



Evaluation Protocol: Referral, Informed Consent, Enrollment, and Data Collection

Dissemination of Evidence Informed Interventions
Enhanced Patient Navigation

January 8, 2018

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About this Protocol

This document serves as a protocol for conducting evaluation activities for the linkage and retention intervention **Enhanced Patient Navigation for Women of Color Living with HIV** of the Health Resources and Services Administration’s Special Projects of National Significance (SPNS) Program initiative **Dissemination of Evidence-Informed Interventions (DEII)** to improve health outcomes along the HIV Care Continuum. It was developed by the Dissemination and Evaluation Center (DEC) at the Boston University.

Structure

This protocol begins with an overview of the Patient Navigation intervention, while the remainder is divided into three main sections:

1. **Referring, Consenting, and Enrolling Participants into the Evaluation Study:**
This section provides guidance on steps for referring a person working with an interventionist to the program evaluation, consenting the potential participant into the evaluation, and enrolling the participant into the evaluation.
2. **Using Data Collection Tools:**
This section provides step-by-step instructions for administering and using data collection tools, including the participant questionnaires, participant chart review tool, and participant encounter form.
3. **Managing Data:**
This section provides guidance on best practices for storing and managing data collected for the DEII evaluation study.

Throughout this protocol, basic steps for navigating the DEC tracking website (https://wwwru.bumc.bu.edu/DCC_DEC/) and the REDCap System (<https://redcap.bumc.bu.edu/>) are provided. For more detailed instructions on how to use these sites, refer to the most recent versions of the following manuals.

- User Manual for the DEC Tracking System (Version 1.1 - November, 7, 2016)
- Training Manual for the REDCap System (Version 1.0 - August 17, 2016)

Common Acronyms

Acronym	Expansion
DEC	Dissemination and Evaluation Center at Boston University
ITAC	Implementation and Technical Assistance Center at AIDS United
DCC	Data Coordinating Center at Boston University
MSE	Multi-site evaluation
REDCap	Research Electronic Data Capture (a data collection system used on this project)

Contact Information

Questions about this protocol or any evaluation-related activities should be directed to the DEC at Boston University:

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Overview of the Enhanced Patient Navigation Intervention

Target population:

HIV-positive Women of Color (WoC) 18 years and older who meet the following criteria: have not been seen at the clinic in the prior 6 months; have missed 2 or more appointments in the prior 6 months; are loosely engaged in care (have cancelled or missed appointments in the prior 12 months); are not virally suppressed; and/or have multiple co-morbidities.

Eligibility criteria:

- Persons 18 years or older
- HIV-positive
- Identify as female
- Persons identify as belonging to one or more of the following racial or ethnic categories:
 - American Indian or Alaska Native
 - Asian
 - Black or African American
 - Hispanic or Latina
 - Native Hawaiian or other Pacific Islander
- Persons receiving their HIV primary care at the clinic offering the intervention
- Persons meet at least one of the following criteria:
 - Has fallen out of care (i.e. have not attended clinic where they receive HIV primary care for 6 months or more)
 - Is loosely engaged in care (have cancelled or missed 2 or more appointment in past 12 months)
 - Not virally suppressed
 - Has multiple co-morbidities that threaten their ability to be retained in care

Time frame of the Intervention:

Patient Navigators will work with patients for a minimum of 6 months and a suggested maximum of 12 months. After 6 months, patients will be reassessed every 3 months using an acuity based system to determine if they still need the support of the Patient Navigator.

Evaluation Study Enrollment Numbers:

At least 70 participants enrolled in the first 12 months of implementation and at least an additional 30 enrolled in the following six months of implementation.

Performance Sites:

- Newark Beth Israel Medical Center/Family Treatment Center-Newark, NJ
- Grady Health System-Atlanta, GA
- Keck School of Medicine USC-Los Angeles, CA

Study Design

Enhanced Patient Navigation for WoC is a prospective study of a convenience sample of HIV-positive WoC. This arm will enroll at least 70 participants enrolled in the first 12 months of implementation and at least an additional 30 enrolled in the following six months of implementation. Subject who are consented and enrolled into the national study will be assigned a local ID and interview, chart, encounter data will be collected at the demonstration sites. Baseline will be administered after the participant consents to the evaluation, and follow-up data will be collected at 6, 12, and 18 months post-baseline. Intervention encounter data will be collected daily by the Patient Navigator implementing the intervention for each subject enrolled in the study and will include type of encounter, location, duration, and content of the encounter. Medical visits, substance use treatment services, mental health visits, and selected laboratory values will be collected via charts and/or electronic medical records. There are no experimental interventions. Chart data will be collected by the Data Manager at each site at 6, 12, and 18 months and will be collected on a Teleform, and uploaded to

the Data Coordinating Center secure data portal. There are no experimental interventions, nor are there control or comparison groups within this intervention. Subjects who agree to participate in the intervention will be offered the services of Patient Navigator who will work with the participant to keep the participant retained in HIV care. The Patient Navigator will work with the participant for up to 12 months. Subjects will be contacted on a daily or weekly basis as necessary by the Patient Navigator to receive health education, supportive services, and to facilitate a successful retention in HIV primary care. Contacts for the intervention services will be made via face-to-face appointments, text, emails, or phone calls. The number of face-to-face study contacts for this arm of the study will be four (baseline and 6, 12, and 18 month follow-up). There are no additional requirements of patients.

Evaluation Study Enrollment Dates

IMPORTANT	
Year 1 cohort of participants enrolled:	November 1, 2016 – October 31, 2017
Year 2 cohort of participants enrolled:	November 1, 2017 – November 1, 2018
Last day to enroll:	November 1, 2018
Last day to enter data:	April 30, 2019

FAQ: If the Multi-site evaluation study (MSE) enrollment deadline is November 1, 2018, then wouldn't all three of the chart abstractions be scheduled for after April 30, 2019 when the last data can be entered? Is the April deadline just referring to interview/encounter data, and, if so, when is the deadline for uploading chart abstraction data?

Answer: We recognize that we will miss some chart abstraction data. You won't be expected to collect data once the grant period ends.

Outcome Measures

The purpose of the evaluation study component of the DEII project is to provide data for assessing the following outcome measures:

Primary Outcomes	Secondary Outcomes
<ul style="list-style-type: none"> • Increase in client retention in HIV primary care • Improvement in the following client outcomes: <ul style="list-style-type: none"> ○ HIV viral load ○ Housing stability and food security ○ Engagement in behavioral health treatment (Substance use disorder; Mental health) • Increase in client satisfaction with care 	<ul style="list-style-type: none"> • Increase in client: <ul style="list-style-type: none"> ○ HIV knowledge ○ Awareness of community resources and ways to access resources ○ Adherence to existing antiretroviral ARV prescription, for those prescribed ARV ○ Adherence to new ARV prescription, for those not prescribed ARV

Overview of Data Collection Tools

The table below provides an overview of the purpose, frequency of collection, and person responsible for each of the data collection tools.

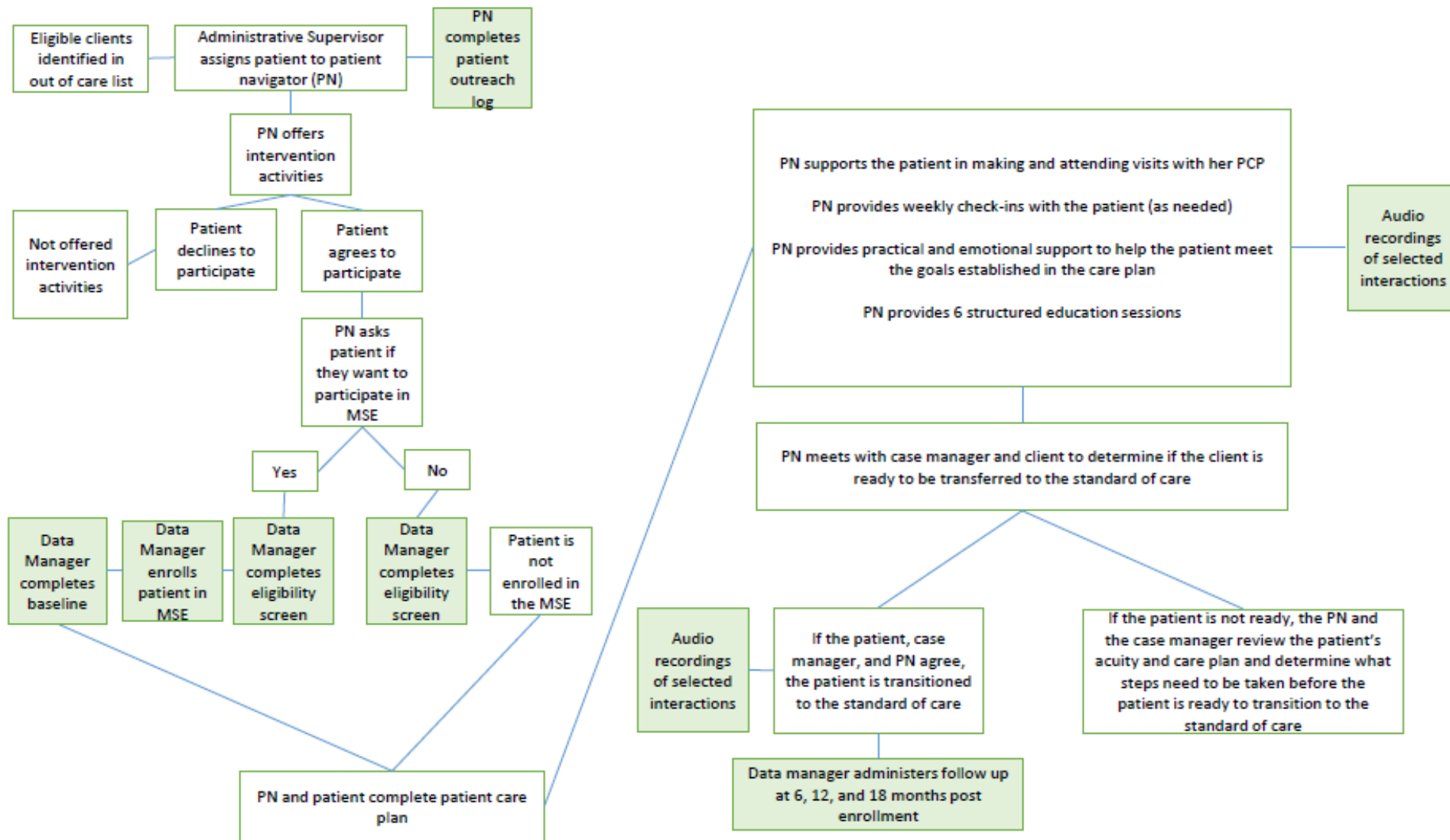
Data Collection Tool	Purpose	Frequency of Data Collection	Study Staff Responsible
Participant Questionnaires	To collect self-report data on: <ul style="list-style-type: none"> • Demographics • Health literacy • Self-efficacy 	<ul style="list-style-type: none"> • Baseline interview • Follow-up interview at 6, 12, and 18 months 	Data Manager

	<ul style="list-style-type: none"> • Unmet needs • HIV stigma • Satisfaction with services 		
Participant Chart Review Tool	<p>To collect primary outcome data on:</p> <ul style="list-style-type: none"> • CD4 lab values • Viral load lab values • HIV primary care visits and other medical and behavioral health visits • Medications • Preventive care screenings • Emergency room and hospital usage 	<ul style="list-style-type: none"> • 6 months after enrollment • 12 months after enrollment • 18 months after enrollment 	Data Manager
Participant Encounter Form	To document and describe the types of activities interventionists are conducting with participants, where they are conducting them, how they are conducting them, and with whom they are conducting them.	<ul style="list-style-type: none"> • One per day on which an encounter was made 	Patient Navigators
Audio Recordings	To record the core components of the intervention	<ul style="list-style-type: none"> • The DCC will generate a list of clients to record each month. Record every interaction with those clients throughout the month. 	Patient Navigators

Evaluation Timelines

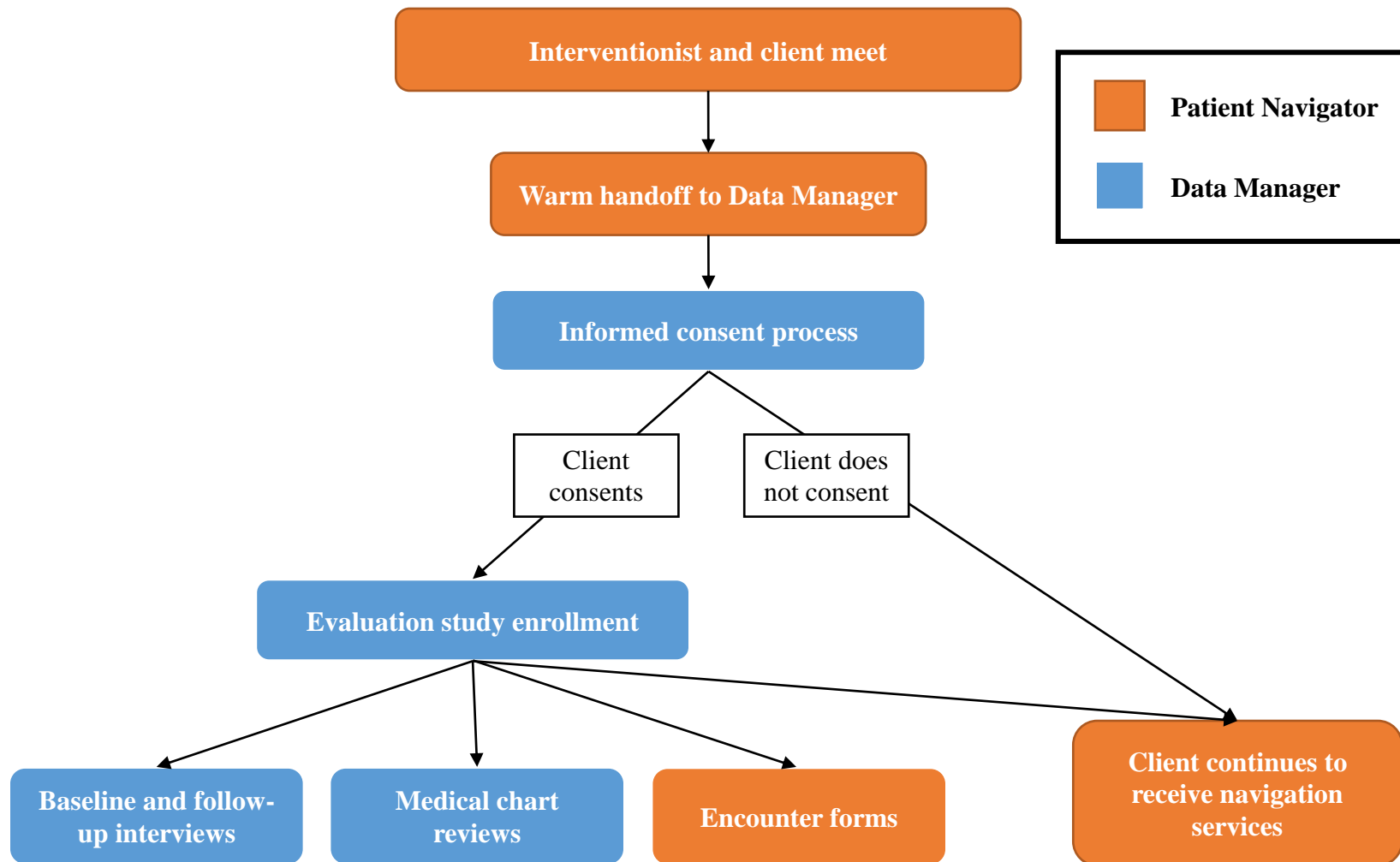
Time Points to Administer Data Collection Tools				
	At Enrollment	6 Months After Enrollment	12 Months After Enrollment	18 Months After Enrollment
Data Collection Tool	Baseline Questionnaire	6 Month Follow Up Questionnaire Medical Chart Review Tool	12 Month Follow Up Questionnaire Medical Chart Review Tool	18 Month Follow Up Questionnaire Medical Chart Review Tool

