PROTOCOL: Workforce Development Initiative Patient Survey

Specific aim (for the patient survey, specifically):

To assess changes in patients' engagement and satisfaction with care in response to practice transformative model

Note: if the patient survey protocol is part of a larger IRB protocol related to the study, this aim will likely be folded in among the larger set of aims related to your local evaluation.

Study design:

This component of the Workforce Development Initiative (WDI) evaluation is a **patient survey**. It will assess basic demographic information about the patients; health history, including HIV-related medical history; satisfaction with and engagement in care; perceived accessibility of care; and healthcare needs and preferences. Demonstration Site investigators will obtain informed consent and then provide patients with an emailed, electronic link to a web-based survey, an electronic tablet on which to complete the survey, or a paper copy of the survey. Patients will enter their answers into the electronic survey, mark their answers directly on the paper copy, or provide their answers verbally to site personnel. For patients with low literacy, the survey may be administered verbally in a private room by Demonstration Site investigators. The survey will be completed by a sample of patients once per year for the duration of the project.

We will obtain a convenience sample of 100 patients per wave (i.e., once per year). The patient survey component of the research has a serial cross-section design, meaning that we will not necessarily sample the same individuals in each wave. Therefore, assuming that all participants are unique, we may sample up to **300 patients** (100 per facility per wave, 3 waves (in years 2016, 2017, and 2018).

Recruitment:

[DESCRIBE YOUR RECRUITMENT PROCEDURE HERE. There is no standardized rule across demonstration project sites. You should follow procedures that work well in your clinical setting. Typically, the procedure will look something like this: "Patients will be referred to project research assistants by clinic personnel. Providers and staff at [name clinical facility or clinical unit] will advise patients of the survey and refer interested individuals to research study personnel to verify eligibility, obtain consent, and conduct the survey. Clinic providers and staff involvement will be limited to referring interested patients. They will not have formal research responsibilities for administering the survey or obtaining consent."]

Process for obtaining informed consent:

Project personnel will be responsible for providing information to potential participants to enable them to make an informed consent decision. Prior to participation in a survey, the investigator will explain in detail the purpose of the survey, outline the topics to be covered as part of the

Comment [WS1]: Note to sites: this is written to handle all possible choices. If you know for certain that you are only using paper surveys or only using the web-based survey, then you can limit the language in your IRB application only to the method you are actually using.

Comment [WS2]: Note to sites: if you have multiple facilities in your demonstration project and if you anticipate that there will be differences across facilities, then we would strongly advised sampling 100 patients per wave per facility (assuming this is feasible). In that case, the language in this paragraph would need to be tweaked.

survey, explain the risk and benefits for participation, highlight to where human subjects concerns may be addressed (e.g., provide the telephone number of the local IRB), and offer to answer any questions that a participant may have. Participants may decide to take the survey at any time during their clinic visit. Verbal consent will be used instead of written consent because written informed consent would constitute the only time that an individual was required to provide his/her name as part of participation. By opting for verbal consent, a participant can remain anonymous.

Inclusion criteria:

1. Receiving HIV care at _____
2. 18 years of age or older
3. Sufficient fluency in English or Spanish to understand and respond to survey questions
4. Able and willing to give informed consent

Exclusion criteria:

1. Not have received HIV care _____
2. Less than 18 years of age
3. Insufficient fluency in English or Spanish to understand and respond to survey questions
4. Not able or willing to give informed consent

Procedures:

For each wave of data collection:

1. Project personnel will arrange a time and place for the surveys to be conducted and coordinate logistics for data collection with the clinic facility. Specifically, the project will need to ensure that it has use of space where project personnel can privately explain the study's purpose to interested individuals and where participants can complete the survey in private. Procedures and location will be coordinated with the facility to ensure that survey activities do not disrupt normal clinic operations.
2. Clinic personnel will refer interested patients to a project investigator.
3. Project investigators or research assistants will review eligibility with referred individuals and verify that these individuals meet all inclusion criteria.
4. Project personnel will review the study's purpose and procedures, and describe potential risks, benefits, and protections against risk, and obtain verbal informed consent from those willing to participate. As part of this process, individuals will be provided with a written Information Sheet summarizing study procedures, risks, and benefits. (See attached Information Sheet.)
5. The survey will be completed in a private location at the healthcare facility. It will be filled out using pen and paper, electronic tablet or computer, or verbally.
6. The participant will complete the survey on his or her own, or, if the patient requests it, with the assistance of a project investigator or research assistant, who will read the survey questions and record the patient's responses.
7. If needed, the participant may request that a project investigator or research assistant answer any questions or address concerns that the participant may have.
8. After the survey is completed, the investigator will thank the participant, collect the tablet or paper survey, and provide the participant with a $15 gift card for his or her time.

