible for Wisconsin Medicaid and willing to enroll prior to release,
- Has a history of one or more of the following: current HIV infection, current or past HCV infection, substance use disorder by self-report .

For our **primary objective**, using existing WIDOC resources, we will obtain a rolling list on a weekly basis of individuals who will be released in the next 6 months from each of the 2 institutions. For everyone on the list, the Nurse Case Manager will complete an initial eligibility assessment by reviewing:

- Anticipated release date (must be within 6 months of review);
- The electronic health record (any positive test or prior treatment for HIV or hepatitis C, or current or previous medications for substance use disorder);
- And results of COMPAS assessments, which include specific criteria for “probable need for SUD services”.

Regardless of evidence of potential eligibility in the EMR or COMPAS review, all individuals releasing within the next 6 months will be sent recruitment letters, offered information about the study, and be invited to screen with the Nurse Case Manager or assisting study team member. The Nurse Case Manager or assisting team member will use a simple screening tool to determine if the interested individual meets all eligibility criteria in order to enroll in the study. **[See Eligibility Screener Document]**

We plan to retain all screening information from individuals if they are not eligible or decide not to enroll in the study for the purpose of retrospectively identifying characteristics of eligible versus ineligible or uninterested participants that could bias our study sample.

5.2 *Describe the criteria that define who will be excluded from your final study sample.*

Study exclusion criteria for the **primary objective** is as follows:

- Unable to provide informed consent form or impaired ability to make decisions
- Planned discharge to another correctional facility or other carceral setting (e.g. release to jail or immigration detention center)

5.3 *If any specific population (e.g., racial/ethnic group, sex or gender) will be targeted or excluded, describe this and provide justification.*

No specific racial/ethnic group will be targeted. We intend to recruit equal numbers of men and women in the study.

5.4 *Describe how individuals will be screened for eligibility. If you plan to retain screening data collected by phone or other methods for people who decline to participate, describe this, including the rationale for retaining the information.*

Primary Objective:

People that meet the following criteria will be included in the sample for our feasibility and acceptability analysis:

- Adults 18 years of age or older,
- Able to understand and speak in English,
- Eligible for Wisconsin Medicaid and willing to enroll prior to release,
- Has a history of one or more of the following: current HIV infection, current or past HCV infection, substance use disorder by self-report.

Secondary Objective:

People that meet the following criteria will be included in the sample for our population-based analysis:

- Adults 18 years of age or older,
- Enrolled in Medicaid within one-month of release,
- Has a history of one or more of the following: current HIV infection, current or past HCV infection, identified need for substance use related services based on COMPAS assessment.

We will use several data sources to determine if individuals meet the inclusion criteria (see "Aim 3 Secondary Objective Data.docx"): Wisconsin DOC administrative, COMPAS, and prescription medication data; Wisconsin Medicaid enrollment data; WEDSS surveillance data; and the Wisconsin State Lab of Hygiene.

5.5 Describe the criteria that define who will be excluded from your final study sample.

After application of the inclusion criteria, there are no additional exclusion criteria.

5.6 If any specific population (e.g., racial/ethnic group, sex or gender) will be targeted or excluded, describe this and provide justification.

No specific racial/ethnic group will be targeted.

6.0 Special Populations

Specify whether the study will include or exclude each of the populations listed in the subsections below. You may enroll only members of the populations you identify as included. Review the checklist (HRP-xxx) or other resources relevant to each population to ensure that the protocol provides sufficient information.

*6.1 If the study will enroll **OR** use data or specimens from any of the populations listed in this subsection, provide **justification** for their inclusion and describe additional **safeguards** included to protect their rights and welfare. Federal regulations and/or campus policy allow inclusion of the populations in subsection 6.1 only when the research meets specific criteria. **Check all that apply.***

☐ Children/Minors (HRP-416 - CHECKLIST - Children)

☐ Pregnant persons / fetuses (HRP-412 - CHECKLIST - Pregnant Women; HRP-413 - CHECKLIST - Non-Viable Neonates; HRP-414 - CHECKLIST - Neonates of Uncertain Viability)

☒ Prisoners (HRP-415 - CHECKLIST - Prisoners)

☐ Participants with impaired decision-making capacity (HRP-417 - CHECKLIST - Adults with Impaired Decision-Making Capacity)

The purpose of the intervention is to improve quality of transitional processes and access to healthcare specifically for incarcerated individuals upon release from prison. This population was identified due to their disproportionate need for improved transitional and health care services.

Primary Objective: It is therefore necessary to enroll people who are incarcerated, as a sample of the general population would not enable us to answer our research questions. Safeguards such as consent forms and study materials written with appropriate, understandable language (e.g. written at or below the 8th grade reading level), as well as study team members who have experience working with and doing research with people who are incarcerated, and institutional policies regarding research with incarcerated individuals will be followed with fidelity to protect participants rights and welfare.

The research follows the guidance from form HRP-415 as our study involves recruitment of people who are incarcerated (prisoners) and presents minimal risk to participants. The research does not study the possible causes, effects, and processes of incarceration, and of criminal behavior. The present study does not study prisons as institutional structures but will involve recruitment and study of people who are incarcerated because of their incarceration.

The research study is focused on people living with HIV, Hepatitis C, and/or substance use disorder which do have higher prevalence in prison settings compared to the community at large. Efforts have been made to ensure the privacy of prospective participants and enrolled participants including in the recruitment process.

Research activities have the intent and reasonable possibility of improving the health outcomes for all participants in the study. The study does not have a control group.

The present study is not an epidemiological study, and the purpose is not to describe the prevalence or incidence of a disease.

Incarcerated people (prisoners) who participate in the study will have the possible advantage to medical care because they will receive the direct benefit of additional discharge support during the release and reentry process, including tailored health teaching and primary care services after release from prison. There are no advantages associated with study participation that relate to quality of food, amenities, and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired.

We believe this study should be categorized as minimal risk since the potential risks detailed below are not believed to be greater than that is normally encountered in their daily lives, or in the routine medical, dental, or psychological examination of healthy persons. All research staff are educated and trained in the areas of confidentiality, HIPAA, and safety. There is also the extra layer of protection covered by the Certificate of Confidentiality. Additionally, the potential risks of the study, which includes breach of confidentiality, are commensurate with risks that would be accepted by non-incarcerated volunteers and will be the same risks that will be carried after the participants are no longer incarcerated.

All documents that will be presented to participants are written in a way that the population can understand. The study team will not engage with parole boards, and prospective participants will be notified that their participation in the study will in no way affect their chance of parole or any other element of their incarceration (e.g security status).

Secondary Objective: The aim of this objective is to describe the contextual trends in health care use among the population of incarcerated individuals. To facilitate the analysis of administrative data collected from incarcerated research participants under this aim, we are requesting a waiver of consent and HIPAA authorization. We have additionally ensured that the procedures ascribed to this

objective are consistent with guidance from HRP-415 regarding the inclusion of incarcerated research participants as detailed below.

We believe this component of the study to be minimal risk and of little to no inconvenience to participants since it only involves the reporting and analysis of administrative data that is routinely collected through pre-existing processes, yielding no more or less risk to this population than a non-incarcerated population. Additionally, the aggregated data will be well protected under the workflows for data sharing and storage detailed throughout the protocol and in the data safety and monitoring plan.

The outcomes associated with the secondary objective are not likely to yield an immediate benefit to those whose data are included, but the inclusion of the data is intended to provide valuable information about the intervention outcomes which could lead to future benefits to incarcerated populations in general. There are no incentives being offered to participants for the inclusion of their data, preventing any undue influence.

This research does not constitute an epidemiologic study. The procedures for the inclusion of subject data are well defined and require meeting predetermined characteristics such as a diagnosis of HIV, Hepatitis C, or substance use disorder. While these health characteristics could have epidemiologic value, the purpose of this objective is to describe contextual trends in health care use among the population rather than describe the infectious disease components themselves. Additionally, the identification and inclusion of participants does is neither conducted by nor shared with any WIDOC authorities who could affect a participant's parole status.

If awarded a waiver of consent and HIPAA authorization, there are no participant facing materials for this study component that would need to be screened for appropriate and understandable language.