Enhanced Patient Navigation Activities



Key:
 PN – Patient Navigator
 MSE - Multi-site evaluation study

DEII Evaluation Flow Chart



Enhanced Patient Navigation Evaluation Checklist

Pre-implementation Phase (6/1/2016 – 9/1/2016)

- Participate in Organizational Readiness to Change Assessment
- Participate in pre-implementation site visit and complete pre-implementation site visit report
- Participate in monthly monitoring calls with ITAC and DEC
- Obtain IRB approval and necessary Data Use Agreements

FAQ: What is a data use agreement? Do I need one?

Answer: Data Use Agreements (DUAs) are contractual documents used for the transfer of nonpublic data that is subject to some restriction on its use. DUAs serve to outline the terms and conditions of the transfer. Specifically, DUAs address important issues such as limitations on use of the data, obligations to safeguard the data, liability for harm arising from the use of the data, publication, and privacy rights that are associated with transfers of confidential or protected data. The understanding established by a DUA can help avoid later issues by clearly setting forth the expectations of the parties (provider and recipient).

- BU does not require that you create a data use agreement (we hold a reactive position to requests). You'll have to check with your institution to see if your institution requires one.

FAQ: People at our site speak a different dialect than the one captured on the Spanish translation. What should we do?

Answer: You can have the documents translated into the dialect spoken in your region, and have those materials approved by your IRB.

FAQ: Some of our clients speak other languages (such a Haitian Creole). Will you be translating the materials into other languages?

Answer: No. You will need to hire an interpreter to complete the interview.

Start-up Phase (9/1/2016 – 1/1/2017)

Daily (dependent on participant enrollment, participant interactions, and transition to the standard of care):

- Screen client for multi-site evaluation eligibility
- Consent participant into the multi-site evaluation study
- Conduct baseline interview
- Conduct follow-up interviews
- Complete the encounter forms
- Collect audio recordings of selected participant and intervention staff interactions

Monthly:

- Participate in monthly monitoring calls with ITAC and DEC
- Participate in monthly cohort calls with ITAC and DEC

Implementation Phase (1/1/2017 – 8/31/2019)

Daily (dependent on participant enrollment, interactions, and transition to the standard of care):

- Screen client for multi-site evaluation eligibility
- Consent participant into the multi-site evaluation study
- Conduct baseline interview
- Conduct follow-up interviews
- Complete the encounter forms
- Collect audio recordings of selected participant and intervention staff interaction

- Complete medical chart abstraction (6, 12 & 18 months after enrollment)

Monthly:

- Participate in monthly cohort calls with ITAC and DEC

Quarterly:

- Participate in quarterly site calls with ITAC and DEC

Annually:

- Participate in site visits
- Participate in key informant interviews (conducted at site visits and throughout three-year study period)

Recruitment and Warm Handoff

How are participants recruited into the evaluation study?

Each site will develop a site-specific referral protocol during the pre-implementation phase of the initiative. Eligible clients may be identified by their primary care provider or other providers at the site and may be referred to participate in the evaluation. Clients also may be self-referred or be referred by any provider in the community. The Patient Navigator Administrative Supervisor will use the out-of-care list to screen eligible patients and the administrative Patient Navigator supervisor assigns eligible patients to the Patient Navigator. The Patient Navigator will make contact with her assigned patients via phone, an in-person meeting, or email (if clinic permits email communication between the Patient Navigator and the patient). During this initial meeting, the Patient Navigator will describe the services provided by the intervention, and if the patient is interested in receiving intervention services, the Patient Navigator will introduce the multi-site evaluation.

What is the “warm handoff”?

The “warm handoff” is when the Patient Navigator introduces the client to the intervention’s Data Manager so that the Data Manager can consent and enroll the client into the evaluation study.

Who conducts the warm handoff?

The Patient Navigator is responsible for the warm handoff.

When does the warm handoff happen?

The warm handoff should take place immediately after the client has met with the Patient Navigator, the Patient Navigator has introduced the idea of the evaluation study, and the Client has expressed interest in participating in the multi-site evaluation.

Steps for conducting the warm handoff:

STEP 1: Patient Navigator provides a brief overview of the intervention project and evaluation activities. The following recruitment script may be used.

“[NAME OF ORGANIZATION] is one of 12 organizations across the country trying to connect people with HIV to medical care and help them stay in care. The information you provide to us will help us to improve care and services for people living with HIV now and in years to come.

If you agree to participate in the study, we will ask you to participate in three interviews to find out about your experience with our program, getting the HIV medical care and other services you need, and to learn about any other changes in your health.

The information provided to us will not be traced to you. Your responses will be given a code that is not traceable to your name. Only selected staff at [NAME OF ORGANIZATION] will know you are part of the study. Your responses will be combined with participants from the other sites across the country with no names attached to this information. Each interview will take about 1 hour. Your decision to participate in the study or not will not impact the quality or amount of services you will receive at this clinic. You do not need to participate in the study to receive services.”

FAQ: Can we enroll individuals who do not want to receive primary care at our site?

Answer: The goal of this project is to design packaged interventions that can be picked up and implemented at future Ryan White (RW) clinic sites. Other RW clinics will not be interested in engaging or re-engaging clients in a clinic that is not their clinic. Other RW clinics may make the referral but they want to engage clients in their own clinic sites. The interventions are designed to engage and re-engage clients into the clinic site where the interventionists are employed and part of the clinic team. We want to capture the encounter data that documents the work conducted by the interventionist to engage and/or re-engage these clients to link or retain the client in their sites clinical care.

- If the client had a bad experience at the clinic, it is our hope that this intervention will turn that around. If the client chooses to go to another clinic before initiating the intervention activities, then she will not be enrolled in the multi-site evaluation.
- If the client decides to transfer her care elsewhere after being part of the intervention and the multi-site evaluation, we will record that as transferred care and she is no longer part of the intervention.
- As for sister clinics – If the clinic is part of the same system (like a hospital system) and is the appropriate place for HIV care then it is fine. The interventions are not designed to support clients linking to other HIV care clinics that are not affiliated to the funded clinics.

STEP 2: Patient Navigator asks the client if they are interested in participating in the evaluation study.

IF YES	IF NO
<p><i>“The next step to participate in the evaluation is to meet with the program’s Data Manager. This person will be able to explain more details about the study, will administer a survey, and will be responsible for reporting all data from [NAME OF ORGANIZATION]. This person is responsible for these tasks so that you can honestly tell us about your experience, and you can be assured that your responses will never affect the quality or quantity of services you receive from the care team at [NAME OF ORGANIZATION].”</i></p> <p><i>“Do you have any questions about the role of this Data Manager?”</i></p> <p><i>“Do I have permission to give your name and contact information to the Data Manager so that they can make an appointment to meet with you about the evaluation?”</i></p>	<p><i>“Thank you for listening to me about the project evaluation. You are still eligible to receive services at [NAME OF ORGANIZATION] and I look forward to continuing to work with you so that we can accomplish your goals and support your engagement in HIV care.”</i></p> <p style="text-align: center;">STOP HERE.</p> <p>Continue working with participant but do not refer for enrollment into the evaluation.</p>

FAQ: When a potential participant asks why we are doing an evaluation, what should I say?

Answer: Here is an example of one response that you could provide:

The only way that we can improve services for people living with HIV is to ask them about their experience with programs like this one, and ask them for their opinions about how we can improve. One of our goals is to learn lessons about the best ways to provide care and improve outcomes for people living with HIV. We are also with national partners to create a manual on how to run a program like this. We hope that the manual will make it easier for clinics across the country to implement this program. In order to create a really strong manual for others, and increase the number of clinics that are able to offer this program, we’d appreciate you telling us about your experience living with HIV and experience in this program.

STEP 3: Patient Navigator notifies the Data Manager

The Patient Navigator will schedule a time for the client to meet with the Data Manager, preferably before the client leaves the clinic or as soon as possible (must happen within 7 days).

- While the Patient Navigator is waiting for the Data Manager to meet with the client, the Patient Navigator can begin to work with the client to address the client’s immediate needs.
- The Data Manager and intervention staff should have regular meetings/team huddles so that the Patient Navigators can let the Data Manager know when they are going to meet with new clients.

STEP 4: Patient Navigator and Data Manager meet with the client to conduct the warm handoff so that the Data Manager can initiate the informed consent and enrollment process.

Informed Consent and Enrollment Process

What is the informed consent and enrollment process?

After the Patient Navigator has completed the warm handoff, the Data Manager will consent and enroll the participant interested in the evaluation study. Informed consent is a process in which the participant grants permission, with knowledge about the possible risks and benefits, to the Data Manager to collect study data about the participant. After receiving informed consent from the participant, the Data Manager verifies that the participant meets the evaluation study eligibility criteria and enrolls the participant into the evaluation study.

Who conducts the informed consent and enrollment process?

The Data Manager conducts the informed consent and enrollment process.

When does the informed consent and enrollment process happen?

The informed consent and enrollment process takes place immediately after the Patient Navigator has referred the participant to the Data Manager. If the participant is unable to meet with the Data Manager immediately after referral, the informed consent and enrollment process should be scheduled to take place no more than 7 days after referral. The study enrollment visit can be scheduled with the participant to take place in the clinic or in the field.

FAQ: What if I miss the 7 day window between introducing the study and intervention to the participant and completing the consent and baseline interview?

Answer: You cannot complete the consent and baseline after this 7 days window. Code the reason for not obtaining consent as – “Discretion of study staff: Other (specify)”, and specify: “missed the 7 day window for enrollment”.

If you obtain informed consent but do not complete the baseline questionnaire with the participant you will have 7 days to complete the baseline questionnaire before you are required to re-consent the participant in order for them to participate in the evaluation.

When is a participant considered enrolled in the evaluation study?

A participant is enrolled in the evaluation study when two criteria are met:

1. Signed informed consent is obtained, **and**
2. The baseline questionnaire has been completed and entered into REDCap.

Materials to have on hand prior to beginning the informed consent and enrollment process:

- Two copies of the informed consent form
- Two copies of the HIPAA authorization form (as applicable)
- Computer with internet access
- Master ID list
- Hard copy of the eligibility and enrollment form
- Hard copy of the baseline questionnaire
- Pens
- Snacks

Who should be offered and consented into the study?

- All participants referred from internal staff and external partner agencies who meet the eligibility criteria for the study.

Is there a time when I may not enroll a person?

- If a person expresses that he/she does not want to participate and does not sign the consent form (verbal agreement does not equal consent).

If you do not believe a patient is able to grant informed consent or lacks decisional capacity (e.g. because of being drunk or high, or otherwise indicates lack of coherence to consent).

What happens if the person is a good candidate but is not sure about participating in the study? Can I re-approach at a later date?

- A person can be approached a maximum of two times to enroll in the study. If at first a person appears to be reluctant or wants to think about it, ask for permission to contact the person in 2-3 days and see if he/she would like to reconsider. However, there should not be intensive service delivery with the person until the eligibility and consent is determined, if possible. If encounters are provided—documentation of activities by staff should be recorded in some form (CAREWare, paper files, logs, etc.).

Important considerations prior to beginning the informed consent and enrollment process:

- Be sure to find a private, space to conduct the interview so that confidentiality is assured.
- The participant must be able to consent on her own behalf.
- If the participant is unable to read, make sure an impartial witness is present during the entire informed consent process. The impartial witness should be someone with adequate reading ability who is not affiliated with the evaluation study. The impartial witness should be willing to attest to this by signing the informed consent form.
- Ensure you have enough time to conduct the entire informed consent and enrollment process. If you obtain informed consent but do not complete the baseline questionnaire with the participant you will have 7 days to complete the baseline questionnaire before you are required to re-consent the participant in order for them to participate in the evaluation.

FAQ: Can someone not at all involved in the project be involved in consenting people in to the intervention and conducting the interviews?

Answer: Ideally we want it to be the data manager because they're the least likely to have any direct involvement in the client's care, but we recognize that it's not always possible to meet with the data manager. We ask that the backup be the person with the next least likelihood of direct involvement with client care who is not one of the interventionists. Even if the site asks a case manager who is not involved in the intervention to consent folks, that case manager could have some decision making power over the client's care, which could be viewed as coercive.

Steps for conducting the informed consent and enrollment process:

STEP 1: Inform the participant about the evaluation study.

The following script is an example of what the Data Manager can say to explain the study. Please make sure it matches the language in the site's IRB-approved consent form and protocol.