Comment [WS3]: Name facility, clinic, or clinical department where the project practice transformation is taking place and from where you intend to recruit.

Comment [WS4]: Note: we are making the survey available in both English and Spanish. If you are not going to utilize surveys in both languages, then the inclusion criterion can be restricted to the language you will be using.

Comment [WS5]: Name facility where the PTM is being implemented.

Comment [WS6]: As noted above, you can limit the survey to only English or Spanish if that makes sense for your patient population.

Comment [WS7]: Please feel free to add other appropriate disqualifying conditions. For example, if you anticipate that there will be patients who have serious mental health issues or will be chemically altered by drug use, then it may be appropriate to include an exclusion criterion for individuals who are not in a state of mind to be able to offer informed consent.

Comment [WS8]: This step may vary based on your recruitment procedures. It should align with the procedures you lay out in the recruitment section.

Comment [WS9]: This may be called an information sheet or consent form, depending on the practices of your local IRB. It is written documentation about the study that participants can opt to take with them.

Comment [WS10]: Local demonstration projects can decide if they will be offering an incentive and, if so, how much it will be. The dollar amount should be appropriate for a survey expected to take about 15-20 minutes.

9. The completed survey will either be uploaded a database electronically upon completion, or will immediately be placed in a supply bag held by the investigator. Before placing a paper survey in this bag, the investigator will ensure that the participant has not made any marks on the survey pages that would reveal his or her identity (e.g., mistakenly writing his or her name on the survey). Completed surveys will not be stored with documentation that could identify participants.
10. After data collection is done each day, all completed paper surveys will be returned to a locked file cabinet in a locked room in the research project team's offices.
11. Data from the paper surveys will subsequently be entered into an electronic REDCap database to be used during analyses. Surveys administered electronically will automatically upload this data to REDCap. The REDCap survey is hosted by the University of California, San Francisco (UCSF), which is the cross-site evaluation center for the HRSA-funded initiative for which this project is one of 15 demonstration sites. UCSF will only have access to the anonymous information collected in the survey. They will never have access to identifying information for the participants who complete the survey. The informed consent documentation and explanation for the survey will explain that data from the survey will be shared anonymously will UCSF.
12. UCSF will clean data from all demonstration projects, including data submitted as part of this project. It will then use a secured, HIPAA-compliant data portal hosted by the university to transfer a copy of the cleaned data back to the local project team. Note that the local project team will only be receiving the data from the participants recruited under this protocol.

Time commitment (per visit and in total):

Completion of the survey may last between 10 and 20 minutes.

Comment [WS11]: This assumes use of a shorter version of the survey. If opting for the full, longer version, the time estimate should be 20 to 40 minutes.

Locations:

Surveys will take place in a private space at_____

Comment [WS12]: Name the facility where data collection is taking place.

Statistical analysis:

We will describe outcomes at each time point using proportions for categorical outcomes and means or medians with standard deviations or inter-quartile ranges for continuous outcomes. We will assess the mean of within-site changes in outcomes using parametric (pair t-test) or non-parametric Wilcoxon Ranked Sum) paired analyses as appropriate. We will use logistic models for dichotomous outcomes, Poisson or negative binomial models for count outcomes and Gaussian models for continuous outcomes. For each model, we will include indicators for each follow-up period. We will use causal inference methods to adjust for difference in the patient populations in each site and for differential follow-up based on patient characteristics. All analyses will account for the similarity of responses within individual sites (adjust for clustering) using generalized estimating equations.

Risks and discomforts:

The primary risk is loss of privacy as a result of accidental disclosure of study data to individuals outside the research team. Individuals may also experience discomfort when answering specific questions. Participants will have the right to decline to answer any question.

Steps taken to minimize risks to subjects:

Data from the patient surveys will be collected anonymously, minimizing the risks of embarrassing information being disclosed. Participants also will have the right to refuse to answer any question and to withdraw from the study at any time without penalty. Findings from the patient survey will only be reported in the aggregate and will not identify individuals.

Plans for maintaining privacy in the research setting:

Participants have the right to end participation in any component of the research at any time. Participants also have the right to refuse to answer any question during an interview or survey. Surveys will be conducted in a private setting or in a manner that no other individual will be able to see a participant's responses.

Comment [SS13]: Adjust as appropriate.

Possible consequences to subjects resulting from a loss of privacy:

The primary risk is embarrassment or discomfort over disclosure of information that was not intended to be shared beyond the research team.