*6.2 If the study recruitment process would be expected to include any of the populations listed in subsection 6.2, describe the **safeguards and accommodations** you will use during their participation, such as interpreters, methods for completing written assessments, etc. during study participation. See the Investigator's Manual, HRP-334, and HRP-090 - SOP - Informed Consent Process for Research. **Check all that apply.***

☐ Non-English speaking participants
☒ Illiterate or Low Literacy participants
☐ Participants with visual or hearing impairments
☐ Status Relationship: Individuals with a status relationship with the PI or other study team members (e.g., employees, students, family members)

Primary Objective: Due to resource constrains precluding the development of intervention materials in multiple languages, we must exclude individuals who cannot understand and speak in English. We anticipate that some eligible participants might have low levels of literacy. In such instances we will take reasonable measures to accommodate low levels of literacy, such as verbally administered questionnaires either in person or via phone and ensuring a research staff member or the Nurse Case Manager can read and explain intervention materials to clients. Additionally, all participant facing materials will be written at an 8th grade reading level using accessible language and no jargon, with new or unusual terms being defined for the participant.

Secondary Objective: Not applicable.

*6.3 If the study may include any of the populations listed in subsection 6.3, provide **justification** for including the population(s) and describe the **safeguards** you will use*

to protect their rights and welfare. Federal regulations, state law, or campus policy may require additional review and/or specific safeguards for these populations. HRP-103 - INVESTIGATOR MANUAL, HRP-013 - SOP - LARs, Children, and Guardians and HRP-334 - WORKSHEET - Vulnerable Populations. ***Check all that apply.***

☒ Individuals who are receiving inpatient or outpatient services for mental illness, developmental disability, or alcohol and other drug abuse (AODA)

☐ Individuals who are protectively placed by a court in a treatment facility

☐ Veterans/Military Personnel

☐ Emancipated minors

☐ Anyone especially vulnerable to manipulation or inducements for participation as a result of their illness or socioeconomic condition

Primary Objective: If other eligibility criteria are met, vulnerable populations or military personnel/veterans will neither prioritized nor excluded from participation. We anticipate the potential benefits of participation to be valuable to a wide variety of people who meet our eligibility criteria and see value in measuring effectiveness of the intervention with as broad of a sample as possible. Additionally, while it is not our only criteria, we are actively seeking to recruit people with problematic substance use histories in an effort to help connect them with live improving or saving treatment options after release. All vulnerable, military, or AODA populations will be treated with compassionate and empathetic care by the Nurse Case Manager and all research staff members. Careful attention will be paid during the consent process to ensure all participants understand their rights, what will be asked of them should they choose to participate, and that they can skip questions or activities that they are not comfortable with or can withdraw from participating at any time with no negative repercussions.

Secondary Objective: applicable. The inclusion criteria include individuals >=18 years of age released from prison in the study years who are enrolled in Medicaid for at least one month. We neither prioritize nor exclude the adult groups identified above. We defined the inclusion criteria to accomplish the research objective: to describe the contextual trends in health care use among the population, from which intervention participants are selected. Safeguards are in place to protect the privacy and confidentiality of subjects as described in the UW IRP data security and monitoring plan (Appendix 11).

7.0 Recruitment Methods

7.1 Describe the source(s) of participants (e.g. community, recruitment registry [specify], health records).

Primary Objective: Sources of recruitment will come from a list of people releasing that is created routinely by the WIDOC. This release list includes all people who are anticipated to be released in the next 6 months. WIDOC EMR Health Records, Opioid Use Screening Questionnaire, Reentry Assessments, or COMPAS scores which indicates challenges with substance use, and referrals will also be used to recruit by identifying people who are incarcerated who have qualifying diagnoses (HIV, HCV, SUD). Regardless of evidence of potential eligibility in the EMR or COMPAS review, all individuals releasing within the next 6 months will be sent recruitment letters, offered information about the study, and be invited to screen with the Nurse Case Manager or assisting study team member.

Secondary Objective: No recruitment is required to accomplish this aim as it only involves analysis of administrative data. We will use several data sources to determine if individuals meet the inclusion criteria. **[See Data Sources for Secondary Objective Document]** Wisconsin DOC administrative, COMPAS, and prescription medication data; Wisconsin Medicaid enrollment data; WEDSS surveillance data; and the Wisconsin State Lab of Hygiene.

7.2 Describe the methods that will be used to identify potential participants. Describe whether participants will self-identify in response to posters, mailings, emails, etc., or whether they will be recruited based on information contained in private/protected records (e.g., medical records, student records; note that this also includes participants who will be recruited from the researcher's or Co-Researcher's patient or participant population).

Primary Objective: Participants will be screened for eligibility as described in 5.1.

In addition, the research team will seek permission to post flyers in the Health Services Unit (HSU) describing the opportunity to participate, allowing individuals to self-refer to the NCM to be screened for eligibility.

The Nurse Case Manager will use the release list created by the WIDOC to cross reference data from the Department of Corrections EMR, Opioid Use Screening Questionnaire, and Reentry Assessments. The Nurse Case Manager also receive referrals from WIDOC Social Workers, Health Service Unit staff, or other staff members within the WIDOC. The Nurse Case Manager will verify the eligibility of the referrals using the WIDOC EMR and eligibility screener administered by the Nurse Case Manager prior to enrollment. Prospective participants may also self-identify in response to study flyers that are posted within prison housing units and consult rooms.

Secondary Objective: We will apply the inclusion/exclusion criteria described in 5.4 to the administrative data to identify individuals eligible for inclusion in the population-based analysis.

7.3 Describe when, where, and how potential participants will be recruited. For example, will recruitment advertisements be sent to potential participants (and how, e.g. mail, email)? Will advertisements be posted publicly, and if so, where? Will potential participants be approached when they come to the clinic for a routine visit? If this is a multicenter study and participants will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) describe those methods. If applicable, describe procedures for oral or written communication with the prospective participant or legally authorized representative that will be done for purposes of screening, recruiting, or determining eligibility.

Primary Objective: We will employ a variety of recruitment methods. One method of recruitment will be through the rolling list of all individuals with anticipated release dates in the next 6 months. Once those with an anticipated release date in the next 3 months have been identified from that list, all will be mailed a letter **[See Recruitment Letter Document]** explaining the study and asked if they would like to come to Health Services Unit to meet with the Nurse Case Manager who will provide further details of the project and conduct an eligibility screening. Additionally, the Nurse Case Manager will assess initial eligibility by reviewing electronic medical records and COMPAS documents (Opioid Use Screening Questionnaires and other Reentry Assessments). If the participant has a visit scheduled in the Health Services Unit, they may be approached by the Nurse Case Manager at that time as well.

If an individual has a one-on-one meeting scheduled with a social worker or Psychological Services Unit staff and indicates interest in the study or the staff member believes the individual may be appropriate for the study, the staff member will notify the Nurse Case Manager who will perform an initial review of assessment following the protocol as detailed above.

Participants who express interest in the study to Social Workers, Psychological Services Unit staff or Health Services Unit staff will be instructed to submit a Health Services Request. Health Service Requests are the standard WIDOC document used throughout WIDOC whereby a person who is incarcerated may correspond with the Health Services Unit. The people who are incarcerated obtain the Health Service Request on their unit, fill it out and then place it in a drop box. The request is

then collected by Health Services Unit staff. A registered nurse reviews all Health Services Requests and triages the request to the appropriate office or person. For this study, if a person who is incarcerated writes indicating interest in the Nurse Case Manager or the study, these requests would be forwarded to the Nurse Case Manager to review, respond, and reach out to the prospective participant, following the protocol as detailed above.

Finally, flyers will be distributed to all housing units. **[See Recruitment Flyer Document]** The flyer details the study and eligibility requirements. Individuals who are interested will submit a Health Services Request to the Nurse Case Manager to express their interest. The Nurse Case Manager will follow up with the potential participant as detailed above. If the potential participant is not within 3 months of release, the Nurse Case Manager will not enroll the individual, but will re-connect with them 3 months prior to their scheduled release date.

Potential participants will not be approached by the Nurse Case Manager on the housing units or in a setting which could potentially expose their medical history or health status. Participants will not be approached at times where other incarcerated persons are congregated.