"[Name of Organization] is one of twelve agencies across the country trying to connect people with HIV to medical care and help them stay in care. The information you provide to us will help us to improve care and services for people living with HIV now and in years to come. If you agree to participate in the study, we will ask you to participate in four interviews over the next two years to find out about your experience with our program, getting the HIV medical care and other services you need, and to learn about any other changes in your health. The information provided to us will not be traced to you. Your responses will be given a code that is not traceable to your name. Only selected staff at (name of organization) will know you are part of the study. Your responses will be combined with participants from the other sites across the country with no names attached to this information. Each interview will take less than 1 hour and you will receive a gift card of \$XX for your time. Your decision to participate in the study or not, will not impact the quality or amount of services you will receive at this clinic. You do not need to participate in the study to receive services."

STEP 2: Obtain informed consent.

1. The Data Manager at the site should start the informed consent process as follows:

"I'm going to start the informed consent process now. I will tell you details about participating in the evaluation

study, and I will explain the potential risks and benefits of participating to you. I will also answer any questions that you have about participating. When we are finished you can tell me what you would like to do."

2. The Data Manager will give the participant an unsigned copy of the informed consent form and explain the study in detail. The Data Manager will review the following sections of the consent form at a minimum:
 - Purpose
 - What will happen in this multi-site evaluation
 - Risks and discomforts
 - Potential benefits
 - Costs to the participant
 - Incentives to the participant
 - Confidentiality
 - Participant's rights, including the right to withdraw at any time from the study
 - Who to contact for questions
3. The Data Manager will give the client time to read the consent form in detail. If the client does not want to read the consent form or is unable to read, the form must be read to him or her verbatim in its entirety. If the client is unable to read, an impartial witness must also be present.
4. The Data Manager will ask the participant if she has any questions about the evaluation study. The Data Manager will answer all questions.
5. If the client agrees to participate in the evaluation study, she will provide informed consent by printing their name, signing, and dating the consent form. The Data Manager will also print, sign, and date their name on the consent form. If an impartial witness was present for the informed consent process they will also print, sign, and date their name on the consent form.

If the client does not agree to participate in the evaluation study, the Data Manager stops the informed consent and enrollment process. The Data Manager will inform the client that she is still eligible to receive intervention services.

6. The Data Manager will introduce the audio recording portion of the study and receive the necessary signed and dated consent for this portion of the multi-site study.
 - a. A person can participate in the baseline and follow-up interviews without participating in the audio recording, but they cannot participate in the audio recording without also participating the baseline and follow-up interviews.
 - b. If a client declines to participate in the audio recording portion of the study, the Data Manager should document the reason for the client declining to participate.

FAQ: If someone does not consent at the beginning but then later does agree to be audio recorded, but agrees to it later, how do you get the consent?

Answer: The participant will need to fill out the audio recording consent form at that point. It might be a good idea just to have those on hand with you when you expect to be with participants.

FAQ: How long will the BU Data Coordinating Center keep audio recordings for?

Answer: The BU Data Coordinating Center will destroy audio recordings after 12 months (12 months after the audio recordings have been uploaded).

7. The Data Manager will make a copy of the signed consent form and provide it to the participant. Two signed copies of the consent form are needed: one for the participant and one for local site. The hard copy consent forms should be stored in a secured locked filing cabinet along with participant contact information. Be sure to give the participant a copy of the signed consent form. If the participant does not want a copy, honor this and tell the participant she can request a copy at any time. If this happens, note it on the consent form.
8. Secure the signed consent form in a locked cabinet at the site separate from any identifiable data belonging to the participant.

It is strongly recommended that all of these steps be completed with the Data Manager during the client’s initial intervention/program intake visit (re-engagement if client has been out of care) in care. If it is not possible to consent and enroll the participant during the seven days after her initial visit and the participant does **not** receive SPNS intervention services, this participant may be re-considered and referred to the study at a later date (as long as the participant meets eligibility criteria at that later date).

Participants that are enrolled into the multi-site evaluation should **be offered services from SPNS intervention staff within one week of** completing the baseline interview. **A SPNS intervention service is defined as an encounter by the intervention staff with or on behalf of a participant to address a client’s HIV medical or service needs.** SPNS intervention services do not include activities to initially refer a participant to the SPNS program (i.e. referrals to the Data Manager).

IMPORTANT

Prior to enrolling in the multi-site evaluation, the individual receiving services is referred to as a client. After they have enrolled, this individual is referred to as a participant (participant of the multi-site study).

A SPNS participant is enrolled in the multi-site evaluation once she has signed the consent form AND completed the baseline interview.

STEP 3: Generate a unique study ID for the participant.

To generate the participant’s unique study ID, the Data Manager will complete the web-based eligibility and participant information form on the DCC tracking website.

ALL clients referred to the SPNS project should be offered to participate in the multi-site evaluation and have a completed an eligibility form. The web-based system will automatically generate a unique 4-digit participant ID for all participant who are deemed eligible and have signed a consent form.

The Data Manager will note the number of times that an interventionist attempted to reach out to a participant or offered any intervention services prior to the date of consent. SPNS intervention services provided to participants prior to multi-site evaluation consent should be documented in a separate local data base system.

1. The Data Manager will click on the “Add New Participant” button on the DCC tracking website, which will direct the staff person to an eligibility form.
2. On the web-based eligibility form, the Data Manager must confirm two criteria by selecting “Yes” to both eligibility checks:
 - Eligibility Check # 1: The participant has met the program’s site-specific eligibility requirements for the evaluation, which at a minimum should include:

- The participant is 18 years of age or older,
- The participant is diagnosed as HIV-positive,
Acceptable documentation of HIV infection includes:
 - Positive HIV antibody test results
 - Documentation of detectable HIV viral load results
 - Physician (M.D., N.P., P.A.) signed/written statements/progress notes
 - Photocopy of enrollment card for the AIDS Drug Assistance Program (ADAP)
 - Photocopy of enrollment card for an HIV Specialty Care program
 - Other medical form documenting HIV status.
 - Participant Self-report (due to the transient nature of the participant population, services are initiated pending HIV/AIDS diagnosis documentation.)
- Exclusion criteria:
 - Individuals who do not have an HIV/AIDS diagnosis.
 - Individuals who are retained in care.
 - Individuals who do not identify as female and WoC
 - Individuals who are not patients at the clinic
- Eligibility Check # 2: The participant has provided a signed consent to participate in the evaluation.

3. Once both eligibility checks have been verified, the Data Manager will be prompted to enter information about the participant: first name, last name, preferred name, date of birth (DOB), and enrollment date (today's date).

After entering the participant information, the Data Manager will hit "Save" at the bottom of the form and a unique participant ID will be generated. The web-based system will advise the Data Manager to write down this participant ID. Record this unique participant ID onto the master ID list, a template of which is provided in appendix J of this protocol.

This will allow the Data Manager to follow up with the participant for subsequent interviews and complete the chart reviews. The participant ID will also need to be shared with the interventionists network Patient Navigators so that encounters can be documented for study participants.

The web-based system allows the Data Manager to print the eligibility form as a pdf, and the pdf copy should be saved in the Data Manager's records. An email will also be generated and sent to the appropriate staff member on the intervention team once the form is completed.

FAQ: The PI is supposed to sign off on the printed version of the enrollment form but there is no designated place to sign. Where should the PI sign?

Answer: The PI can sign anywhere on the form.

STEP 4: Administer the baseline questionnaire (more details in the next section).

The Data Manager will use the baseline interview available through the Data Coordinating Center link and will follow the question by question script in this document when interviewing each participant.

1. The Data Manager will login to REDCap to access the baseline questionnaire, opening the REDCap project.
2. The Data Manager will click on "Add/Edit Records" in the toolbar on the left-hand side of the screen.
3. The Data Manager will enter the participant ID generated in STEP 3 of the informed consent and enrollment process into the "Enter a new or existing Participant ID" field.
4. A page showing all the possible forms for the participant at each time point will become available. The Data Manager will click on the grey bubble for the baseline questionnaire.

5. The Data Manager will administer the baseline questionnaire following the guidelines in the “Using Evaluation Study Data Collection Tools: Participant Questionnaire” section of this protocol.

Participant Questionnaires (Baseline and Follow-Up)

What is the purpose of the participant questionnaires?

The purpose of the participant interview is to gather information about the participants served by the SPNS interventions/programs in order to assess the effectiveness of the interventions in achieving the primary outcomes of the initiative based on the HIV/AIDS Care Continuum.

Data collected through the participant questionnaire includes:

- Demographics & background characteristics
- Housing
- HIV & adherence
- Case management & competing service needs
- Substance use
- Exposure to violence/victimization
- Health-related quality of life
- Patient feedback (collected during both follow-up interviews)

Who administers the participant questionnaires?

The participant questionnaires are administered by the Data Manager. All baseline interviews must occur in person (on-site or in field) with the Data Manager. **BU CANNOT ACCEPT PARTICIPANT SELF-ADMINISTERED QUESTIONNAIRES OR PORTIONS OF AN INTERVIEW. ALL SECTIONS MUST BE INTERVIEWER-ADMINISTERED.**

How long does it take to administer the participant questionnaires?

It takes approximately 60 minutes to complete the participant questionnaires.

How are participant questionnaires submitted?

Participant questionnaires are submitted online through REDCap.

When are the participant questionnaires administered?

Questionnaires can be completed at any time during the window. In other words, you can start an interview with a participant on the first day of the window and finish the interview with the participant on the last day of the window. However, we encourage evaluation staff to complete the questionnaires with participants in one sitting.

Windows around each time point (Peers, Navigation, Buprenorphine)

Time point	Target Date	Window Opens	Window Closes
Baseline visit	Consent date		7 days after target (10 days for <u>bup</u>)
Follow-up visits		30 days before target	45 days after target
Chart reviews			
6m	First day of (Enrollment date + 6m)	Target date	60 days after target
12m	First day of (Enrollment date + 12m)	Target date	60 days after target
18m	First day of (Enrollment date + 18m)	Target date	60 days after target

What happens if I get through consent and part of the interview but not completely?

We strongly recommend that you complete the baseline interview at the time of the consent process. No incomplete interviews will be accepted. Some tips to make the process smooth and engaging:

- Before starting the interview, advise the participant that the interview will take approximately 1 hour. Give the participant the option to reschedule the interview appointment to complete the questionnaire.
- Bring snacks and/or a beverage for the participant. If the participant has children have materials such as toys. Remind the participant that there are personal questions on the survey and that they might not want to have their children in the room with them.

If it is not possible to complete the interview on the same day:

- Save the form as an “incomplete record”. REDCap will leave any incomplete sections “red” and sections that are not started as white. se
- Go to the tracking/scheduling form; enter “partially completed” or “not done” and the reason for not completing the interview.
- Reschedule with the participant in the next 2-3 days to complete the interview questionnaire. When you log-in into the system REDCap search for the participant ID. When you select the participant ID, REDCap will automatically have saved any recorded data for that participant. The system cannot delete records for a participant ID and assign a new ID once the eligibility form has been completed.
- **CONTACT the BU team** with any questions/concerns!

IMPORTANT

Participants with incomplete baseline interview data will not be able to remain in the study.

What materials should be available prior to administering the participant questionnaire?

- A computer with Internet access to enter the web-based participant interview form on REDCap.
- A hard copy of the participant questionnaire and eligibility forms in case Internet access or REDCap is not working. The eligibility criteria form should appear as the first page of the participant baseline questionnaire in hard-copy versions. If data is collected on paper forms, completed forms must be stored in the corresponding participant’s study record located in a locked file cabinet that is accessible only by the Data Manager, and is stored separately from the participants’ medical records.
- The participant’s unique study ID (from the DCC tracking website).
- **Incentive and Waiver for Receipt of Incentive (if applicable):** Upon completion of the interview, the Data Manager will give the participant compensation. This compensation **cannot be a monetary reward** (i.e. cash, checks, etc.). The provision of compensation be documented, and the participant should sign the ***Waiver-for-receipt of compensation*** to acknowledge receipt of the compensation and that it will not be used for alcohol, firearms, or tobacco products. The documentation of the compensation should be kept with all study records in a locked, password protected file (if electronic) and stored with the copies of the participant’s consent form.
- Some participants may have trouble remembering dates or time frames. Use a calendar and/or prompt the participant by referring to times of the year or events, e.g. “Was it around the new year?” or “Was it before Barack Obama was elected president?”
- Bring appointment cards to give the participant a reminder of when the next follow-up interview will be.

General Guidelines for Administering the Baseline and Follow-Up Questionnaires

- All questionnaires must occur in person with the Data Manager. Patient Navigators are not allowed to administer questionnaires.
- The Data Manager should administer the baseline questionnaire only after confirming eligibility and obtaining signed informed consent from the participant at the time of enrollment into the evaluation study.
- Read questions and response options as indicated in the questionnaire. DO NOT READ the response option “Refused” to the participant.
- Mark a response option for each question; if the participant does not want to answer a question mark “Refused.”
 - Some items do not include response options “Refused” or “Don’t know.” These items are part of validated scales which we are not able to adapt in any way – for this reason we cannot include additional response

options such as “Refused” or “Don’t know.” For these items, it is acceptable to leave the response as blank and move on to the next item.

- For some validated scales such as the self-efficacy and quality of life you may want to prepare visual response options to help the participant with their answers.
- For “Other” response options, be sure to ask the participant to describe in their own words their answer and record EXACTLY what the participant says. The responses will be recoded or used to create new response options if necessary.
- Breaks are recommended between sections 5 and 6. If the participant requests to take a break at any other point of the interview ask if she minds waiting until the end of whatever section you are in the process of completing.

Reading Response Options. Throughout the interview several of the questions include response options that are italicized, such as “*Refused*”, “*Don’t know/Unsure*”, and “*Unknown*.” Do not read any of these italicized response options out loud for the participant. Italicized text **besides** response options can (and should) be read out loud.

Notes for the interviewer begin with “*Interviewer:*” and are italicized; they are instructions for you and are not to be read aloud.

Continuing to Next Question. After entering a response to a question, press “Tab” button on your keyboard to continue to the next question (or click on the next question with you mouse). Do not press the “Enter” or “Return” buttons on your keyboard to continue to the next question – this will save the page you are working on and take you back to the homepage.

Form Status. This section appears at the bottom of each page of the interview. If you have to return to the page after verifying certain information, select “Unverified.” Once you have completed the page to the extent possible, select “Complete.”

- Click “Save Record” to save the information entered on this page and go back to home page.
- Click “Save and Continue” to save the information entered on this page and remain on this page to continue working.
- Click “Save and go to Next Form” to save the information entered on this page and move onto the next section (i.e. page) of the questionnaire.