Financial considerations:

Participants will be provided with a $15 gift card in appreciation of their time. An appropriate vendor for the gift card will be selected in consultation with the demonstration sites. Likely vendors include iTunes, Walgreens, Safeway, or Target. We selected $15 as the payment amount because it is consistent with the amount of money being offered for other studies with similar methods and time commitments. The payment will be supplied to the participant by the study investigator or research assistant at the conclusion of the person's participation (i.e. at the end of the survey or at a point when a participant decides to withdraw from participation while completing the survey). Because participation involves only one survey, the maximum amount of money a participant can be paid is $15.

Comment [WS14]: As noted: it is up to site to decide if, and how much, incentive to offer. Please remember that you cannot pay participants in cash on a HRSA-funded project. Incentives must be given as gift cards.

[SITE]
INFORMATION SHEET

Study Title: Special Projects of National Significance (SPNS) Program: System-level Workforce Capacity Building for Integrating Primary Care in Community Health Care Settings

This is a research study about transforming clinical practice among providers and staff serving HIV-infected patients. The study researchers, [investigator names here] will explain this study to you.

Research studies include only people who choose to take part. Please take your time to make your decision about participating, and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers.

You are being asked to take part in this study because you receive care at [site], which is taking part in the *System-level Workforce Capacity Building for Integrating Primary Care in Community Health Care Settings* project, funded by the Health Resources and Services Administration Special Projects of National Significance (HRSA SPNS).

Why is this study being done?

The purpose of this study is to evaluate fifteen demonstration projects within the United States which aim to develop or enhance Practice Transformative Models for the care and treatment of people with HIV. This research is funded by HRSA SPNS to evaluate the effectiveness of each PTM as a model of service delivery for HIV care.

How many people will take part in this study?

About 4,500 people will take part in this study across all fifteen demonstration sites.

What will happen if I take part in this research study?

If you agree, the following procedures will occur:

- You will complete a short pen-and-paper survey that may last up to 15 minutes. The survey will ask you about your satisfaction with and engagement in care at [site].
- A researcher from [site] will provide you with a copy of the survey, a pen, and a clipboard, and then you will complete the survey on your own. The researcher will be available to answer any questions or address any concerns should you have them.
- To help protect your confidentiality, the survey will not collect any information that personally identifies you. In addition, because you will complete the survey on your own, the researcher will not know what answers you are giving to the questions.

How long will I be in the study?

Participation in the study will take a total of about 10-15 minutes.

Comment [KV15]: Sites: adjust text here to reflect the mode of delivery (paper, tablet, verbal etc.) and the length of survey you have chosen for your site – 10-20 for shorter version and 20-40 for longer.

Comment [KV16]: Again, adjust to reflect procedures selected for your site.

Comment [KV17]: Adjust to reflect the length of survey selected for your site.

Can I stop being in the study?

Yes. You can decide to stop at any time. Just tell the study researcher or staff person right away if you wish to stop being in the study.

Also, the study researcher may stop you from taking part in this study at any time if he or she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What side effects or risks can I expect from being in the study?

There are very minimal risks associated with this study. Some of the interview questions may make you uncomfortable or upset, but you are free to decline to answer any questions you do not wish to answer or to leave the interview at any time. For more information about risks and side effects, ask one of the researchers.

Are there benefits to taking part in the study?

There will be no direct benefit to you from participating in this study. However, the information that you provide may help health professionals and [site] better understand/learn more about Practice Transformative Models.

What other choices do I have if I do not take part in this study?

You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you.

Will information about me be kept private?

We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your research records for research, quality assurance, and data analysis include:

[Insert the name of your IRB here]

Because this project is part of a larger HRSA-SPNS initiative, your responses and the responses of other participants will be submitted to collaborating investigators at the University of California, San Francisco (UCSF) so that they can compare patient perspectives at [site] to the perspectives of patients from other sites in the initiative. UCSF investigators will not be given your name. It is also extremely unlikely that they or anyone else would be able to identify you from the responses to the questions in this survey. To maximize protection to you, UCSF investigators will not share the survey with anyone who is not part of their evaluation team. Any findings from the survey will only be reported in the aggregate, meaning your individual responses will not be reported.

What are the costs of taking part in this study?

You will not be charged for any of the study treatments or procedures.

Will I be paid for taking part in this study?

You will not be paid to participate in this study.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. You will not lose any of your regular benefits, and your job will not be affected by your decision to participate or not participate in this study.

Who can answer my questions about the study?

You can talk to the researchers about any questions, concerns, or complaints you have about this study. Contact [site investigator] or the other study investigators at [telephone number]
If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the [IRB] at [telephone number].

CONSENT

You have been given a copy of this consent form to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

_____ _____

Date Person Obtaining Verbal Consent

Comment [KV18]: Adjust to reflect size of incentive, if one will be offered.

Comment [wts19]: Please remember that participants in HRSA-funded evaluations cannot be paid cash incentives. Gift cards, however, are acceptable.