Participants who complete the screening process and are eligible for enrollment in the study will be enrolled if the nurse case manager has capacity in their case load to enroll a participant at the time. If the nurse case manager does not have capacity, the participant is placed on a wait list. If the condition that placed the participant on the wait list changes prior to 1 month before their anticipated release date, they will be enrolled at that time.

Secondary Objective: Not applicable. Population-level analyses will be done through administrative data only.

7.4 Describe materials that will be used to recruit participants, addressing when and how often they will be used. Upload copies of these documents in the application. When audio or video will be recorded, upload the script. Submit the script prior to recording because the IRB may request changes.

Primary Objective: Flyers detailing the project will be posted on all housing units in both institutions where the study is taking place. This flyer contains instructions for how to contact the Nurse Case Manager through a Health Service Request or Interview Request Form. We will not be doing audio or video recordings.

Secondary Objective: Not applicable.

7.5 Compensation: Describe the amount, timing, and type of any compensation to participants.

Study Activity	Compensation
Baseline Study Assessment	$5
3 Month Survey	$30
Exit Interview	$30
	Max amount of payment: $65

More information on these data collection activities and compensation is located in 13, Procedures Involved.

8.0 Consent/Assent Process

8.1 Indicate whether you will you be obtaining informed consent, and if so describe:

- *Who will obtain informed consent.*

Primary Objective

Oral Consent prior to screening potential participants: We request an alteration of consent to allow for the use of an abbreviated script for the purposes of retention and future analysis of the preliminary data collected through the screening process, and waiver of signed consent to conduct the initial eligibility screening. The screening process involves no more than minimal risk and could not be practicably carried out without the waiver due to the limited time available to potential subjects and prohibitive length of a full consent process, which would adversely affect our ability to screen and enroll in a manner that is minimally intrusive to the environment and participants. Additionally, this component involves no procedures for which written consent is normally required outside of the research context. We request to keep screening data even if persons decide not to join the study or do not meet eligibility criteria to be used to determine why people did not join the study. Retaining this information poses no more than minimal risk since information collected during screening will be assigned a unique identifier and their name will not be linked to the data collected if they are not enrolled in the study. All subjects will be given a brief verbal consent document prior to providing any information. This study is not FDA-regulated, does not involve non-viable neonates, will not adversely affect the rights and welfare of subjects. Information collected will not be shared outside the research team. Data points collected at screening to kept include date of birth, gender, race, limited diagnosis (HIV, HCV, SUD), county after release, language, Medicaid eligibility. **[See Eligibility Screener Document]**

Alteration of HIPAA authorization requirements: We request an alteration of HIPAA authorization requirements for the eligibility screening process to allow abbreviated HIPAA language in the pre-screening script and oral authorization from participants. This process will pose minimal risk to participant privacy as all screening encounters will be conducted by an IRB approved research team member in a private location and the participant's name will not be collected on the screening tool. This alteration of HIPAA authorization is necessary to ensure that potential participants meet the eligibility criteria which is partially defined by the presence of at least one health diagnosis of interest prior to enrolling and participating in the study, and could not practicably be done without the alteration due to the undue time burden it would place on the participant and environmental resources needed to facilitate securing a private space for a brief period of time to conduct the eligibility screening.

Informed Consent for participants enrolling in the study will be obtained by the Nurse Case Manager. No prison staff (e.g. Health Services Unit staff, custodial staff, Psychological Services Unit staff) will participate in obtaining consent from prospective participants, but WIDOC staff may serve as a witness if needed for participants who cannot read or write.

In addition, the research team will also ask for permission to get records from the clinic where participants will receive care in the community after release. The ROI will include dates of clinic visits, clinical notes, medications prescribed, and results of lab tests. **[See ROI Document]**

Secondary Objective: We are requesting a waiver of consent for the population-based analyses; it is exclusively a secondary analysis of administrative data. Our request for a waiver of consent for this objective meets the following six criteria according HRP-410: not FDA-regulated, does not involved non-viable neonates, involves no more than minimal risk to the subjects, could not practically be carried out without the waiver, the research includes using PHI and could not practicably be carried out without such information in an identifiable format, the waiver will not adversely affect the rights and welfare of the subjects. The potential risk to subjects is a breach of confidentiality. However, the data security systems in place at the UW-IRP strongly mitigate this possibility (see Section 23.0). As part of data security and management process, we note that the study's investigators will only have access to a limited data set observe data that includes masked study IDs. Only aggregated statistical results may be removed from the UW-IRP's secure server. This study objective could not be carried out without a waiver of consent because it is not practicable to locate and contact 20,000 individuals. PHI is needed to create the analytical dataset which links data across different sources at the individual level, to define the sample, and to construct study outcomes.

We request a partial waiver of HIPAA authorization for this component and our justification meets the criteria according to HRP-441. The PHI, described in Appendix 2, is necessary to conduct the research as noted in the above paragraph; the specific and necessary function of each data type is noted justifying its role/necessity in conducting this secondary objective. Matching across multiple data sources requires use of several different types of identifiers (e.g., names, date of birth, social security numbers) to increase the likelihood of a correct match. The UW IRP has a data safety and monitoring plan in place to protect identifiers from improper use and disclosure (See Appendix 11). The PHI will not be reused or disclosed to any other person or entity except as required by law, for authorized oversight of the study, or for other research for which the use or disclosure of PHI for which an authorization or opportunity to agree or object is not required by 45 CFR 164.512. Finally, we are not practicably able to locate and contact the 20,000 subjects.

- *Where the consent process will take place. How the consent process will be conducted (e.g., face to face, phone or video discussion) and how consent information will be provided to participants (e.g., in person, mailed/emailed).*

Primary Objective:
The consent process will take place in the prison setting, in a private office. Consent will take place in person, face to face. Consent information will be provided to prospective participants through a written document, which will be read to all participants. Participants will be given an opportunity to ask clarifying questions of the Nurse Case Manager and will be asked to summarize the consent document to ensure comprehension. Participants will be able to retain a copy of their consent document. After the initial consent process, participants may also request a copy of the consent document at any time. If requested while incarcerated, consent can be delivered directly by the Nurse Case Manager or requested via a Health Services Request or Interview Request Form if the Nurse Case Manager is not available. If requested after release, it will be mailed to the mailing address provided by the participant.

Secondary Objective: Not applicable.

- *Any waiting period available between informing the prospective participant and obtaining the consent.*

Primary Objective: Prospective participants may decide not to complete the consent process at the initial meeting with the Nurse Case Manager. If interested, they may take study information with them. **[See Study Summary for Participants].** If prospective participants has questions or if they are interested later as indicated by a Health Service Request or Interview Request Form, they will be called to the Health Services Unit by the Nurse Case Manager at a scheduled time to complete enrollment.

Secondary Objective: Not applicable.

- *Steps that will be taken to ensure the potential participant's understanding and who will determine that a potential participant understands the information.*

Primary Objective: To be eligible for the study, participants must be able to speak and understand English. Language in the consent document was written at an 8th grade reading comprehension level to ensure accessibility to our population of interest. Participants will be provided with a written copy of the consent document to independently review and will be given an opportunity to have the consent read aloud to them and to ask questions with the Nurse Case Manager. Lastly, interested participants will be asked to summarize the consent document to ensure comprehension prior to participating. Should the participant not

be able to accurately summarize the research activities and their rights as a research participant, the Nurse Case Manager will clarify information until the participant is able to summarize the information accurately.

Secondary Objective: Not applicable.

- *Any process to ensure ongoing consent.*

Primary Objective: After completing the initial consent process, the Nurse Case Manager will begin each encounter with the participant by asking if the participant has questions about the consent, the study, or their participation. If the participant indicates a question, no study procedures will occur until the participant's questions are resolved. The participant will also receive a copy of the consent form in their discharge materials upon their release from the Department of Corrections.

Secondary Objective: Not applicable.

- *Whether you will be following HRP-090 - SOP - Informed Consent Process for Research.*

Primary Objective: We will be obtaining informed consent in alignment with HRP-090-SOP. **[See Informed Consent Document]** Informed consent will be obtained exclusively by the Nurse Case Manager.

Secondary Objective: Not applicable.

9.0 Process to Document Consent in Writing

Primary Objective (feasibility and acceptability): We will be following HRP-091 - SOP - Written Documentation of Consent and obtaining participant signatures on consent documents.