FAQ: When initially filling in the participant form I always enter the 6 month follow-up interview date at that time. So my question is if the follow-up interview is completed prior to or after that date, should the date be changed to represent the date the follow-up interview was actually completed?

Answer: Yes, please update the Participant form to reflect the date the 6m was actually done.

FAQ: If a patient enrolls in the MSE, falls out of care for multiple months, and then resurfaces, should we do another consent and baseline for them?

Answer: No! Once someone is enrolled, they cannot be “reconsented”. You will pick up right where they left off and offer them the appropriate survey (indicated by the participant tracking report)

General Guidelines for Navigating the REDCap Questionnaire

These are general guidelines for using the participant questionnaire in REDCap. More detailed information can be found in the manual titled “Training Manual for Using the REDCap System.”

- **Continuing to the next question.** After entering a response to a question on the participant questionnaire, press the “Tab” button on your keyboard to continue to the next question (or click on the next question with your

mouse). Do not press the “Enter” or “Return” buttons on your keyboard to continue to the next question – this will save the page you are working on and take you back to the homepage.

- **Form Status.** This section appears at the bottom of the questionnaire in REDCap. If you have to return to the page after verifying certain information, select “Unverified.” Once you have completed the page to the extent possible, select “Complete.”
 - Click “Save & Exit Form” to save the information entered on this page and go back to the home page of REDCap.
 - Click “Save & Stay” to save the information entered on this page and remain on this page to continue working.

Section by Section Guidance for the Participant Questionnaire

Participant Interview Administration: Beginning the Interview

Enter Interview Information. All of the following information must be entered into the Data Coordinating Center’s online system prior to conducting interview:

- Select the demonstration site with which you are affiliated.
- Enter your 3-digit Staff ID assigned by BU.
- Enter the date of the interview in the MM-DD-YYYY format. Alternatively, you can click on the calendar to the right of the textbox and click on the date of the interview. A red warning message, “Please enter the form date before continuing,” will appear until you have entered the baseline form date. An ERROR message will also appear for Q1 which will restrict you from continuing the interview if the baseline form date is missing.

Data Manager Script:

Thank you for agreeing to participate in this study. We are going to cover many topics, including your health, your needs, and your experiences with HIV health care. Some of these questions may be about things you’ve already discussed with other people at [NAME OF ORGANIZATION]. We are asking you again because this interview is part of a national study that includes people living with HIV from different parts of the country. The data we collect in this survey will not be shared with anyone providing services.

Everything I ask you in this interview is confidential. We would like you to feel comfortable, and be as honest and open as possible. None of your answers will be linked to your name, so please be candid. We hope this study will help us to improve care for people living with HIV.

If a question makes you feel uncomfortable, or brings up feelings or situations you want to talk about, we can refer you to someone you can speak with. Also, if there are any questions you don’t feel comfortable answering, you don’t have to answer them.

This interview will take less than 1 hour. If at any time you would like to take a break, please let me know. After each question I will read you response options to choose from. As I go through the questions, let me know if there is anything that is unclear. Are you ready to begin?

Baseline Questionnaire

Section I: Demographic & Background Characteristics

Q1. *Date or Year of Birth.* Enter the two-digit month, the two-digit day and the four-digit year for the participant’s date of birth (MM-DD-YYYY).

Q2. *Current Gender Identity.* Ask the participant to choose one of the response options for current gender identity.

Q3. *Hispanic, Latino/a, or Spanish origin.* Ask if the participant considers herself to be of Hispanic, Latino/a or Spanish origin.

Q4 a-e. *Racial/Ethnic Background.* Ask the participant to answer “yes” or “no” to each of categories listed.

Q5. *Language.* Ask the participant which language she speaks the majority of the time with family and friends. If the participant responds that she is bilingual, ask if there is one language they prefer; or if they continue to say bilingual mark “Other” record bilingual and the respective languages.

Q6. *Birth Country.* Ask the participant what country she was born in.

Q7. *Education.* Ask the participant what the highest level of education is that she has completed.

- “Some college” refers to having completed some (but not all) of a four-year college or university program
- “College graduate” refers to completion of a four-year college or university program.

Q8. *Household.* Ask the participant to describe her household by telling you how many adults and dependents (children, elderly, or individuals living with disabilities that are legally dependents) she lives with.

Q9. *Children.* Ask the participant to describe how many children under the age of 18 she lives with.

Q10. *Basic Necessities.* Ask the participant to choose the one response option that she feels most accurately describes how frequently she has run out of basic necessities in the past six months.

Q11. *Jail.* Ask the participant how many times she has been in jail in the past five years, even if it was just for one night. If response is none or never enter “0”. If the participant reports that she has been in jail or prison, mark the number of times in Q11a and/or Q11b.

Q12. *Insurance.* Record the kind of health insurance the participant has and make sure to check all that apply. If the participant mentions a local Medicaid plan i.e. MEDI-CAL, please check "Medicaid". If you are unsure if the insurance falls into a specific category, just mark "Other" and fill in the name of the insurance mentioned by the participant. These can be recoded at a later time. ****Ryan White is NOT considered an insurance****

Section II: Housing

Q13. *Live Now.* Ask the participant where she lives right now. Record one response.

Q14. *Locations of Stay.* Ask the participant if in the past 12 months there was a time even for just one night where s/he had no place to stay.

Section III: HIV & Adherence

Q15. *Date of HIV Diagnosis.* Enter month, day, and year for when the participant first tested positive for HIV (MM-DD-YYYY). Alternatively, you can click the calendar button to the right of the text box, choose the month and year in the drop down menus, and click the day that the participant was diagnosed. If the participant cannot recall the month enter “01,” if the participant cannot recall the day enter “01.” If the participant cannot recall the exact year, prompt by asking if she recalls approximately how old she was and/or if she can recall other life events that took place around the same time.

FAQ: What if someone doesn't know the exact date of their diagnosis, and they only know their year of diagnosis?

Answer: Enter January 1 as the date, and then enter the year that the patient reports.

Q15a. *Perinatal Infection.* Ask the participant if she were infected perinatally (at birth)?

Q16. *Currently Taking HIV Medications.* Ask the participant if she is presently taking HIV medication.

Section IV: Case Management & Competing Service Needs

Q17. *Case Manager*. Ask participant if she has a case manager at this clinic that helps with medical OR social services—including HIV health care and housing services (****This is NOT the intervention staff, i.e. the peer, enhanced Patient Navigator, the buprenorphine coordinator or the jails intervention care coordinator or the jail community case manager****).

Q18-19. *Service Needs*. Ask the participant whether she has needed each of the listed services (Q18a-g) in the past 6 months. For each of these items that the participant responds "Yes", ask the follow-up question that appears (Q19a-g), i.e. if the participant was able to receive the service needed. Follow this process for each of the listed services (Q19a-g).

BREAK: Ask the participant if she would like to take a break. The participant can use this opportunity to use the restroom, have a snack, or drink some water. If she feels comfortable continuing, proceed to the following section.

Section V: Substance Use

Q20-Q29. *Substance use history*. Ask the participant if she has used the substances identified in each question. Record the answer "daily or almost daily", "weekly", "monthly", "less than monthly", or "never". If the participant does not want to answer the question, mark "refused".

Q30-30a. *Substance Use Treatment*. Ask the participant if she has participated in any substance use treatment in the 3 months just before her most recent incarceration. If the participant answers "yes", ask the participant what kind of treatment. Ask the participant to listen to all of the options and record all of the responses that are applicable for the type of substance use treatments. Ask the participant if there are any other substance use treatments that she participated in, mark "other" and record the response.

Section VI: Exposure to Violence/Victimization

Before starting the section, read the following statement to the participant: The next questions are about abuse and interpersonal violence. Let me know if you would like to stop at any point. As a study interviewer, I am not permitted to discuss any specific incidents of abuse with you, but there is someone on hand who can talk with you if you would like to do so.

Q31-36. *Exposure to Violence/Victimization*. Read each question as written, and ask the participant if she has ever been experienced that situation. Record the answer "yes" or "no". If the participant does not want to answer the question, mark "refused".

Section VI: Health-Related Quality of Life

Q37. *Self-Perceived General Health*. Ask the participant how she would rate her general health during the past 4 weeks. Read the question and response options exactly as written.

Q38-40. *Health-Related Limitations to Daily Activities*. Ask how the participant's health is limiting her daily activities during the past 4 weeks. Read each question and its corresponding response options exactly as written.

Q41-44. *Emotional Well-Being*. Ask about the participant's energy level, how the participant's physical and/or emotional health is limiting her daily activities, and the impact of her personal or emotional problems during the past 4 weeks. Read each question and its corresponding response options exactly as written.

Section VII: Additional Information

Q45. *Any other information*. Ask the participant if she would like to share anything else about her experience living with HIV. Record the response as accurately and completely as possible.

[Follow up Questionnaire](#)

Section I: Demographic & Background Characteristics

Q1. *Household*. Ask the participant to describe her household by telling you how many adults and dependents (children, elderly, or individuals living with disabilities that are legally dependents) she lives with.

Q2. *Children.* Ask the participant to describe how many children under the age of 18 she lives with.

Q3. *Basic Necessities.* Ask the participant to choose the one response option that she feels most accurately describes how frequently she has run out of basic necessities in the past 6 months.

Q4. *Jail.* Ask the participant how many times she has been in jail in the past 6 months, even if it was just for one night. If response is none or never enter “0”. If the participant reports that she has been in jail or prison, mark the number of times.

Q5. *Insurance.* Record the kind of health insurance the participant has and make sure to check all that apply. If the participant mentions a local Medicaid plan i.e. MEDI-CAL, please check "Medicaid". If you are unsure if the insurance falls into a specific category, just mark "Other" and fill in the name of the insurance mentioned by the participant. These can be recoded at a later time. ****Ryan White is NOT considered an insurance****

Section II: Housing

Q6. *Live Now.* Ask the participant where she lives right now. Record one response.

Q7. *Locations of Stay.* Ask the participant if in the past 6 months there was a time even for just one night where she had no place to stay.

Section III: HIV & Adherence

Q8. *Currently Taking HIV Medications.* Ask the participant if she is presently taking HIV medication.

Section IV: Case Management & Competing Service Needs

Q9. *Case Manager.* Ask participant if she has a case manager at this clinic that helps with medical OR social services—including HIV health care and housing services (****This is NOT the intervention staff, i.e. the peer, enhanced Patient Navigator, the buprenorphine coordinator or the jails intervention care coordinator or the jail community case manager****).

Q10-11. *Service Needs.* Ask the participant whether she has needed each of the listed services (Q10a-g) in the past 3 months. For each of these items that the participant responds "Yes", ask the follow-up question that appears (Q11a-g), i.e. if the participant was able to receive the service needed. Follow this process for each of the listed services (Q11a-g).

BREAK: Ask the participant if she would like to take a break. The participant can use this opportunity to use the restroom, have a snack, or drink some water. If she feels comfortable continuing, proceed to the following section.

Section V: Substance Use

Q12-21. *Substance use history.* Ask the participant if she has used the substances identified in each question in the past 6 months. Record the answer “daily or almost daily”, “weekly”, “monthly”, “less than monthly”, or “never”. If the participant does not want to answer the question, mark “refused”.

Q22-22a. *Substance Use Treatment.* Ask the participant if she has participated in any substance use treatment in the past 3 months. If the participant answers “yes”, ask the participant what kind of treatment. Ask the participant to listen to all of the options and record all of the responses that are applicable for the type of substance use treatments. Ask the participant if there are any other substance use treatments that she participated in, mark “other” and record the response.

Section VI: Health-Related Quality of Life

Q23. *Self-Perceived General Health.* Ask the participant how she would rate her general health during the past 4 weeks. Read the question and response options exactly as written.

Q24-26. *Health-Related Limitations to Daily Activities*. Ask how the participant's health is limiting her daily activities during the past 4 weeks. Read each question and its corresponding response options exactly as written.

Q27-30. *Emotional Well-Being*. Ask about the participant's energy level, how the participant's physical and/or emotional health is limiting her daily activities, and the impact of her personal or emotional problems during the past 4 weeks. Read each question and its corresponding response options exactly as written.

Section VII: Patient Feedback

Q31. *Identify Interventionist*. Ask the participant for the name of the interventionist that the participant has interacted with most frequently over the past 6 months.

Q32-41. *Interventionist feedback*. Based on the response to Q31, ask the participant to rate the interventionist identified in Q31 using response options of "poor", "fair", "good", "very good", or "excellent". If interventionist did not provide the service identified in Q32-41, mark "n/a".

Q42. *Care at the clinic*. Are the participant to identify all of the words that come to mind when thinking about her care at the clinic. Read the participant the words in the list provided on the survey, and then ask if they would like to identify additional words. Mark those additional words in the "other" write in boxes.

Q43-44. *Courtesy and respect*. Ask the participant if she was treated with respect at the clinic. If answer is "never" or "rarely", continue to question 44. If answer is "sometimes", "usually", or "always", skip to 45. For Q44, ask the participant to identify the reasons why she felt as though she was not treated with respect and courtesy by reading the response options listed. If a participant feels as though she was not treated with respect and courtesy for reasons that were not listed on the survey, write in the participant's response in "Other".

Q45-53. *Clinic experiences*. For each question listed, ask the participant for her level of agreement with the experiences at the clinic over 6 months. If the participant did not experience one of the experiences listed, mark "n/a".

Q54. *Recommending the clinic*. Ask the participant if they she would recommend the clinic to other HIV-positive patients with similar needs.

Q55. *Additional feedback*. Ask the participant if she would like to share anything else about her experiences living with HIV.

FAQ: If one of our participants went out of town and isn't going to be back until later than she initially expected, are we allowed to do the follow-up over the phone?

Answer: No! All interviews must be conducted in person. The system will allow visits to be captured out of window. You can still do the visit out of window if you are close to being within the window (i.e. don't conduct the 3 month follow-up after 6 months). We'd like the actual dates to be captured in the database.

Participant Chart Review Tool

What is the purpose of the chart review tool?

The purpose of the chart review tool is to collect outcome data related to engagement and retention of study participants in HIV care, changes in HIV clinical measures (CD4 and viral load), other medical or behavioral health visits, medications, preventive care screenings, and emergency room and hospital use.

Who completes the chart review tool?

The chart review tool is to be completed by the Data Manager.

When does the chart review need to be submitted for each participant?