Secondary Objective (preliminary assessment of effectiveness): We are requesting a waiver of signed consent for our population-level analyses.

10.0 Setting

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

Primary Objective: The study will take place primarily within two Wisconsin Department of Corrections (WIDOC) facilities*:* Oakhill Correctional Institute which is an all-male facility and an all-female facility in the Wisconsin Women's Correctional System (WWCS). The Nurse Case Manager will travel between the two facilities to screen, complete the consent process, enroll, and meet with participants. After participants are released from prison, contacts will be made remotely via telephone. Research team meetings, data storage, and some follow up calls as needed will be made from the research team's offices at 1685 Highland Ave.

Secondary Objective: Preliminary assessments for effectiveness only involves secondary data analysis using administrative data. This objective does not require any in-person encounters with participants or site visits to either WIDOC facility in the study.

- *Identify where research procedures will be performed.*

Primary Objective: While the individual is still incarcerated, research procedures will be performed in person, on site in a private office at the institution where the participant is incarcerated (Oakhill Correctional

for males, or a facility in the Wisconsin Women's Correctional System for females). After the individual is released to the community, research procedures will take place over the phone. The Nurse Case Manager will ask if the participant is in a private place to talk at the time of the phone call.

Secondary Objective: Preliminary assessments for effectiveness only involves secondary data analysis using administrative data. This objective does not require any in-person encounters with participants or site visits to either WIDOC facility in the study.

- *Describe the composition and involvement of any community advisory board.*

Primary and Secondary Objectives: This study does not have a community advisory board.

- *For research conducted outside of the organization and its affiliates describe:*
  - *Site-specific regulations or customs affecting the research for research outside the organization*.

Primary and Secondary Objectives: Prior to commencing study activities, the Wisconsin Department of Corrections Research Review Committee will review the study. If amendments are requested, those will be addressed in the protocol prior and submitted to be re-reviewed by UW IRB before commencing study activities.

  - *Local scientific and ethical review structure outside the organization.*

Primary and Secondary Objectives: The Wisconsin Department of Corrections Research Review Committee reviews all research that is done within the Wisconsin Department of Corrections. The Research Review Committee will review this protocol prior to beginning research activities.

11.0 Study Intervention

11.1 *Description: Describe the study intervention and/or agent (e.g., drug, device) that is being evaluated.*

The study utilizes a behavioral case management intervention and will not include and devices, drugs or agents. The intervention, CJC-TraC, has been adapted from an existing tool called C-TraC as described above. The intervention involves in-person and telephone-based meetings with a Nurse Case Manager. Activities that will be addressed or completed by the Nurse Case Manager include Medicaid enrollment, identifying a provider network, scheduling medical or mental health appointments, review of current medications and treatment plans, community resources, and signs of a deteriorating condition.

12.0 Study Timelines

Study Duration: September 30, 2019 – June 30, 2024	
Phase 1: September 2019-December 2021	**Phase 2:** March 2022 – February 2024
IRB ID #2020-0749	**Current submission**
Data Collection Building Stakeholder support within the WIDOC Adaptation of C-TraC Intervention	Implementation of the CJC-TraC Program

12.1 *Describe:*

- *The duration of an individual participant's participation in the study.*

Primary Objective (feasibility and acceptability): We will engage with study participants who are within 3 months of release from prison and will follow them up to 3 months after release.

Interactions between the study team and participants will end upon completion of the 3 Month Survey and exit interview following a post-release outpatient visit or after 3 months of follow up. The final assessment may be delayed no-longer than 6 months after release if the participant is incarcerated, hospitalized or out of contact with the study team for other reasons. Data will continue to be collected from the Medicaid database for 1 year after release from prison.

Secondary Objective (preliminary assessment of effectiveness): This objective only involves secondary data analysis using administrative data. This objective does not require any in-person encounters with participants or site visits to either WIDOC facility in the study. We plan to use population-level data of all individuals >=18 years of age released from the Wisconsin Department of Corrections between 1/1/2020-12/31/2023.

- *The duration anticipated to enroll all study participants.*

Primary objective: We plan to have enrollment open for two years.

Secondary Objective (preliminary assessment of effectiveness): This objective only involves secondary data analysis using administrative data. This objective does not require any in-person encounters with participants or site visits to either WIDOC facility in the study. We plan to use population-level data of all individuals >=18 years of age released from the Wisconsin Department of Corrections between 1/1/2020-12/31/2023.

- *The estimated date for the researchers to complete this study (complete primary analyses).*

Primary and Secondary Objectives: Analysis is anticipated to be completed by June 2025.

13.0 Procedures Involved

13.1 Describe and explain the study design using basic terms. If you have any sub-groups, sub-studies, or retrospective collection of data and/or biospecimens, remember to address them here.

Primary Objective: The primary study objective proposed is a pilot intervention study to examine the feasibility and success of assigning adults living with HIV, Hepatitis C and/or substance use disorder who are releasing from the WIDOC to a Nurse Case Manager with the goal of connecting the participants with primary care services, as defined by this study as any non-emergent scheduled outpatient visit, within 30 days of release. The study is adapting the Coordinated Transitional Care (C-TraC) Model as described in IRB application #2020-0749.

While still incarcerated but within 6 months of release, participants will connect with a Nurse Case Manager who has an office in the Health Services Unit of the WIDOC facility. The Nurse Case Manager will meet with the participant pre-release a minimum of 3 times and up to 6 times as needed. Following release, the Nurse Case Manager will connect with the participant on a weekly basis until they attend an outpatient medical appointment. Thereafter, the case manager will ensure the participant is connected with appropriate support resources and minimize contact. A study team member will contact the participant three months after release in order to complete study activities.

Assessments:
Baseline Survey: We will ask each participant to complete a baseline assessment upon enrollment or approximately 3 months prior to their release. The assessment has two components: an interviewer-administered questionnaire **[See Research Baseline Survey]** conducted by UW-based research staff via phone or by the nurse case manager in person, and an in-person interviewer-administered questionnaire **[See NCM Intake Assessment]** conducted by the nurse case manager. To protect participant privacy, the phone call will be scheduled for a time and setting when the participant can speak on an unmonitored line, such as in an examination room in the Health Services Unit. Participants will receive $5 at the time of release for completing the NCM Intake Assessment and Research Baseline Surveys.
Some questions were modified or added from the original survey. If a participant is administered a baseline survey and those survey questions are subsequently modified, the participant will be contacted to complete those modified questions. Participants will only be contacted for completion of these modified questions if they have not yet released from prison. The nurse case manager will ask the modified questions at a pre-release encounter, integrated into the normal workflow. Efforts will be made to avoid extraneous encounters or undue burden related to completion of these items. Questions repeated or added due to survey modification will not exceed 20.

3 Month Survey: Participants will complete a second, end-of-study questionnaire **[See 3 Month Survey]** by telephone 3 months after release. They will receive a $30 incentive for completing the 3 Month Survey. This can be given by Venmo, PayPal, or cash by mail, based on participant preference.

Exit Interview: Participants may be asked to participate in an exit interview as subset of participants for qualitative substudy. Upon completing the study, 30 participants will be purposively sampled to gain insights into the success or shortcomings of the intervention. Interviews will take place via phone by a member of the research team. The question guide (will be used to guide the interview **[See Exit Interview Question Guide]** with the interviewer using probes to encourage more detail or to elaborate on the participant's response. Interviews will be conducted via Webex, a secure software approved by the University of Wisconsin. All interviews will be audio recorded and transcribed verbatim by a trained member of the research team. All identifiers will be removed from transcriptions. Recordings and transcripts will be stored separately on a password protected, encrypted network. A participant key will be kept in REDCap, separate from either the recording or transcript of the interview. The subset of individuals who participate in the Exit Interview will receive a $30 incentive in the same manner described for the End-of-Study Assessment.