The chart review tool is submitted three times for each participant once at 6 months post enrollment, once at 12 months post enrollment, and once at 18 months post enrollment.

Chart Review Target Dates

Chart Review	Window Opens	Target Date	Window Closes
6-Month	First Day of Month (Enroll Date + 6 Months)	First Day of Month (Enroll Date + 6 Months)	Last Day of Month (Enroll Date + 6 Months)
12-Month	First Day of Month (Enroll Date + 12 Months)	First Day of Month (Enroll Date + 12 Months)	Last Day of Month (Enroll Date + 12 Months)
18-Month	First Day of Month (Enroll Date + 18 Months)	First Day of Month (Enroll Date + 18 Months)	Last Day of Month (Enroll Date + 18 Months)

Note: For reference, window periods for completing chart reviews will be pre-populated on the participant’s scheduling page on the DCC tracking website.

How is the chart review tool submitted?

The chart review tool is submitted as a TeleForm online through REDCap.

Question by Question Guidance for Chart Abstraction

Prior to data collection

- From the multi-site evaluation web-based system, view or download the report, “**DECChartTrackingReport**” for a monthly list of participants who are due for 6-month, 12-month, and 18-month.
- Print the TeleForm for each participant ID listed on the “**DECChartTrackingReport**” - the system will automatically pre-populate the fields on page 1:
 - **Date of Study Enrollment**
 - **Participant ID**
 - **Site ID**
 - **Chart Review period**
- Enter the appropriate Staff ID for the person filling out the form

Tips for completing TeleForms

- Use a pen with black ink. Blue ink or pencil will not be recognized by the software.
- Print your information in upper-case letters, and avoid contact with the edge of boxes.

- Remember that the scanner will only read what is entered into the boxes. This means that anything written outside of the boxes will not become part of the study data set.
- Check boxes: completely fill in the check boxes. It is the safest way to ensure proper scanning of the field.
- Corrections: If you would like to change your answer, please line through the incorrect answer, draw an arrow to the correct answer, darken the correct square completely, and initial and date the change. Do not use correction fluid. Corrected forms will need to be resent to the DCC tracking website so that the database can be updated.
- Numbers can be entered starting in the left-most box. For any check box, please fill in completely (see Data system protocol)
- Be sure that all fields on the TeleForm have a value, especially visit fields. Dates maybe left blank if “0”, “No”, or “N/A” value is entered for a visit field.
- Services provided by intervention team members should not be documented on the chart review form. Intervention team-participant interactions are documented using the encounter form.
- If the chart review form is completed on paper before it is entered into REDCap, the paper forms should be stored in a secure file separate from any identifiable participant information.

Instructions for each measure

1.0a Participant's HIV Diagnosis Date: *Enter the month, day, and year of the participant's earliest documented HIV diagnosis date in the chart. If the HIV diagnosis date documented in the chart is known to be inaccurate, please enter the earliest viral load lab date.*

PLEASE NOTE:

- *This date may be before enrollment.*
- *If only year is indicated, enter 01/01 as the month/year.*

1.0b Perinatal Infection Status: *Was this patient perinatally infected?*

FAQ: If there are no previous negative HIV test results found and no indication of a suspected transmission method, should we record “No” or “Unknown”?

Answer: Unknown.

1.0c Participant's AIDS Diagnosis Date: *Enter the AIDS diagnosis date that is documented in the medical chart. In lieu of an AIDS diagnosis date, or if any of the following are earlier than the AIDS diagnosis date, please enter the **earliest** of the following dates:*

- *Date of CD4 count below 200.*
- *Date of patient-reported AIDS diagnosis year, as reported in a clinician note. For example, if a clinician note states “patient reported AIDS was diagnosis on January 15, 2008”, enter 01/15/2008.*
- *Date of clinician note in which he/she indicates that there is a history of AIDS (maybe self-reported) and there is no diagnosis date indicated. For example, if a clinician note written on 05/15/2015 states “patient reports being diagnosed with AIDS” without a year documented, enter 05/15/2015.*

PLEASE NOTE:

- *This date may be before enrollment.*
- *If only year is indicated, enter 01/01 as the month/year.*
- *If the participant does not have an AIDS diagnosis, check the “N/A” box.*
- *Please enter all CD4 lab dates, values, and percent up to 6 months prior to the scheduled date of the chart review, starting with the earliest date. Enter up to 6 dates and values.*
- *If no CD4 data is recorded in the medical record, then select “No CD4 lab data were recorded in the medical record during the past 6 months.”*

2.0 Date of the Last HIV Primary Care Visit PRIOR to Enrollment: *Enter the most recent HIV primary care visit date-recorded in the chart **PRIOR** to the date of study enrollment. This visit does not need to fall into any particular time frame. If there is no date for the last primary care visit prior to enrollment and the patient is newly diagnosed, fill in the box: “Participant is newly diagnosed”. If there is no date for the last primary care visit prior to enrollment and the patient is not newly diagnosed but new to the clinic, fill in the box: “Participant is not newly diagnosed but new to the clinic”.*

- An HIV primary care visit is a visit with a provider who has prescribing privileges (MD, NP, PA), not an emergency room visit, urgent care visit, nursing visit, specialty care visit, or case management visit.
- Visits with HIV primary care providers that are non-HIV related visits should not be documented as “HIV primary care” visits.

FAQ: Is this the last recorded HIV primary care visit anywhere or only at intervention clinic?

Answer: Anywhere

FAQ: So in a situation where a patient met with a provider before being enrolled into the MSE (which we have a few of), for the “LAST HIV primary care visit PRIOR to enrollment” question, I should still just list their most recent correct?

Answer: You want the primary care visit prior to completing the consent into the MSE and the baseline survey, whenever that occurs.

FAQ: Most of the time folks come into the clinic for HIV care, they are seeing their provider and getting labs done in the same day. Am I correct in documenting this as both an HIV primary care and HIV nursing visit? Initially, I thought it would only count as HIV primary care, but then if a patient were to come in for just labs, this would be considered an HIV nursing visit only-since they are not seeing a prescribing provider- correct? In which case, labs would always be documented as HIV nursing.

Answer: You should record it as a primary care visit and a HIV nursing visit.

3.0-3.1 Hepatitis C Diagnosis: *Please indicated whether the patient is currently positive for Hepatitis C and if they are positive, if they are receiving treatment for their Hepatitis C at your clinic.*

4.0 - 4.3 Date of CD4 Lab Tests and Values AFTER Enrollment: *Please enter the participant's CD4 lab dates and values starting with the first date following study enrollment. Enter up to four test values and dates. Be sure that a numeric value is entered for at least one value and date. Please no missing data.*

- *Fill in the “data pending” box if there is a date recorded in the chart for a test ordered but the value is pending. Be sure the date that the test was ordered is recorded.*
- *Fill in the “QNS” (quantity not sufficient) box if the value was not readable on the lab slip.*
- *If no CD4 labs were conducted in the time period fill in the box at the bottom of the table “No CD4 data was collected or recorded in the chart during this time period”.*

5.0 - 5.3 Date of Viral Load Lab Tests and Values AFTER Enrollment: *Please enter the last viral load values and dates recorded in the chart starting with the first date following study enrollment. Record the EXACT value if listed in the chart. If no numeric value is given, fill in the box “undetectable”. Record both the cut-off value and fill in the box “undetectable” if both are documented in the chart. If the patient is newly diagnosed or new to the clinic, and no test is recorded, fill in the box: “No CD4 or viral load data was collected or entered into the chart during this time period”.*

- *Fill in the “Data pending” box if there is a date recorded in the chart for a test ordered but the value is order. Be sure the date that the test was ordered is recorded.*
- *Fill in the “QNS” (quantity not sufficient) box if the value was not readable on the lab slip.*

- *If no viral load labs were conducted in the time period fill in the box at the bottom of the table “No viral load lab data was collected or recorded in the chart during this time period”.*
- Some lab results may be listed as less than the current test is able to detect
- Enter these by just filling in the “Undetectable” check box
- Do NOT also enter “<20” (or similar) in the viral load numeric boxes
- Numeric boxes should not include characters such as “<”

6.0 HIV Primary Care Medical Visits and Dates AFTER Enrollment: *Data should be collected from electronic or paper charts. In collecting these data, each 3- month period will be prepopulated based on the participant’s date of enrollment as follows:*

Months 1- 3 : January – March

Enter the dates of the HIV primary care medical visits for the 3-month period listed. Please note, for Months 1-3, you should include any visits that occurred prior to study enrollment date in month 1 [for 6-month chart review only].

If there were NO visits that occurred or were documented in the chart over the 3-month period, check the box “No primary care visits were recorded in the chart during this time period” and leave date fields blank.

7.0 – 7.7 HIV Health Care Visits AFTER Enrollment: *Data should be collected from electronic or paper charts. In collecting these data, each 3- month period will be prepopulated based on the participant’s date of enrollment as follows:*

Months 1- 3 : January – March

Enter the number of health care visits for each listed provider for each 3-month period. Please note, for Months 1-3, you should include any visits that occurred prior to study enrollment date in month 1 [For 6-month chart review only]. For visits with a provider that is not listed, use “other” and specify the provider type.

If there were NO visits that occurred or were documented in the chart over the 3-month period for a provider, check the box “No visits recorded in this period” and leave the number blank.

FAQ: Do we only record health care visits specifically related to HIV care?

Answer: HIV specific for 7.0 and 7.1. If so, which mental health counseling, substance use disorder counseling & psychiatrist visits would qualify? All mental health, substance use, and psych visits would count (regardless of whether or not they are related to HIV) If not, should we include things such as non-HIV primary care, ER visits, specialists, etc. as “Other” visits? Those can be included in “other”.

8.0 HIV Antiretroviral Therapy Prescriptions in the Past 12 Months: *(Note: this includes new and existing prescriptions) Fill in “Yes” if there is a documented prescription in the chart and enter the most recent date of prescription. Also note the number of refills on the prescription.*

9.0 Mental Health: *Fill in “Yes” if there is documentation of a mental health condition. If “Yes” check the corresponding condition, and use “other, specify” if the condition is not listed. If there is no documentation of a mental health condition, and the participant is new to the clinic or newly diagnosed fill in “No medical records available prior to study enrollment”.*

10.0 Substance Use Disorders: *Fill in “Yes” if there is documentation of a substance use disorder. If “Yes” check the corresponding used substances, and use “other, specify” if the substance is not listed. If there is no documentation of a substance use disorder, and the participant is new to the clinic or newly diagnosed fill in “No medical records available prior to study enrollment”.*

FAQ: What if a participant does not have substance use issues? Should we record “no visits” or “N/A”?

Answer: If a participant does not have substance use issues (or whatever type of visit is listed in the chart review), the Data Manager should still fill in the “no visits recorded during this period” check box INSTEAD of writing “N/A”. The subsequent question about whether the participant has SUD (or whatever) will help inform the analyst about the “no visits recorded”. The # visits/no visits recorded table should not include missing data because the participant does not need the service noted.

FAQ: Record substance use disorders, not just indication of substance use, correct?

Answer: Correct!

Internal Referrals:

This section refers to participant referrals to services that are housed in your agency and would be recorded in the participant's chart.

11. Since enrolling in this study, was the participant referred for mental health services (including residential treatment) within your agency?

- Mark “Yes” there is documentation that the participant was referred internally for services
- Record the number of internal mental health visits attended by the patient.
- Mark “Yes” even if there is not a **formal** internal referral documented or if the referral date is prior to study enrollment, but the participant is receiving mental health services at your agency.
- Mark “No” if the participant has a diagnosed mental health condition (as recorded in question 8), but was not referred for mental health services.
- Mark “N/A” indicating the participant does not have a diagnosed mental health condition needing a referral for mental health services.

12. Since enrolling in this study, was the participant referred for substance abuse treatment services (including residential treatment) within your agency?

- Mark “Yes” if there is documentation that the participant was referred internally for substance abuse treatment services (both outpatient and residential)
- Record the number of internal substance abuse treatment visits (outpatient only) attended by the participant.
- Mark “No” if the participant has a diagnosed substance abuse condition, but was not referred for substance abuse treatment services.
- Mark “N/A” indicating the participant does not have a diagnosed substance abuse condition needing a referral for substance abuse treatment services.
- Mark the corresponding box if the substance abuse treatment was residential treatment.

External Referrals:

This section refers to participant referrals to services that are housed outside of your agency and would be recorded in the participant's chart.

13. Since enrolling in this study, was the participant referred for mental health services outside of your agency? NOTE: if patient was referred internally, mark “No”

- Mark “Yes” if there is documentation that the participant was referred externally for services.
- Record the number of external mental health visits attended by the participant.
- Mark “No” if the participant has a diagnosed mental health condition, but was not referred for external mental health services or the participant was referred internally for mental health services.

- Mark “N/A” indicating the participant does not have a diagnosed mental health condition needing a referral for mental health services.
- **If yes, record the number of external mental health visits attended as recorded in the chart, OR**
 - If there is no access to data on completion of external mental health services, mark the box “Not recorded in the chart” to indicate that follow-up data is not available in the chart.

14. Since enrolling in this study, was the participant referred for substance abuse treatment services (including residential treatment) outside of your agency?

- Mark “Yes” if there is documentation that the participant was referred externally for substance abuse treatment services.
- Record the number of external substance abuse treatment visits attended by the participant.
- Mark “no” if the participant has a diagnosed substance abuse condition, but was not referred for external substance abuse treatment services or the participant was referred internally for substance abuse treatment services.
- Mark “N/A” indicating the participant does not have a diagnosed substance abuse condition needing a referral for substance abuse treatment services.
- **If yes, record the number of external substance abuse treatment visits attended as recorded in the chart, OR**
 - If there is no access to data on completion of external substance abuse treatment services, mark the check box “Not recorded in the chart” to indicate that follow-up data is not available in the chart.
- Mark the corresponding box if the substance abuse treatment was residential treatment.

15. Name of data source (i.e.): Please mark one category for the source of the data; if other please write in the source.

FAQ: The 12-month and 18-month chart abstractions for someone enrolled on November 1, 2018 would fall well after the study funded period has ended (~Aug 2019). Should we be pushing to get our participants enrolled by ~Jan/Feb 2018 so all 3 abstractions fall within the funded period or is the DEC team okay with not having these data points for participants enrolled after that point?

Answer: Yes! We are keeping firm on the following deadlines:

- Last day to enroll participants into the multi-site evaluation: November 1, 2018 ·
- Last day to enter data into the online system: April 30, 2019.