Cell Phone: (optional)
Participants will need to have access to a phone after release. They will be given the option to receive a cell phone upon release from prison with an unlimited services plan (paid by the University with grant funding) for up to four months. Consistent with WIDOC policies, the participants will receive the cell phone when they leave the prison facility and receive the rest of their personal belongings upon release. The cell phone plan could be extended if their scheduled medical appointment cannot be scheduled within the three-month time frame. Upon completion of the study, participants will not be required to return the cell phone, but the service plan will be terminated. If the Nurse Case Manager is unable to reach the participant for more than one month, phone service may be terminated. Any participant that chooses not to use the phone will not receive any other compensation in lieu of the phone and plan. If a participant loses or breaks a cell phone during the study, one replacement phone will be provided if requested by the participant. The replacement phone will be hand delivered to the participant in the community by the nurse case manager. If a participant would like to retain the number of the study provided cell phone and voices interest to a research team member, research staff will submit a change request ticket to Doit including the participant first and last name and email address. Doit will follow up with the participant and service provider directly to coordinate the transfer of the phone number and line of service from the university to the participant. A

participant will have two weeks to complete this process after their scheduled phone deactivation date. If uncompleted during this timeframe the line of service will be deactivated.

Secondary Objective: We will gather preliminary evidence regarding the effectiveness of CJC-TraC for improving the rate of outpatient care utilization by examining the trends in health care use among the overall population from which CJC-TraC participants were recruited. The population-level trends serve as the counterfactual, the observed trends in health care use among individuals who were plausibly eligible for, but did not receive, the CJC-TraC intervention. We will use a retrospective cohort study design to describe post-release health care use among individuals who meet the sample criteria noted in 5.4. Results from this aim, will inform the interpretation of our findings from the Primary Objective including whether and to what extent we observe indications of intervention effectiveness (per deviations of post-release health care use among intervention participants from population-based trends).

13.2 Include a schedule of procedures

EXAMPLE: SCHEDULE OF STUDY PROCEDURES

Study Phase	Screening	Study Visits – *While Incarcerated*				Study Visits –*After Release*			
Visit Number		1	2	3	4*	1	2	3*	4*
Informed Consent	X								
Review Consent	X	X	X	X	X	X	X	X	X
Review Eligibility	X								
Demographics/ Medical Hx	X								
Adverse Event Assessment	X	X	X	X	X	X	X	X	X

**indicates additional study visit if needed*

13.3 Describe all research procedures being performed and when they are performed. Only list procedures that will be done for the research. For example, if a lab value will come from a test performed in a clinical care visit, describe this as data pulled from the medical record, rather than as a test procedure performed as part of the study. Include:

- *Procedures performed to monitor participants for safety and to lessen the probability or magnitude of risks (e.g. physical examinations, imaging, lab tests).*
- *Biospecimens to be collected, and whether you will collect them directly from participants for research only or from another source (e.g., another research study or pathology laboratory, either fresh or archived/diagnostic tissue). For specimens obtained directly from participants, include the amount collected, the collection schedule, and collection method. In addition, researchers should describe any expected deviations from standard of care workflows to collect the biospecimens. Researchers should also confirm with pathology that any workflow deviations are acceptable (see HRP-103 - INVESTIGATOR MANUAL).*
- *All drugs and devices used in the research and the purpose of their use.*

Primary Objective: In person visits between the Nurse Case Manager and the participant will begin while participants are incarcerated at the study site. Due to certain circumstances, such as changing COVID-19 regulations in the prisons or participant circumstances, some visits will be conducted via telehealth and/or phone calls in lieu of in person visits. Prior to the first visit, the Nurse Case Manager will complete pre-appointment background information.

The initial visit with the Nurse Case Manager will consist of screening the participant for eligibility and detailing the study procedures. If the participant and Nurse Case Manager complete the consent process during the initial study visit, the information gathered in the pre-appointment background will be reviewed and confirmed with the participant. If the participant chooses not to enroll in the study, all pre-appointment background information, except for presence or absence of eligible diagnoses in the electronic health record and COMPAS, will be destroyed.

The Nurse Case Manager will have an Encounter Guide to follow for each meeting with the participant. **[See Encounter Guide]** The study visits will include going over background information, review discharge plan as detailed by the patient and WIDOC documents completed by staff (e.g. Health Services Unit staff, social workers) within the institution, as well as conversations with the participant to review health 'red flags' and if the post-release primary care appointment has been scheduled, the date, time, and location of the primary care appointment. If a fourth visit is necessary, the Nurse Case Manager will meet with the participant an additional time to complete necessary steps to prepare for release, up to 6 visits as needed to complete the encounter guide activities. The Nurse Case Manager may also move activities to different study visits based on availability of information, participant willingness to engage, and appropriateness.

After release, all visits will be conducted on the phone. The first post-release, phone-based visit will be scheduled prior to release to take place within 72 hours after release. Another post-release, phone-based visit will occur within 48 hours prior to the scheduled primary care appointment to review and verify the plan to attend. As needed, additional calls will be decided upon and scheduled by the participant and Nurse Case Manager, up to 4 calls.

Secondary Objective: We will gather preliminary evidence regarding the effectiveness of CJC-TraC for improving the rate of outpatient care utilization by examining the trends in health care use among the overall population from which CJC-TraC participants were recruited. The research procedures include receipt of administrative data noted in **Appendix 2** and analyses of those data.

13.4 What data will be collected during the study and how that data will be obtained.

- *List of data elements*

Primary Objective: The following data elements will be collected from the EMR/Department of Corrections documents or databases. The data will be manually extracted on-site by the Nurse Case Manager or Research Assistant for the purpose of assessing eligibility (pre-consent), and formulating a re-entry plan (post-consent).

- Name (first, middle initial, last)
- Date of Birth
- Race/ethnicity
- Sex
- Insurance status at release
- Medical history
    - Medications
    - Diagnoses/problem list
    - Procedures or previous treatments

  - Dates and test results for HIV and HCV
  - Previous and upcoming medical appointments
- Post-release health care use

The following data elements will be collected from the participant:

- Social Determinates of Health plan post-release
  - Housing
  - Employment
  - Transportation
  - Health Literacy Screening and history
- Family engagement plan or other sources of support post-release
- Lifetime years spent in:
  - Prison
  - Jail
- Number of times incarcerated in lifetime
- Amount of time spent incarcerated during current incarceration
- Pre-incarceration:
  - History of drug/substance misuse prior to incarceration
  - Use of primary care services prior to incarceration
  - Health insurance coverage prior to incarceration
- Pre-incarceration social determinants of health
  - Homelessness/housing insecurity

Secondary Objective: Please see **Appendix 2** for all data elements and their sources for the secondary objective.

- Post-release health care use

- *Questionnaires, structured interviews, or other assessments. (Upload all surveys, scripts, and data collection forms in the ARROW application.)*

(Please see Appendix numbers 1, 3, 4 for more details on this information)

For data collection, participants will be asked to complete the questionnaire in the Encounter Guide.

- *Source records that will be used to collect data about participants. Check all sources that apply:*

  Services

  ☐ Data from publicly available datasets (e.g., U.S. census data)

  X☐Data from outside institutions or organizations (specify: Wisconsin Medicaid Data, COMPAS Case Management and Risk Assessment Instrument, DOC Central Pharmacy Database, Wisconsin Electronic Disease Surveillance System DOC Administrative Records)

  ☐ Other (specify: _____)

13.5 If there are plans for long-term follow-up (once all research related procedures are complete), what data will be collected during this period and how.

Primary and Secondary Objectives: There is no plan for long-term follow up for either study objective.

14.0 Comparison of usual care and study procedures

14.1 Describe the current alternatives to participation in this research study. For example, alternative treatments or alternative care the participant could receive outside of the study. Describe factors that influence which treatments a participant receives.

CJC-TraC activities are optional and intended to supplement, not replace, existing WIDOC activities that help coordinate release planning.

WIDOC Social Workers use the list created of all releases happening within the next 6 months and use that to start the release process with individuals. This process includes a working document to make sure people are set with living arrangements and other priorities before leaving the facility. All people will receive the same standard of care even if they choose not to enroll in the study. Study participants will get the additional support pre- and post- release, in a way that is coordinated and not duplicative of what is being done.

14.2 Describe standard practice or standard of care for this participant population at the UW-Madison/UW Health. For example, a certain treatment or follow-up schedule that is recommended.

Patients with HIV who receive care at UW Health will receive case management from the UW HIV Clinic prior to release and those people who choose to enroll in CJC-TraC will be coordinated with this in a patient centered way, to reinforce any other care plans or referrals rather than replace or duplicate.