Enrollment into the multi-site evaluation will end Nov. 1, 2018. We’d like you to keep enrolling folks into the intervention itself long after that, and that is what we’ll be providing TA on in Year 2 of the project. Our larger goal is to have this model financially sustained and fully integrated into your standard of care.

FAQ: Should one TeleForm be submitted for each data source for a client (e.g., each clinic where medical records were obtained) or should just a single TeleForm for each participant using information gleaned from multiple data sources?

Answer: One TeleForm per client, per time point.

FOR ENHANCED NAVIGATION SITES ONLY

EN1 - 2 Acuity Assessment and Score: Please record the participant's acuity assessment dates and scores starting with the first date following study enrollment. Enter up to two acuity assessment date and scores. If an acuity assessment was not conducted or recorded in the chart during this time period mark the corresponding box. ** For the 6-month chart review – the first acuity assessment should occur within 7 days of enrollment into the multi-site study. **

12 and 18 Month Chart Abstraction – additional variables to collect

1. Date and value of CD4 lab test prior to enrollment: Please record the most recent date of the client's last CD4 lab test and the value prior to study enrollment. If there is none recorded in the chart please check the box "none recorded".
2. Date and value of viral load lab test prior to enrollment: Please record the most recent date of the client's last viral load lab test and value prior to study enrollment. If there is none recorded in the chart please check the box "none recorded".

FAQ: Would a phone call, text message, or email be considered a visit?

Answer: Only in person medical visits count for chart abstractions. Phone calls, texts, and emails would count for encounter forms.

FAQ: What about Pharmacist visits? Does this have to be with the actual pharmacy? I see visits with nurses where the client is picking up their script. Could that count?

Answer: We are just looking for visits with the pharmacist.

Participant Encounter Form

What is the purpose of the participant encounter form?

The participant encounter form collects information about the encounters that Patient Navigators have with or on behalf of study participants. The purpose of this form is to document the types of activities Patient Navigators are doing and with whom they are collaborating to conduct those activities.

Who is responsible for completing the participant encounter form?

The participant encounter form should be completed by the Patient Navigators.

When and how often should the participant encounter form be completed?

The participant encounter form should be completed anytime the Patient Navigator conducts an activity with a participant either in person or on behalf of the participant. Only one participant encounter form should be submitted per participant per day of services provided.

How is the participant encounter form submitted?

The participant encounter form can be found on the web-based DCC tracking website (https://wwwru.bumc.bu.edu/DCC_DEC/).

What types of activities should be documented on the participant encounter form?

Dos & Don'ts:

- **Do document each activity you completed with a participant in the course of a day.**
- **Do document attempted encounters with participants.**
- **Do document activities related to scheduling future appointments with the Patient Navigator**, such as scheduling, rescheduling, or cancelling appointments between the community health worker and the participant.
- **Do NOT document any evaluation activities on the participant encounter form:**
 - Do not fill out an encounter form to document enrolling a client into the multi-site evaluation or for conducting a baseline interview.
 - Do not fill out this form to document contact attempts to bring a participant in for a scheduled participant interview.
 - Do not fill out this form to document conducting follow-up interviews.

Additional Reminders:

- Enter “type” and “duration” for each checked/selected encounter activity.
- For “other” activities, enter the text field specifying what the other activity was.
- If you are deleting previously selected encounter activities, delete/clear the associated “type” and “duration” fields (and “other (specify)” text field if an “other” activity) before you uncheck the activity. If you click the check box to un-select the activity first, the data in “type” and “duration” remain saved and will trigger data cleaning queries.
- When noting that a participant’s transition to standard of care is complete, write “BINGO” in the Progress Notes section of the encounter form. “BINGO” should NOT be entered as a separate “other” encounter activity.

FAQ: If the interventionist meets with client multiple times in 1 day, which means multiple “encounters.” Is the encounter simply updated with new Encounter activities or is a new encounter created each time the Patient Navigator meets with client?

Answer: All encounters on a single day by a single interventionist should be entered into one encounter form. In the scenario you describe, Patient Navigator #1 (PN1) would go back to add additional encounter activities to the existing encounter form for that day, for that client. Encounter forms can be edited after they are originally entered, so PN1 can log in and update the encounter form later with additional encounter types/durations for that same client if the activities were all on the same day. Note that if interventionist Patient Navigator #2 (PN 2) also meets with the same client on the same day, PN 2 would enter a separate encounter form, because those encounter activities were completed by a different interventionist. When PN 1 logs in, PN 1 will be able to edit only PN 1’s encounter forms. PN 2 will only be able to edit PN 2’s encounter forms. However, both PN 1 and PN 2 would be able to see all encounter forms for the same client using the “Encounter View” button.

How do I fill out the encounter form?

1. First, navigate to the encounter form on the web-based DCC tracking website (https://wwwru.bumc.bu.edu/DCC_DEC/).
 - a. Login to the web-based DCC tracking website.
 - b. From the main menu, select “Encounters”.
2. Select the participant for whom you are submitting an encounter form from either the “Participant ID:” or “Participant Name:” drop-down lists.
3. Enter the date of the encounter.
 - a. If adding to an existing encounter form, select the appropriate form date from the “Select Date:” drop-down list.
 - b. If creating an encounter form with a new date, select the “Add New Date” field and type in the correct form date.

Note: Enter the date of the encounter as the month, day, and then year. You do not have to enter preceding zeroes for the month or day. For example, if an encounter took place on January 1, 2017, you would enter the date as 1/1/2017.
4. Encounter made
5. Encounter location
 - a. If you select “Medical, social service, or community based organization setting” or “Other” as the location of encounter, please specify where the encounter occurred in the supplied text box.

Note: If you select “Other” for location, please do not use names of facilities or locations, but rather describe them and the services they provide. For example, instead of writing “Boston HOPE Project” for a location, write “Housing service agency”.
6. Look through the activities on the encounter form and click on the checkbox next to each activity that you completed with the participant on the day for which you are submitting the form.
 - a. If one of the activities you select activates a drop-down menu of additional sub-activities, also select the sub-activity or activities that match most closely what you did with that participant.
 - b. If you do not see any activities on the encounter form that match what you did with the client, select the “Other” activity option at the bottom of the form and write in a brief description of what you did with the participant.

Note: Do not use names of programs or facilities, rather describe them. For example, instead of writing “Went to B&G Club with client,” write “Accompanied client to basketball facility.” In general, provide as many specific details as possible about the activity itself. The DEII evaluation staff will periodically review data with sites to discuss the need for recoding “other” category data and the potential for creating new categories for encounters.
7. For each activity you selected, indicate using the drop down menus what type of activity you conducted and the location you conducted the activity. If you select other for “Type” or “Location,” please specify in the “other” text box that will appear. If you select “Other” for location, please do not use names of facilities or locations, but

rather describe them and the services they provide. If an encounter was made with another provider on behalf of or for the participant (without the participant present), select “Collateral” for “Type”.

8. Duration (in minutes)
9. Progress Notes (if applicable)
10. Once you have completed the above steps, hit “Save” at the bottom of the encounter form. You have successfully submitted an encounter form!

Note: The DEC tracking website will log you out after remaining idle for more than a few minutes. Save often to ensure that your encounter form progress is not lost.

Question by Question Guidance for Encounter Form

Date of contact: The date the encounter contact(s) occurred.

Staff ID: The DCC-assigned staff ID of the Patient Navigator who had the encounter contact(s). This is auto-populated when entering data directly into the DCC tracking website.

Client ID: The DCC-assigned participant study ID number.

Site: The DCC-assigned ID of the intervention site. This is auto-populated when entering data directly into the DCC tracking website.

Encounter made:

- Mark “yes” if there was a direct encounter with the participant or an encounter on behalf of the participant.
- Mark “no” if you attempted to have an encounter or had an appointment for an encounter but it did not occur.
 - Mark the corresponding reason as to why an encounter did not occur. If the reason is not listed, mark “other” and write in the reason.

Location of encounter(s): Mark all of the locations in which the encounter(s) occurred in the day of the encounter.

If the location was in a setting external to the intervention site, write in the name of the location.

If the encounter occurred at a location not listed, mark “other” and write in the location.

Type of contact: Use the following number codes to indicate the type(s) of contact of the activities conducted in the following “Encounter content” section.

#	TYPE OF CONTACT
1	Face-to-face (individual)
2	Electronic (email, text, phone, fax)
3	Collateral (client not present)
4	EMR
5	Other

Encounter content: Indicate all encounter activities conducted for the day of the encounter, including the type of contact and the duration (in minutes) of each activity.

Total duration of this encounter (in minutes): The total number of minutes of the encounter(s) with the participant in the day of the encounter. This is automatically calculated when entering data directly into the DEC tracking website.

Progress Notes (Optional): Use this space for progress notes that you would like to share with the evaluation team.

ENCOUNTER CONTENT: ACTIVITY DEFINITIONS & EXAMPLES

For each of the activities conducted in a day with a client please note the *Type* of contact using the corresponding numbers above (1 – 5) and *Duration* as the total number of minutes spent on the activity.

Activity	Definition	Example of Activities	Examples previously marked as OTHER	Type	Duration (minutes)
1. Find client/conduct outreach	Any activity that helps to locate or reach out to a client in the community	“Arranged time to meet with client”	Status check with client Attempted to schedule an appointment with client Contacted client and left message Trying to locate client		
2. Conduct client intake and/or needs assessment	Completing an intake or follow-up needs assessment	“First meeting with patient” “Assessed immediate needs of the patient”	Assessment completed		
3. Develop patient care plan	Completing patient care plan or patient agreement (for buprenorphine treatment). Work to identify goals and develop action items to meet those goals. Goals may be related to any health or health care (including HIV, mental health, substance use, other health or health care areas). NOTE: Creating a transitional care plan (for the jail-based intervention) should be marked in activity 41, not here	“Create patient care plan” “Complete patient care agreement”	Update patient care plan		
4. Conduct acuity assessment	Completing the patient acuity tool.	“Complete patient acuity assessment” “Assess patient acuity”			
HEALTHCARE ACTIVITIES					
5. Arrange HIV primary care appointment	Any activity that helps the client get a HIV primary care appointment	“Scheduled first appointment with HIV primary care provider”	HIV appointment Made follow up appointment		

Activity	Definition	Example of Activities	Examples previously marked as OTHER	Type	Duration (minutes)
6. Arrange mental health services appointment	Any activity that helps the client get a mental health or psychosocial service appointment or meeting	“Called mental health provider with client to schedule next appointment”	Requested mental health appointment		
7. Arrange for substance use treatment / services appointment	Any activity that helps the client get a substance use service providers	“Arranged admission to detox”			
8. Arrange for other medical care appointment (not for HIV, mental health, or substance use)	Any activity that helps the client get an appointment with any medical provider EXCLUDING HIV primary care, mental health, substance use treatment, or psychosocial service providers	“Assisted in making eye appointment”			
9. Accompany client to a medical appointment	Any activity in which Intervention Staff goes with a client to a scheduled or unscheduled visit with a medical provider, including primary health providers, specialty health providers, lab technicians, pharmacists, ER or Urgent Care providers, etc. <u>EXCLUDING</u> mental health, substance use treatment, or psychosocial service providers	“Accompany client to dental appointment” “Accompany client to hospital” “Accompany nurse to home visit” “Dropped off client at doctor’s appointment”	Mammogram Eye Doctor’s appointment OB/GYN		
10. Accompany client to mental health appointment	Any activity in which Intervention Staff goes with a client to a scheduled or unscheduled mental health or psychosocial service appointment or meeting	“Took client to support group meeting”			
11. Accompany client to a substance use	Any activity in which Intervention Staff goes with a client to a scheduled or	“Accompany client to detox”			

Activity	Definition	Example of Activities	Examples previously marked as OTHER	Type	Duration (minutes)
related services appointment	unscheduled substance use treatment service appointment or meeting	“Went with client to a NA meeting”			
12. Discuss medical appointments with client	Any discussion that covers what occurred in a medical appointment (defined as a scheduled or unscheduled visit with a medical provider, including primary health providers, specialty health providers, lab technicians, pharmacists, ER or Urgent Care providers, etc.)	“Client shared what happened at her dental appointment” “Spoke with client about a recent hospital visit” “Discuss hospital discharge plan with doctor”	Followed up with client about mental health appointment Followed up with client after medical appointment		
13. Discuss lab values with a client.	Specifically review lab values as they relate to medical care, treatment, and HIV-related health status.	“Reviewed lab values with participant”			
APPOINTMENT REMINDERS AND FOLLOW UP					
14. Provide appointment reminders (medical and non-medical appointments)	Any activity done to remind client of an upcoming appointment	“Called client to remind of appointment with HIV provider tomorrow”	Offered to schedule medical appointment SS Reminder call		
15. Follow up with provider to discuss client	Any activity where the interventionist meets, works with, or contacts the client’s provider to discuss the client.	“Called dentist to see if client has scheduled appointment after being referred” “Schedule appointment with nutritionist who she had been referred to” “Sent message to client’s nurse through the EMR”	Contacted ID nurse ID nurse provided update about transfer Spoke with ID nurse about MH evaluation Spoke with nurse case manager in regards to client Discuss patient care plan with housing SW Followed up with nurse to discuss patient Discuss client with nutritionist Discuss patient with in-house SW		
EDUCATIONAL AND EMOTIONAL SUPPORT					

Activity	Definition	Example of Activities	Examples previously marked as OTHER	Type	Duration (minutes)
16. Relationship building (e.g. checking in with the client; providing emotional support)	Any contact that with a client to check on how they are doing generally, to follow up on previous conversations about general well-being, or to check and see if they need anything	“Check in with client” “Home visit to see how client is feeling” “Wellness checks”	Phone call from client Spoke with client Stopped by residence to drop off clothing and talk Text patient a supportive message Discussed stress-reducing strategies Met with client after court Met with client after appointment		
17. Talk with a client about disclosure	Any discussion that covers reasons for wanting to or not wanting to disclose, or discussions to check-in with clients after disclosure	“Discussed client’s fears about telling his family that he is HIV-positive”			
18. Provide coaching on living skills	Any discussion about basic tools to use in order to navigate everyday life	“Discussed ways to better communicate with landlord” “Talked about strategies to reduce stress”			
19. Provide general health education/risk reduction education	Any discussion that covers general health education or risk reduction.	“Discuss personal hygiene and sharing razors, needles, etc.”			
20. Provide basic HIV treatment education, support, and/or advocacy	Any discussion that covers information around how HIV treatments work, how to take them, or tips for treatment adherence/management	“Discuss HIV treatment” “Discuss needs related to HIV treatment”	Discuss medication/side effects Review the basics of lab tests Talked with client about meds Help with finding a good support group for HIV		
21. Provide safer sex education	Any discussion around safe sex practices	“Discuss client safety and healthy relationships”			
22. Provide harm reduction, education, and supplies (i.e.	Any work done that enables the client to reduce substance use (including reviewing treatment options), OEND	“Discuss cutting down substance use with client”	Discuss substance abuse treatment center with client Spoke with client about needing substance use treatment		