14.3 List any research procedures that overlap with standard practice or standard of care at UW-Madison/UW Health. For example, does study follow-up occur at the same timepoints as standard of care follow-up? Would the same screening or follow-up assessments be done as part of standard care?

As stated above, CJC-TraC will be used to reinforce the care plan that is made as part of routine procedures, educate about its importance, and supplement case management activities that address needs still unmet.

14.4 Describe whether / how research participation would affect standard clinical care (e.g., require participants to delay or withhold standard clinical treatment for x period, substitute the most common Rx with an investigational treatment, etc.). Describe how the study will minimize risks associated with delaying or withholding clinical alternatives.

Participation in the study would not affect standard clinical care of the participant. If a participant has care arranged after release from prison (e.g. pre-scheduled provider visits or activities completed by a different case manager), the Nurse Case Manager will integrate the established care into the participant plan.

15.0 Withdrawal of Participants

15.1 Describe anticipated circumstances under which participants will be withdrawn from the research without their consent.

Primary Objective (feasibility and acceptability): Participants will be withdrawn if they're exhibiting ongoing aggressive, harassing, or threatening behavior. Participants will be evaluated individually by the Nurse Case Manager and research staff, and the subject may be removed from study if we feel it is in the best interest of the subject, staff, and other study participants.

Participants will also be removed from the study if they have an extension to their sentence and they are no longer within 3 months of release. They will be eligible to re-enroll in the study if their release date falls within 3 months while the study is ongoing.

The Nurse Case Manager will attempt to reach the participant 4 times after release. On the 5th unsuccessful contact attempt, the participant will be considered lost to follow up and the nurse case manager will cease attempts to contact. The Nurse Case Manager will fill out the Post-Release Contact Log to keep track of these attempts. **[See Contact Log]** If the participant has a cell phone provided by the study, the cell phone's plan may be terminated at this point. A study team member will attempt to contact the participant through various means to complete the End-of-Study Assessment.

Secondary Objective (preliminary assessment of effectiveness): Not applicable. Preliminary assessments for effectiveness only involves secondary data analysis using administrative data. This objective does not require any in-person encounters with participants or site visits to either WIDOC facility in the study.

15.2 Describe any procedures for orderly termination.

Participants who are terminated early from the study will be notified by the Nurse Case Manager. After termination, no additional data will be collected directly from participants the context of the intervention. Population-level data for the secondary objective will continue to be collected. Data previously collected to that point will be used in analyses as appropriate.

15.3 Describe procedures that will be followed when participants withdraw from the research, including partial withdrawal from procedures with continued data collection.

Primary Objective: If participants wish to withdraw from the study, they can do so at any time by contacting the Nurse Case Manager or any of the study contacts listed in the consent form. If a participant indicates they wish to withdraw, they will not be asked to complete the 3 month survey or exit interview as detailed above. If a participant indicates that they do not wish to participate in any aspect of the intervention (i.e. phone calls with the case manager after release), they will be allowed to decline. They will be asked if they would agree to participate in the 3 month survey and potentially the exit interview. They will receive the same compensation as participants who completed all aspects of the study. Both the 3 month survey and the option for an exit interview are documented in the consent form.

Any meetings or appointments with health care providers or others that have already been scheduled will remain in place in the event of a participant's premature withdrawal from the study.

Secondary Objective: Not applicable. Preliminary assessments for effectiveness only involves secondary data analysis using administrative data. This objective does not require any in-person encounters with participants or site visits to either WIDOC facility in the study.

16.0 Data Management and Confidentiality

16.1 Describe any procedures that will be used for quality control of collected data.

16.2 Describe the steps the researchers will take to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission. If HIPAA rules apply to the study, review information on the Office of Compliance HIPAA page and consult HIPAA Privacy and Security Coordinators to ensure that data management methods are compliant. Select all that apply:

- X Data will be coded, and the "key" linking identities to codes will be kept separately from the data.
- ☐ Data will be coded, and the "key" linking identities to codes will be kept on paper only. The study data will be stored electronically and labeled only with codes.

- ☐ Only those listed as key personnel will have access to the "key."
- ☐ Access to the "key" will be limited to the following person (e.g., Database Administrator): _____
- X This study is funded by the National Institutes of Health and is covered by a Certificate of Confidentiality.
- ☐ This study is NOT funded by the National Institutes of Health but because it will collect sensitive information, the research team will apply for a Certificate of Confidentiality to protect data from being requested without the subject's consent as part of a legal proceeding.
- ☐ Other: _____

16.3 Describe how and where data and/or specimens will be stored and maintained. The following list is provided for convenience but is not an exhaustive list. Select all that apply:

- ☐ Online Collaborative Research Environment (OnCore) Biospecimen Management
- X Research Electronic Data Capture (REDCap) *Specify which instance you will be using (e.g., ICTR's, Department of Medicine's)*: __DOM REDCap_____
- ☐ Other software option that will be stored on departmental server. *Specify the department*: _____
- X Locked filing cabinet or drawer inside a locked room. Specify the building: _____
- ☐ Other (describe): _____
- **X** Data will not be stored or accessed on portable devices.
- ☐ Portable devices will be used to access secure web-based data collection sites such as ICTR's REDCap. No data will be stored locally on the device.
- X Data stored on portable devices will be coded with the key stored separately. No identifiers will be stored on portable devices.
- ☐ Data stored on portable devices and therefore only encrypted devices will be used.

16.4 Management of Identifiers: *Explain whether there will be a unique code on the specimen/dataset that can be used to LINK to a participant's identity, but will not, by itself, reveal who the participant is. If you will create and maintain a "key" linking identities to codes, explain where this key will be stored. Define when identifiers (such as names) or the "key" linking codes to identifiers will be destroyed, if known. Please modify the common options below as needed.*

- ☐ Identifiers will be destroyed after all data has been collected.
- X Identifiers will be destroyed at study closure.
- ☐ Identifiers will be destroyed at study closure or at the time of publication.

Primary Objective: For purposes of the study, participants will be labeled with a unique identifier. The key linking the participant to their identifier will be stored on a password protected, encrypted computer and will be saved separately from the participant information.

Hard copies or printed materials that are saved will be stored in a locked cabinet in within the DOC until it can be transferred and stored at UW Medical Foundation Centennial Building (MFCB) in a locked cabinet with all CJC-TraC Study documents. Paper documents (e.g. notes written by the NCM, Health Service Requests, Interview Request Forms) may be scanned into an electronic file and then destroyed. The participant key will be destroyed upon closure of the study.

Secondary Objective: Identifiers associated with the Medicaid enrollment system are maintained as part of a large integrated data set at IRP through omnibus data sharing arrangements in the support of multiple UW projects. The destruction of these identifiers will comply with terms of agreements between IRP/UW and the WI Department of Health Services Identifiers from the WI Department of Corrections, the WI Department of Public Health, and the WI State Lab of Hygiene will be retained on the restricted IRP server only until analyses are complete and the findings have been presented and/or published. IRP will comply with each agency's data destruction terms in the respective data use agreements.

16.5 Describe any planned sharing of data and/or specimens outside the study team / institution. Include sharing required by funding agencies and publications.

- *What data and/or specimens will be shared.*
- *Whether data/specimens will have all identifiers (including linking codes) removed prior to sharing, or if they will remain linked to participant identifiers.*
- *How data and/or specimens will be transmitted or transported.*
- *If the study will share large-scale genomic data under the NIH Genomic Data Sharing Policy, review HRP-064, SOP – NIH GDS Institutional Certification and HRP-332 Worksheet – NIH GDS Institutional Certification to ensure that you provide adequate information for institutional certification.*

Primary and Secondary Objectives: All data access will be done by people who are part of the study team. No data will be shared outside the study team.

17.0 Provisions to Protect the Privacy Interests of Participants

17.1 Describe the steps that will be taken to protect participants' privacy interests. "Privacy interest" refers to a person's desire to place limits on with whom they interact or to whom they provide personal information. If any of the following apply, check the box for convenience:

Primary Objective: Procedures will be performed in a private area where others (e.g. prison staff) will overhear the conversation between participant and the Nurse Case Manager.
All members of the study team are up to date on their institutional HIPAA training, as well as CITI training.
The study is not collecting information that could pose legal or reputational risks to participants.

Secondary Objective: As stated in the Phase 1 IRB application (2020-0749), collection of sensitive information about subjects is limited to the amount necessary to achieve the aims of the research.

17.2 If the study collects sensitive information (e.g., sexual health information, communicable disease status, genetic test results), provide a justification for this.

Due to the goal of connecting people with health care services after release from prison, the study will collect information related to HIV status, HCV status, and substance use history. These data will be collected firstly for the purpose of eligibility, but also for more complete post release care planning by the Nurse Case Manager.

17.3 Describe what steps you will take to make the participants feel at ease with the research situation in terms of the questions being asked and the procedures being performed. "At ease" does not refer to physical discomfort, but the sense of intrusiveness a participant might experience in response to questions, examinations, and procedures.

Primary Objective: Our research team has previous experience working respectfully and sensitively with vulnerable populations in research settings and have learned additional strategies for building rapport and trust with incarcerated individuals through the qualitative interviews conducted in Phase I of this study.

The Nurse Case Manager is taking a patient-centered approach. This means that the meetings with the participants and the peripheral duties performed (e.g., finding additional resources, making referrals) will be tailored to the specific needs of the patient/participant. In the interviews performed in Phase 1 we learned that oftentimes after release individuals feel overwhelmed by all that they need to accomplish and by the variety of concerns that they carry with them. By addressing concerns that are raised beyond accessing primary care after release, the Nurse Case Manager will help the participant feel more in control, decreasing feelings of discomfort.

Lastly, participants can take breaks as needed or choose not to complete any study activity that causes undue stress or discomfort.

Secondary Objective: Preliminary assessments for effectiveness only involves secondary data analysis using administrative data. This objective does not require any in-person encounters with participants or site visits to either WIDOC facility in the study.

17.4 If any medical records from UW Health or other sources will be used, confirm that the study team has authorized access to the records and that this use is allowed by the legal medical record holder.

Primary and Secondary Objectives: No medical records from UW Health will be accessed as part of the study. The Wisconsin Department of Corrections will grant EMR access to the Nurse Case Manager, so they are able to gather information needed to determine eligibility and to see a more complete clinical picture of the participant.

18.0 Sharing of Results

18.1 Describe whether results (study results or individual participant results, such as results of investigational diagnostic tests, psychological assessments, genetic tests, or incidental findings) will be shared with participants or others (e.g., the participant's primary care physicians) and if so, describe how the results will be shared. Specify whether individual results will be reported in participants' health records.

Data obtained from participants through research assessments and surveys will not be shared outside the study team. There will be no diagnostic assessments done as part of research activities. The Nurse Case Manager may document information relevant to the transitional care plan or nursing assessments or interventions (including referrals to medical providers) in the EMR.

18.2 Describe plans to share study results with the public.

Results from the study will be deidentified prior to any publications or presentations. It is anticipated that upon study completion manuscripts will be prepared for publication. Presentations at the National Commission for Correctional Health Care and the Academic Consortium for Criminal Justice Health conferences will be possible venues for sharing findings of the study.

19.0 Data and Specimen Banking

19.1 If data and/or specimens will be banked for future use, indicate whether banking is optional. Describe what data/specimens will be banked, where they will be stored, how long they will be stored, how the data/specimens will be accessed, and who will have access to the data/specimens. Describe any procedures that will be used for quality control of collected data and specimens.

Primary Objective: No specimens will be used in this study. Data collected from participants (e.g. survey responses) will be removed of identifiers prior to banking at the completion of all study activities. No identifying participant data will be banked. Banking the participant data is not optional in this study. Banked data will be kept indefinitely for future use. Data will be banked to assist in future analyses to improve implementation at future sites. All banked data will be stored on an encrypted, password protected server accessible only to the research team.

Multiple de-identified databases (e.g. survey data and Medicaid outcomes) will contain a unique code number that is linked to identifying information in a separate master list that matches participant identifiers to their unique research code. This linking database is only accessible to research staff and will be destroyed after data analysis has concluded. Banked data will include a unique code, but will not include direct identifiers including name and date of birth.

Secondary Objective: Not applicable. There will be no data banking as part of the secondary objective.

19.2 List the data to be stored and/or the data associated with each specimen. Specify whether data/specimens will have all identifiers (including linking codes) removed prior to banking, or if they will remain linked to participant identifiers.

The data from the baseline and follow up assessments. All banked data will be stored on an encrypted, password protected server accessible only to the research team with no identifying participant data.

19.3 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. Describe any limits on future research use of the banked data/specimens.

The PI of the study, Dr. Westergaard, will review all requests to release banked data. The banked data will only be accessible to the research team unless a written request is approved by the study PI.

19.4 State whether participants may withdraw their banked data/specimens from future research use. If yes, explain whether data/specimens would be destroyed or fully anonymized in response to a withdrawal request. If no, explain why (e.g. data/specimens are fully anonymized prior to banking).

All banked data will be fully anonymized prior to banking.

20.0 Study Analysis

20.1 Statistical Hypotheses: State the formal and testable null and alternative hypotheses for primary and key secondary endpoints, specifying the type of comparison (e.g., superiority, equivalence or non-inferiority, dose response) and time period for which each endpoint will be analyzed.

Primary Objective: The main hypothesis to be tested in this pilot study is that the CJC-TraC protocol is feasible and acceptable to WIDOC staff and incarcerated patients.

Secondary Objective: The secondary objective is descriptive and not hypothesis driven. The objective is to describe secular trends in health care use among the population from which CJC-TraC participants were recruited. These trends provide a counterfactual regarding what we observe in the absence of the intervention.

20.2 Sample Size Justification: Include number of participants to recruit, screen, and enroll to have adequate power to test the key hypotheses for the study. Include anticipated impact of drop-out/withdrawal/cross-over rates, missing data, etc. on study power. Provide all information needed to validate your calculations.

The proposed sample size was chosen by considering what would be an appropriate case load and frequency of client interactions for the Nurse Case Manager. This level was informed by focus group data collected in Phase 1 and input from collaborators, and eligible participants at the two correctional institutions where the study will occur. Publicly available data from the Department of Corrections indicates that Oakhill Correctional has approximately 316 annual releases while Robert E. Ellsworth Correctional Center (REECC), a facility in the Wisconsin Women's Correctional System (WWCS), has approximately 327, for a total of 643 annual releases at the two study sites. There are 112 and 65 people released to Dane and Milwaukee counties annually at Oakhill and REECC respectively, for a total of 177. These counties will be prioritized for recruitment. An additional 126 individuals released annually to Rock, Waukesha, Racine, and Kenosha counties, 62 from Oakhill and 64 from REECC. These counties can be adequately serviced by the NCM at this time, and the number of serviceable counties will increase throughout the intervention. Assuming that 50% of people incarcerated at the two facilities and releasing to a serviceable county will be eligible and enroll in the study, we would expect a total of 168 participants at Oakhill Correctional Institution and 120 at REECC over the 24-month study period, for a total of 288 total participants. Our recruitment goal is 220 individuals.

20.3 Participant Population(s) for Analysis: Identify and describe the analysis datasets (e.g., which participants/populations will be included in each).

The dataset construction begins with all individuals released from a WI state correctional facility between 1/2020-12/2023. From this universe of individuals, we will apply the sample criteria noted in 5.4 to generate the analytic dataset: adults who have a history of, or living with, SUD, HCV or HIV and enroll in Medicaid within the month of release.

20.4 Statistical Methods: Summarize the overall statistical approach to the analysis of the study data.

We will implement descriptive analyses to achieve the following objectives: a) to characterize and compare the equivalence of sample characteristics and outcomes across study years; b) to describe, and test for change over time in unadjusted study outcomes; and c) to quantify the association between study outcomes and factors that may influence those outcomes including beneficiary characteristics. We will use bivariate statistical tests (e.g., t-test, chi-square test) to determine the equivalence of unadjusted characteristics and outcomes over time, and regression methods to estimate changes over time in study outcomes, controlling for individual and areas-level characteristics. For binary outcomes, we will implement logistic regression. For count outcomes, we will implement Poisson regression.

20.5 Planned Interim Analysis: Interim efficacy or safety analyses if planned,and include a description for stopping rules for efficacy and stopping rules for safety.