Activity	Definition	Example of Activities	Examples previously marked as OTHER	Type	Duration (minutes)
clean syringe/naloxone)	(Overdose Education and Naloxone Distribution)	“Assisted client in obtaining naloxone prescription”			
23. Mentoring/coaching on provider interactions	Any discussion that helps prepare the client to communicate more effectively with medical, mental health, substance use treatment, or other service providers	“Brainstormed ideas to prepare for next medical visit with HIV primary care provider”			
24. Provide education and emotional support to client’s family/partners	Any discussion with a participant’s family or partners (with the client’s consent) in order to help the family/partner be a better support system for the participant.	“Spoke with client’s boyfriend about harm reduction, safer sex practices, and HIV medication regimen”			
SOCIAL SERVICES-RELATED ACTIVITIES					
25. Accompany client to social service appointments (i.e. related to benefits, housing, food, etc.)	Any activity in which Intervention Staff goes with a client to a scheduled or unscheduled visit with a non-housing social service provider (e.g. food, social security, etc.)	“Accompany client to social security office” “Accompany client to SNAP”	Assisted client with food pantry Correspondence with social service agency		
26. Assist with obtaining transportation services	Any activity in which the Intervention Staff helps the client gain access to transportation, including coordinating car/taxi service, providing bus cards to clients, helping client determine what transportation to use in arriving to appointments, etc.	“Give bus pass” “Called a cab to pick up the client and take him to his appointment” “Showed client how to use Maps application to find best bus route”	Dropped off a bus ticket Transported from SEPTA		
27. Assist with obtaining child care services	Any activity in which the Intervention Staff helps the client gain access to child care	“Helped client find day-care”			
28. Assist with obtaining housing services (i.e.	Any activity in which the Intervention Staff helps the client obtain or maintain housing.	“Read through lease agreement with client to	Assist client with obtaining housing Assist client with finding housing Call with housing case manager		

Activity	Definition	Example of Activities	Examples previously marked as OTHER	Type	Duration (minutes)
support for finding or maintaining housing)		understand expectations in new apartment” “Assist client with housing referral” “Assist with obtaining shelter”	Discussed hotel voucher request with patient		
EMPLOYMENT AND OTHER PRACTICAL AND SOCIAL SUPPORT					
29. Assist client with finding employment/provide employment support	Any activity that assists in identifying employment opportunities, and supporting client in obtaining or maintaining employment for the client	“Accompany client to job interview” “Discuss vocational goals” “Fill out job application”	Career Link – looking for job		
30. Assist client in obtaining legal assistance, obtaining legal documents, or obtaining legal advocacy services	Any activity that assists the client in identifying, obtaining, or managing legal assistance or advocacy	“Accompanied client to court” “Accompany client to probation appointment” “Assist client with warrants” “Advocacy for benefits” “Client is incarcerated”	Contact ID office Contacted public defender Drafted letter for court Spoke with public defender		
31. Assist client with obtaining benefits (e.g. SSI, social security, disability, food assistance, or health insurance)	Any activity that assists the client in obtaining benefits such as SSI, social security, disability, or health insurance benefits.	“Made appointment to meet about social security benefits.” “Provided assistance for social security disability application.” “Assisted client in enrolling in health insurance”	Completed ADAP and Ryan White Check status of FEMA application		

Activity	Definition	Example of Activities	Examples previously marked as OTHER	Type	Duration (minutes)
32. Provide practical support (i.e. obtaining cell phone, budgeting/financial planning)	Any activity in which the Intervention staff is completing tasks for or with the client that they need in order to improve their health or well-being and are unable to complete on their own	“Accompanied client to grocery store” “Assist client with laundry” “Assist client with paying bills” “House cleaning” “Accompanied client to grocery store” “Assist client with laundry” “Assist client with paying bills” “House cleaning”	Assist patient with utility assistance documents Accompany patient to financial counseling Provided resources to reduce internet services Assisted client with snack bag request Enrolled patient in GED classes		
OTHER ACTIVITIES					
33. Other 1:	Any activity that does not fit into an encounter outlined in another section of the encounter form.				
34. Other 2:	Any activity that does not fit into an encounter outlined in another section of the encounter form.				
35. Other 3:	Any activity that does not fit into an encounter outlined in another section of the encounter form.				
TRANSITION TO STANDARD OF CARE					
36. Meet with client to discuss transitioning to the standard of care	Any discussion that prepares a client to transition from the intervention activities and from working with the interventionist to the standard of care.				
37. Transition client to treatment with a case manager or	Any activity related to transitioning a client to the standard of care outside of the organization.	“Held meeting with client and case manager”			

Activity	Definition	Example of Activities	Examples previously marked as OTHER	Type	Duration (minutes)
treatment at external/partner agency					
38. Officially transitioned patient to standard of care.	Any activity related to transitioning a client to the standard of care within the organization.				
ENHANCED PATIENT NAVIGATION INTERVENTION: STRUCTURED CURRICULUM SESSIONS					
39. Session 1: HIV, the Viral Life Cycle	Complete the curriculum outlined for session 1				
40. Session 2: Communicating with Provider, Adherence & Managing Side Effects	Complete the curriculum outlined for session 2				
41. Session 3: Review understanding of basic lab tests: CD4 and Viral Load	Complete the curriculum outlined for session 3				
42. Session 4: Stigma & Disclosure	Complete the curriculum outlined for session 4				
43. Session 5: HIV and Substance Use	Complete the curriculum outlined for session 5				
44. Session 6: HIV and Mental Health	Complete the curriculum outlined for session 6				
TRANSITIONAL CARE COORDINATION INTERVENTION SPECIFIC ENCOUNTERS					
45. Create or modify transitional care plan	Working with the client to create or modify transitional care plan.	“Complete transitional care plan”			
46. Conduct health liaison to the court activities					

Activity	Definition	Example of Activities	Examples previously marked as OTHER	Type	Duration (minutes)
47. Provide/arrange transportation/escort from jail	Any activities that support the safe transportation of the client from the jail post-release.	“Arranged for a taxi for client”			
48. Provide supply of bridge medications or prescription (during incarceration or post-release)	Any activity that supports the uninterrupted availability of prescriptions for the client post-release	“Met with provider in the jail to receive prescription for client”	BC dropped off HIV Meds for a client Picked up meds for a client		
49. Facilitate placement in diversion program, ATI, compassionate release	Any activity that connects a patient with resources geared towards diversion, ATI, or compassionate release				
BUPRENORPHINE INTERVENTION SPECIFIC ENCOUNTERS					
50. Provide client education and support prior to treatment	Any activities related to educating patient about buprenorphine treatment.	“Provided patient with handouts on buprenorphine treatment” “Discussed what to expect when starting buprenorphine treatment”			
51. Provide client support during treatment initiation	Any activities related to helping a client through either the home or office based initiation process.	“Provided patient with home induction handout”			
52. Provide client support during maintenance or stabilization	Any activities related to helping a client during their maintenance or stabilization phases.	“Discussed buprenorphine adherence with patient” “Discussed patient emotions related to being on buprenorphine treatment”			

Activity	Definition	Example of Activities	Examples previously marked as OTHER	Type	Duration (minutes)
53. Provide client with referral to supplementary or higher level of addiction treatment	Any activity to connect a client to a supplementary or higher level of addiction treatment.	“Connected patient with inpatient treatment facility”			
54. Conduct monitoring appointment	Meeting with the patient to monitor his/her dosage, treatment, or experience on buprenorphine.	“Met with client to adjust dosage”			
55. Obtain prior authorization for buprenorphine prescription	Work done to overcome insurance barriers to obtaining buprenorphine.				
56. Obtain buprenorphine for client	When the provider obtains buprenorphine from the clinic pharmacy for a client.				
57. Urinalysis	Any time spent requesting urinalysis, reviewing urinalysis values.				

Progress Notes (Optional): *You may use this space for progress notes that you would like to share with the evaluation team*

Managing Data

Storage of Study Documents

The Data Manager is responsible for securely storing study documents in appropriate locations. It is recommended that **separate** storage locations be provided for the following documents.

- **Master ID list:**
 - This document provides a key linking participants' names and study ID numbers (see example in appendix J). This list should be securely stored apart from all other study documents and should never be shared with anyone outside of the evaluation study.
 - If kept as an electronic file:
 - DO save this file to a single, unique location on either a secure server or encrypted computer requiring user access authorization.
 - DO use a password to lock this file from viewing.
 - DO **NOT** copy this file to any other location.
 - If kept as a physical file:
 - DO keep this list locked in a secure place at all times.
 - DO keep this list separate from any collected data with identifiable information.
 - DO **NOT** make copies of this list.
 - DO **NOT** let anyone borrow this list.

- **Individual participant files:**
 - Each evaluation study participant should have a separate file (one per participant) that is securely stored apart from other participant files. Documents kept in this file include:
 - Signed informed consent forms
 - Signed HIPAA authorization forms (as needed)
 - Signed waivers for receipt of compensation (if applicable)
 - **Note:** If you are required by your IRB or system to keep a master list of incentives or reimbursements, this should **NOT** be kept here.
 - **Note:** Documents with a participant's name and those with their study ID should not be stored together, so data collection forms should NOT be stored here.
 - DO keep these files locked in a secure place at all times.

- **Blank data collection forms & other study documents:**
 - Participant baseline and follow-up questionnaires
 - Participant encounter forms
 - Eligibility & enrollment forms
 - Informed consent forms
 - HIPAA authorization forms
 - Waiver for receipt of compensation

- **Master list of incentives/reimbursements (if required):**
 - If you are required by your IRB or system to keep a master list of incentives or reimbursements, this should be kept separate from the Master ID list and other study documents containing participant information.

Data Management & Cleaning

- Each site will work with a DEC team member who will conduct data management activities for the program evaluation and will also be responsible for tracking completed and upcoming participant interviews and chart reviews.

Participant Visual Tracking Report

The visual tracking report is a key data collection report that can help you to track your work with each participant. You can log into the DCC website to see your site’s participant tracking report and the DEC team suggests sharing this tracking report with your team through email or a printed handout once a week so that your site can use a team approach to connecting with clients for both the intervention and the evaluation activities.

Please refer to the tracking system manual for the step-by-step instructions for changing a participant’s status.

Code	Appropriate way to use this code
Check Mark	Visit/evaluation activity completed
---	Not yet in window (there is no action to be taken for this activity at this time)
DUE	This activity is due to be completed.
D	Deceased
W	Withdrawn at this time point. Withdrawn is reserved for times when a client is removed from the study for harassing and endangering study staff or if they have asked to be removed from the study. W is NOT to be used when a client is lost to follow up, is no longer working with the intervention staff, has transferred care to another facility, is incarcerated, or is not making progress towards completing their intervention activities.
X	Visit/Chart is not done/was partially completed and no reason was specified
When the visit/chart was not done/was partially completed and you have a reason, you can use the following codes:	
A	Assessment was taking too long. The client wasn’t able to stay for the entire visit and had to leave
L	Lost to follow up for that activity. You were unable to locate them to complete that activity. This is NOT a terminal status so someone can be lost for a period of time and then re-engage with the evaluation and/or the intervention
I	Incarcerated (in jail or prison)
T	Transportation difficulties
M	Moved care to another location
S	Sickness
H	Hospitalized
O	Other reason

Appendices

Appendix A: Data Sources Overview

Data Sources for Implementation Evaluation

Data Source	Description	Relationship to Proctor Model	Responsible party	Frequency of data collection	Collection method
Organizational Readiness to Change Assessment - ORCA	The scales were designed to assess organizational readiness to change in preparation for testing interventions designed to implement evidence-based changes in clinical practice. The scales are intended for diagnostic use, to identify needs or conditions that can be targeted by implementation activities or resources, and to provide a prognosis of the success of the change effort at the organizational level. (Helfrich, Li, Sharp, Sales 2009).	Implementation outcomes: acceptability, adoption, appropriateness, integration	DEC	Pre-implementation (post funding, pre-site visit), and start of Year 2	Online through web-based data portal
Pre-implementation qualitative interview	Conducted with project staff and site leaders prior to implementation to determine training and technical assistance needs, staff readiness, willingness, and self-efficacy related to implementation.	Implementation outcomes: acceptability, adoption, appropriateness	ITAC and DEC	One time	Initial site visit
Enrollment data reports	Used to report on the number of patients eligible, number of patients enrolled, barriers to enrolling eligible patients, and reasons why eligible patients declined to enroll.	Implementation outcome: coverage	Data Manager at each site	1x month	Online through web-based data portal
Encounter form	Used to record each encounter with each individual client. The encounter form tracks the kind of interaction the interventionist had with the client (in person, through phone call etc.), the services provided to the client during the interaction, and how long the interaction lasted.	Implementation outcomes: feasibility, fidelity, Service outcomes: efficiency, equity, timeliness	Interventionists at each site	1x per interaction with each individual client	Online through web-based data portal
Monthly site call form	60 minute calls with project staff will be used gather general information about implementation process and issues, staffing,	Implementation outcomes:	DEC	Monthly	Template completed