Interim analyses for feasibility and fidelity will be conducted aligned with the Replicating Effective Programs, such as logging the intensity and frequency of time spent by the Nurse Case Manager on participants, as well as analyses to identify statistically significant barriers to accessing care after release.

20.6 Handling of Missing Data: Describe how missing data will be handled, e.g., type of imputation technique, if any, and provide justification. (Most methods for handling missing data assume that the data are missing at random, which may not be a valid assumption.) WIDOCument reasons for missing data and evaluate the impact of missing data using sensitivity analysis. (If

the missing data are extensive, model-based approaches will estimate their effects under various assumptions regarding missingness.)

Missing data will be considered based on the extent and intensity of the missingness. Steps have been implemented to reduce missingness such as researcher administered surveys, and so we anticipate that missing data will occur randomly. If missing data is extensive, approaches to mitigate the effect of the missing data will be used to generate a functional final model.

21.0 Potential Benefits to Participants

21.1 Describe the potential benefits that individual participants may experience from taking part in the research. Include the probability, magnitude, and duration of the potential benefits.

Individual participants will receive the direct benefit of additional discharge support during the release and reentry process, including tailored health teaching and primary care services after release from prison.

21.2 Indicate if there is no direct benefit. Do not include benefits to society or others in this section.

N/A

22.0 Risks to Participants

22.1 List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the participants related the participants' participation in the research. Include as may be useful for the IRB's consideration, a description of the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks.

We believe this study should be categorized as minimal risk since the potential risks detailed below are not believed to be greater than that is normally encountered in their daily lives, or in the routine medical, dental, or psychological examination of healthy persons. All research staff are educated and trained in the areas of confidentiality, HIPPA, and safety. There is also the extra layer of protection covered by the Certificate of Confidentiality.

There could be a breach of confidentiality that could result in disclosure of research data outside of the study team. This could carry economic or legal risks for subjects. To prevent this, all subjects will be assigned a unique identifier. These lists will be kept in a locked file in the UW Madison office and will not be shown to staff. Data collected from clinic records will have the name removed and the unique identifier will be attached by the UW study coordinator. Meetings will be conducted by staff trained in protecting participant confidentiality. Project staff who have access to the data will not have access to subject names. No clinic staff who have direct contact with the subjects will have access to data until the names are removed and the data is labeled with the blind code number.

All visits with the Nurse Case Manager will be completed in a private office. After the participant has released from prison, the Nurse Case Manager will complete all phone calls in a private setting. Participants will be encouraged to complete phone calls in a private setting.

Participant subjects might use the phone for unintended harmful purposes such as procuring drugs or alcohol.

22.2 If applicable, describe risks associated with participants delaying, being withdrawn from, or being asked to forgo standard treatment to participate in the study. Examples include holding medication prior to study visits, weaning off a standard medication, or receiving investigational treatment instead of an effective standard therapy.

Not applicable

22.3 If applicable, indicate which procedures may have risks to the participants that are currently unforeseeable.

Not applicable

22.4 If applicable, indicate which procedures may have risks to an embryo or fetus should the participant be or become pregnant.

Not applicable

22.5 If applicable, describe risks to others who are not participants (e.g., blood relatives and genetic research).

There are no perceived risks to others who are not participants.

22.6 Describe how the study design, inclusion/exclusion criteria, and any other relevant factors minimize risks of harm or discomfort. (Section 12.0 describes procedures performed to monitor participants for safety and to lessen the probability or magnitude of risks; do not repeat this information here.)

The inclusion/exclusion criteria and study design specifically aim to reduce challenges to accessing primary care services frequently faced by adults leaving prison.

23.0 Provisions to Monitor the Data to Ensure the Safety of Participants

23.1 Describe:

- *The plan to periodically evaluate the data collected regarding both harms and benefits, identify any unanticipated problems new risks, or potential changes in risk/benefit ratio. For more than minimal risk studies, the plan might include establishing a data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor. For minimal risk studies, describe how the study team will work together to monitor study progress and identify potential problems.*

All research staff who will have access to the medical records and personal data for study participants will receive extensive training and certification according to the institutions obligations under the Health Insurance Portability and Accountability Act (HIPAA).

Robust data safety protections are in place through the Institute for Research on Poverty to minimize risks to confidentiality, as described in detail in the Data Safety and Monitoring Plan. These include using multiple server storage environments with different levels of security: one for access to “limited data sets (LDS),” and a second for data sets classified as fully-identified “protected health information (PHI).” Access to full PHI will be limited to designated trained programmers, and researchers will conduct analyses using only LDS be conducted using dedicated operating systems that are unable to access the internet.

To protect against breach in confidentiality in participants, all subjects will be assigned a blind code number. While data generated through participants’ interaction with the CJC-TraC program may be recorded in the electronic health record if and when it is relevant to their ongoing medical care, any data that is collected strictly for research purposes and will be stored outside of WIDOC will be stripped of direct identifiers and labeled only with the unique code. Lists linking participant identifiers and study data will be kept in a locked file at the WIDOC central office or electronically in the WIDOC encrypted server infrastructure. Engagement with participants will be conducted by staff trained in protecting patient confidentiality. Project staff who have access to the data will not have access to subject names. No clinic staff who have direct contact with the

subjects will have access to data until the names are removed and the data is labeled with the blind code number.

To handle both physical and psychological risks, the research team will establish working relationships with prison-based medical and mental health providers and will maintain a directory of local urgent care providers and crisis hotlines in the communities where participants will reside after release. We will develop a streamlined process to refer subjects to local urgent care clinics if urgent health needs are identified through post-release telephone assessments. Subjects who report relapse to active drug use will be offered referral for drug counseling and treatment.

Additional Protections for Prisoners. Individuals will be incarcerated at the time of recruitment and enrollment, and their participation will continue after they are released from the community. It is also likely that some participants will become re-incarcerated within the 3-month follow-up period after release. As such, this research will adhere to all requirements specified in 45CFR46 Subpart C, including review by a convened IRB with a prisoner representative and supplemental OHRP certification.

- *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).*

This information will be collected from EMR records, at study visits, and telephone calls from participants.

- *The frequency of data collection, including when safety data collection starts and end*
- *Who will review the data.*
- *The frequency or periodicity of review of cumulative data.*
- *The statistical tests for analyzing the safety data to determine whether harm is occurring (if not described in section 20.0).*
- *Any conditions that trigger an immediate suspension of the research.*

24.0 Economic Burden to Participants

24.1 Describe any costs that participants may be responsible for because of participation in the research.

The participant will be responsible for co-pays or any other charges resulting from attending a non-emergency health care appointment scheduled by the Nurse Case Manager. No other economic burden is anticipated.

25.0 Resources Available

Will the research be conducted outside School of Medicine and Public Health or UW Hospitals and Clinics (e.g. the researcher does not have an SMPH research feasibility attestation for this study)?	☐ YES (complete 25.1) ☐ NO (remove text below, but retain this section)

26.0 References

This is the bibliography section for any information cited in the protocol.

Weiner, B.J., Lewis, C.C., Stanick, C. et al. *Psychometric assessment of three newly developed implementation outcome measures.* Implementation Sci ***12,*** *108 (2017).* https://doi.org/10.1186/s13012-017-0635-3

27.0 Documents

	Study Documents
1	**Recruitment Flier**
2	**Recruitment Letter**
3	**Talk Points & Study Info Sheet**
4	**Release List**
5	**Recruitment Tracker**
6	**Encounter Guide**
7	**Pre-Release Contact Log**
8	**Eligibility Screener**
9	**Consent**
10	**ROI for Clinic(s)**
11	**Locator Form**
12	**NCM Intake Assessment**
13	**Insurance and Appointments**
14	**Research Baseline Survey**
15	**Post-Release Contact Log**
16	**NCM Navigation**
17	**3 Month Survey**
18	**Exit Interview**

Research tools attached separately (Recruitment Flier, Recruitment Letter, Talking Points and Study Info Sheet, Eligibility Screener, Consent, ROI for Clinic, NCM Intake Assessment, Research Baseline Survey, 3 Month Survey, Exit Interview). Case management process tools available upon request.

11 UW IRP Data Security and Monitoring Plan

Attached separately.