Data Source	Description	Relationship to Proctor Model	Responsible party	Frequency of data collection	Collection method
	<p>budgetary and evaluation progress and evaluation TA needs. Calls will track progress on project implementation; changes in staffing, key program elements, partners and resources; progress on multi-site evaluation (data collection, IRB updates, data entry, etc.); and integration throughout the organization (impact on programs and staff) outside of the intervention team members. Contextual tracking (policies, funding announcements, political climate, etc.) will be included in this monthly form.</p>	<p>feasibility, fidelity, integration Service outcomes: Efficiency, safety</p>			<p>by DEC liaison</p>
Key informant qualitative interviews	<p>Conducted with project staff and key partners to determine barriers and facilitators to implementation of the protocol; perceived efficacy in implementation; clinical, programmatic, and systemic outcomes; and progress towards long term integration of the intervention at the site. Key informant interviews happen at multiple levels of the intervention team and organizational chart at the clinic.</p>	<p>Implementation outcomes: feasibility, fidelity, integration Service outcomes: efficiency, safety, effectiveness, equity, patient-centeredness, timeliness</p>	DEC	TBD	<p>Conducted onsite or via telephone by an interviewer using the qualitative interview guide</p>
Site visit report	<p>The site visit report form will record staff group and individual feedback regarding implementation process, barriers, facilitators and situational inputs and variations impacting implementation. The DEC will also collect information on contextual factors related to integration, partnerships (client linkage to community resources, community resource capacity to meet the needs of clients in the intervention), and funding. Site visit report forms will also record any training or technical</p>	<p>Implementation outcomes: feasibility, fidelity, integration Service outcome: efficiency, safety</p>	DEC	1 per each site visit	<p>Site visit report template completed by DEC liaison based on the site visit guide</p>

Data Source		Description	Relationship to Proctor Model	Responsible party	Frequency of data collection	Collection method
		assistance needs identified by the DEC or by the site staff members.				
Audio Recording		Audio recording will be used determine the quality of client and interventionist interactions. Random samples of audio recordings will be used by the DEC to monitor for fidelity. A checklist developed by the DEC will be used to evaluate fidelity of the content of the recording.	Implementation outcome: Fidelity	Data Manager at each site and DEC	Selected interactions between interventionist and client	Digital recording upload to DCC
Patient Care Plans	Transitional Care Plan (Jails)	Filled out by the care coordinator and patient, updated by the care coordinator and the community based case manager	Implementation outcome: Fidelity	Care coordinator, Community based case manager	1x client, revised as needed	Reviewed by the DEC Team at site visits
	Patient Care Plan (Peer)	Filled out by the peer and the patient, used to monitor progress towards goals and transition a patient into standard of care	Implementation outcome: Fidelity	Peer	1x client, revised as needed	Reviewed by the DEC Team at site visits
	Patient Care Plan (Navigation)	Filled out by the navigator and the patient, used to monitor progress towards goals and transition a patient into standard of care. Note: the patient care plan for this intervention includes an acuity tool.	Implementation outcome: Fidelity	Navigator	1x client, revised as needed	Reviewed by the DEC Team at site visits
	Patient Agreement (Buprenorphine)	Filled out by the prescribing provider or the clinical coordinator and the patient, used to monitor progress towards goals and transition a patient into standard of care	Implementation outcome: Fidelity	Prescribing provider or clinical coordinator	1x client, revised as needed	Reviewed by the DEC Team at site visits

Data Sources for Cost Analysis

Data Source	Description	Relationship to Proctor Model	Responsible party	Frequency of data collection	Collection method
Cost analysis worksheet	Worksheet to track overall intervention costs, labor and programmatic costs, cost per client served, cost per client retained	Implementation outcome: implementation cost	Data Manager at each site and DEC	TBD	Submission of worksheet to AU with monthly invoicing
Clinic budget	Used to determine if the interventions are financially possible without continued financial and technical assistance support from HRSA	Implementation outcome: integration	Data Manager at each site and DEC	Annually	Requested and collected at the annual site visit

Data Sources for Outcome Evaluation

Data Source	Description	Relationship to Proctor Model	Responsible party	Frequency of data collection	Collection method
Baseline client survey	Socio-demographics, risk and needs variables, barriers to care, stigma, violence and trauma, use of services including health care, support services, mental health and substance use, services, adherence to treatment outcomes, quality of life	Client outcomes: Satisfaction, function,	Data Manager at each site	1x client	Direct web-based data entry with paper copies for back-up
Follow-up client survey	Risk and needs variables, barriers to care, stigma, violence and trauma, use of services including health care, support services, mental health and substance use, services, mediators such as relationship with providers, adherence to treatment outcomes, quality of life, patient experience and satisfaction with care	Client outcomes: Satisfaction, function,	Data Manager at each site	At 3, 6, 12 and 18 months (depending on intervention)	Direct web-based data entry with paper copies for back-up
Medical Chart Abstraction	Based data elements outlined in the RSR: core medical services including outpatient ambulatory medical care, CD4 counts and dates, viral load counts and dates, mental health services, medical case management, prescribed HART; support services including case management, referral for	Implementation outcomes: timeliness Client outcomes: function, symptomatology	Data Manager at each site	At 6, 12 and 18 months	TeleForm to be completed and uploaded to the DCC

Data Source	Description	Relationship to Proctor Model	Responsible party	Frequency of data collection	Collection method
	health care and supportive services, and substance use services.				
Qualitative client interviews	Interviews with patients about their experience in the intervention	Client outcomes: Satisfaction, function, symptomatology	DEC	TBD	Interviews conducted by DEC team

Appendix B: Evaluation FAQ Handout for Study Participants

1. Check in with *name of intervention staff* on DATE, at TIME, in ROOM NUMBER

Name of intervention staff will escort you to *the name of the Data Manager*, who is the Data Manager on our team.

- Map of the clinic marked with the location of *name of intervention staff*, *name of the Data Manager*, exit that is closest to public transportation or parking
- Time when *name of intervention staff* will pick you up from your meeting with *name of Data Manager*
- DATE, TIME, LOCATION of your next appointment
- If you have questions today, you can reach:
 - *name of intervention staff* at phone number
 - *name of Data Manager* at phone number

2. Meeting with *name of the Data Manager*. This meeting will take about 45 minutes. If you are feeling concerned time (running late for a bus, etc.), let *the name of the Data Manager* know so that they can make sure that you stay on schedule.

When you meet with *name of the Data Manager*, the Data Manager on our team, you will cover the following:

- An overview of the evaluation
- A screening to make sure that you are eligible for the evaluation
- An explanation of the time commitment for the evaluation, and the compensation for each portion of the evaluation
- Consent to participate in the baseline survey and follow-up surveys
- Consent to participate in the audio recording portion of the evaluation
- Your baseline survey
 - Demographics and background information
 - Housing
 - HIV and medication adherence
 - Case management and service needs
 - Substance use
 - Exposure to violence and victimization (*Note: not for jails intervention)
 - Health-related quality of life
 - Additional information
- Receiving your compensation for the baseline survey
- Scheduling for your follow-up survey. Your follow-up survey will be on DATE, at TIME, in ROOM NUMBER
- Name of Data Manager* will provide you with the following information:
 - Their contact information
 - Contact information for crisis counselors/behavioral health support team
 - A copy of your signed consent forms

3. *Name of intervention staff* will pick you up at the end of the appointment to answer any questions and check in after the baseline survey.

Appendix C: Screening and Eligibility Form

*See PDF on DEC Website

Appendix D: Evaluation FAQ Handout for Study Participants

1. Is it mandatory that patients in the interventions also be part of the multi-site evaluation?
All patients should be informed and asked to enroll in the multi-site evaluation, however, participation is completely voluntary. Patients can decline and still receive the intervention services. There will be a form you will be asked to complete about why the patient declined. These data will be collected and used only in the aggregate.
2. Will my answers to surveys be kept private?
Yes, all answers will be kept private and confidential. After conducting the patient survey interviews, site staff will never have access to individual responses with identifiers. Individual responses will only be kept by the Data Coordinating Center at Boston University, and the individual responses will be de-identified prior to release to the DEC team and other researcher for analysis, meaning that the people who are reviewing the responses will not be able to match the responses back to an individual participant.
3. Who can see my answers?
Researchers at Boston University and other approved agencies will have access to review the de-identified data for the multi-site evaluation. Your peer/patient navigator/care coordinator/doctor will not be able to see these responses.
4. How long will the interview take?
The time for this interview varies, but it generally takes about [XX] minutes. Of course, each person may take a little more or less time, depending on that individual's pace. I think you'll be surprised at how fast the time goes by.
5. Why should some participate in the multi-site evaluation?
The information you provide will be used to help your community. Most people that complete the survey find it interesting. We understand that your time is valuable. Your participation in the survey can help efforts to bring needed medical care and health promotion services to your community. Because of strict scientific research methods, you cannot be replaced by anyone else for this study.
6. What if "I'm too busy," "I'm not feeling very well," "This is a bad time"
I understand. We need to learn about the experiences of busy people like you. Our results would be incomplete if we only included respondents who could immediately make the time to talk with us. We can make an appointment for me to visit again, at a time that would be better for you. I can come back in the morning, afternoon, or evening on the best day for you. We can start now and finish when you have more time. Let's start and see how far we can get. We may be able to finish it.
7. Are we offering compensation for completing the surveys?
Yes. We are offering a thank-you gift [describe compensation] to those who complete the interview. Explain the amount your agency is offering
8. Can patients get the results of the study?
Summary reports will be available from [name your health organization] at the end of 3 years. Here is the name of the person to call to obtain a copy: [Data Manager at your site].

Appendix E: Audio Recording FAQ Handout for Study Participants

1. Why do you want to record my conversations?

- a. The audio recordings will be reviewed to make sure that we are providing services that address patient needs and will help us to identify opportunities to strengthen the way we provide services to you. The recordings will be used to learn more about the services you may need, and will help me to improve at my job.

2. Who will listen to the recording?

- a. There will be 3 people who will review your recordings. These 3 people have human subjects training and are ethically bound to not disclose any of the information that they hear on the recording.

3. I don't want people to know my HIV status.

- a. The audio recordings are confidential. The people who are reviewing them will not know your name or any other identifying information about you. They will not be able to link your name to your recording.

4. How long will they have the recording?

- a. All recordings will be completely destroyed and deleted from any systems 12 months after they have been uploaded into the secure, password protected site at Boston University. Boston University will keep them for a maximum of 12 months but they may delete them earlier than that.

5. Do I have to be recorded?

- a. You do **NOT** have to consent to be recorded in order to participate in the evaluation (the baseline and follow-up) or to receive intervention services. Even if you do consent to participate in audio recording, you can always choose not to be recorded for one session, or part of a session. If you do not consent to be audio recorded, it will not affect the social services or medical care that you receive.

6. When will I be recorded?

- a. Each month, we receive a random sample of patient ID numbers to record over the course of a month. Your number may be on our list for one month or may never be on our list – again, it is a randomly generated list. Once we get that list, your Peers counselor will let you know that they would like to record their interactions with you during that month. The number of times that you are recorded will depend on the number of times that you meet over the course of the month.

7. How do the recordings work? What will happen when I am recorded?

- a. Your peer counselor will use a handheld audio recorder to record your in-person conversations. The peer counselor will ask for your permission again before each and every session where they plan on recording, and you can always decline to have that conversation recorded. They will then upload that file to a secure online computer system to share the file with Boston University, who will review the audio file.

[Appendix F and G: Participant Questionnaire \(Baseline and Follow-Up\)](#)

*See PDF on DEC Website

[Appendix H: Participant Encounter Form](#)

*See PDF on DEC Website

[Appendix I: Participant Chart Review Form](#)

*Available to download from DCC system.

Appendix J: Template Master ID List

Instructions:

- When you enroll a participant in the multi-site evaluation, the DEC tracking website will create a unique study ID number for that person.
- Record the study ID number and the person's name on this list.
- Use this study ID number on all evaluation study data collection tools.

Important:

- DO keep this list locked in a secure place at all times.
- DO keep this list separate from any collected data with identifiable information.
- DO **NOT** make copies of this list.
- DO **NOT** let anyone borrow this list.

#	PARTICIPANT NAME	PARTICIPANT ID	DATE OF ENROLLMENT
<i>E.g.</i>	<i>John Doe</i>	<i>9999</i>	<i>01/01/2017</i>
1			
2			
3			
4			
5			
6			
7			
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10			
11			
12			
13			
14			
15			

Appendix K: Reaching the Hard to Reach Resources

- **Engaging hard to reach populations (enrollment and recruitment)**
- **Locating hard to reach populations**

HRSA, Innovative Approaches to Engaging Hard-to-Reach Populations Living with HIV/AIDS into Care
http://careacttarget.org/sites/default/files/file-upload/resources/Outreach_trainingmanual_final.pdf

HRSA, Outreach: Engaging People In HIV Care
<https://careacttarget.org/library/outreach-engaging-people-hiv-care>

SAMHSA, Reaching and Engaging “Non-College” Young Adults in Prevention Efforts
<https://www.samhsa.gov/capt/sites/default/files/resources/reaching-noncollege-young-adults.pdf>

HHS, Recruitment, Retention, & Engagement
<https://www.hhs.gov/ash/oah/resources-and-training/tpp-and-paf-resources/recruitment-retention-and-engagement/index.html>

Resources for Integrated Care, Hard-To-Reach Populations: Innovative Strategies To Engage Isolated Individuals
https://www.resourcesforintegratedcare.com/behavioral_health/member_engagement/webinars

Resources for Integrated Care, Hard-To-Reach Populations: Innovative Strategies To Engage People With Mental Health Conditions Or Substance Use Disorders
https://www.resourcesforintegratedcare.com/MemberEngagement/2017_ME_Webinar_Series/Innovative_Strategies

BMC Medical Research Methodology, Reaching the hard-to-reach: a systematic review of strategies for improving health and medical research with socially disadvantaged groups
<https://bmcmmedresmethodol.biomedcentral.com/articles/10.1186/1471-2288-14-42>

NHCHC, Outreach & Enrollment Quick Guide: Promising Strategies for Engaging the Homeless Population
<http://www.nhchc.org/wp-content/uploads/2014/01/outreach-enrollment-quick-guide.pdf>

MedHeart – Finding and Engaging People in Care
<http://cahpp.org/project/medheart/resources>

Engaging Young MSM of Color in HIV Prevention in the Primary Care Setting
http://www.lgbthealtheducation.org/wp-content/uploads/2012/06/Fields.HIV_Prevention_in_young_MSM_of_color.pdf

Using Surveillance and Other Data to Improve HIV Care Linkage and Retention
https://effectiveinterventions.cdc.gov/docs/default-source/data-to-care-d2c/Think_Tank_Report-Surv_Data_for_LTC.pdf?sfvrsn=0

Data to Care: Using HIV Surveillance Data to Support the HIV Care Continuum
<https://effectiveinterventions.cdc.gov/docs/default-source/data-to-care-d2c/pdf-of-important-considerations.pdf>