Section 13. Peer Health Navigation, Counseling, Qualitative Research

13.1 Overview of Section 13

This section provides information on preparation for and execution of three components of the HPTN 061 study: peer health navigation, counseling, and qualitative research. The information in this SSP section is supplementary to the detailed information about these components that can be found in the operations manuals appended to this SSP manual:

- HPTN 061 Peer Health Navigation Operations Manual and Appendices (Appendix E)
- HPTN 061 Counseling Manual (Appendix F)
- HPTN 061 Qualitative Manual (Appendix G)

13.2 Peer Health Navigation

As described in the HPTN 061 protocol, the Peer Health Navigator (PHN) will help participants overcome their particular barriers to obtaining health care through a step-wise methodology of:

- building rapport with the participant,
- helping the participant identify barriers to accessing needed services,
- devising a plan to overcome those barriers
- directly and indirectly assisting the participant in implementing the plan

The types of services each client needs, the barriers they might experience and their priorities (in the case of several needs) will vary from client to client. The PHN should work with each person to help them identify their area of greatest need, develop an action plan to meet those needs and build the necessary skills so the participant can continue to address their own needs in the future.

13.2.1 Documentation

PHNs will complete a PHN Encounter Form and the PHN Referral Log (if appropriate) after each contact with their clients. The PHN Encounter Form must be faxed to SCHARP after each client contact. The PHN Referral Log will be maintained throughout study participation and faxed to SCHARP at the conclusion of the participant's study participation. Other documentation maintained by the PHN such as case notes, Intake Assessment, and Action Plans are not DataFax forms but should make up a participant's file. See the Operations Manual and Appendices for templates of these forms.

13.2.2 Health Navigation Contacts

PHN contact with participants through meetings, phone calls or other contacts will vary in type, length and frequency based on the needs of the participant. Ideally, the participant will meet the PHN during their enrollment visit and set an appointment for an intake meeting for a later date. The first full meeting of the PHN and participant will include completion of the Intake Assessment and developing an Action Plan. For more details and examples of high and low intensity participants see the PHN Operations Manual. Although there is no minimum number of required contacts, PHNs should target to achieve the following minimum number of contacts with participants identified below based on enrollment category.

Participant Enrollment Category	Target minimum number of PHN contacts during the first 3 months	Target type of additional meetings
HIV positive, not in care	9	At least two accompanied visits to health provider
HIV positive, in care, but reports unprotected anal sex with HIV negative or unknown partners	3	
HIV positive, newly diagnosed at enrollment	9	At least two accompanied visits to health provider
HIV negative	3	
HIV unknown	3	

PHNs should also work with other site staff to help remind participants of upcoming study follow-up visits at 26 and 52 weeks. No PHN meetings will occur after the 52 week study visit. The PHN should begin transferring participants to local service providers for additional needs several weeks before the 52 week follow-up visit for participants who need additional long-term services.

13.2.3 Distinguishing the roles of the Counselor and Peer Health Navigator

There are two staff roles in this study that will have the greatest level of direct contact with participants, the Counselor and the Peer Health Navigator (PHN). These roles are distinct, although they may overlap in some places, and clarifying who will be doing what is important for defining how this study will be executed. Some sites (as discussed below) will have individuals who fulfill both roles. Some basic distinctions between the Counselor and the PHN are provided below.

The Counselor will always see the participant in the clinic, and almost always during a scheduled visit (enrollment, 6- or 12-months). The Counselor will inquire about a participant's emotional responses to the ACASI instrument, and will use their counseling experience and training to determine when a participant requires a referral to a licensed mental health provider. The Counselor will also provide pre- and post-test HIV counseling, as well as STI counseling and risk reduction counseling directly to the participant. Based upon the participants' needs identified during the counseling session, the Counselor may make a referral for care, or may engage the PHN to make these referrals. The interaction between Counselor and participant will be of limited duration and infrequent, since only three study visits are scheduled, six months apart.

Ideally, the PHN will usually meet the participant for the first time during their enrollment visit but this is likely to be brief due to time constraints. The PHN will most often use this meeting to be introduced and set up the first full meeting to take place within a week. Subsequent meetings between the PHN and participant will occur on a schedule independent of the regular study visits, and may often take place outside of the clinic. The primary role of the PHN is to identify the needs of the participant for health care or other services and to help the participant acquire those services. The PHN is not expected to provide pre- or post-test counseling for HIV or STI testing, or risk reduction counseling, or to assess participant distress or mental health (except to recognize signs of a participant in distress and to respond appropriately by contacting the licensed clinician for evaluation or instruction). Interactions between the PHN and participant may be less formal than the participant's interactions with the Counselor. The PHN will likely meet and/or communicate with the participant much more often than the Counselor, particularly at the beginning of their work together.

A summary of activities for a Counselor and a PHN in their interaction with a client is provided below, based upon a model in which the Counselor and PHN are different site staff. A description of issues that arise when these roles are performed by the same person follows.

Counselor Responsibilities:
1) Provides "invitational" post-ACASI counseling for all participants
2) Introduces the concept of PHN to those who are eligible
3) Provides HIV and STI pre-test counseling
4) Provides HIV and STI post-test counseling
5) Completes risk reduction counseling and planning for participants who are either HIV negative or known HIV positive
6) Makes a referral for care if the participant has a need for one. For participants who will work with a PHN, the counselor can decide with the participant to let the PHN make the referral
7) Performs an end-of-visit "check in" to make sure participant is not in crisis/needing to talk to a licensed mental health provider, or if he is, contacts the provider
8) Introduces participant to PHN, if eligible/interested.

PHN Responsibilities:
1) Explain to participant the role of the PHN and set expectations for navigation
2) Complete Intake Assessment to assess participant needs for health care or other services
3) Complete an Action Plan with the participant to prioritize their needs and identify next steps to reaching their goals
4) Provide referrals, assistance, encouragement, skills training, accompaniment, and support to the participant to help them obtain the services they have prioritized

13.2.4 Counseling/PHN Approaches

Sites participating in HPTN 061 will use at least three different approaches to dividing the responsibilities of counseling and peer health navigation among study staff.

- **Option 1:** Some sites will divide the counseling and navigation roles among separate staff, so that a Counselor will not have any navigation responsibilities and the PHN will not have any counseling responsibilities.
- **Option 2**: Some sites will cross train all counseling/navigation staff so that everyone who is a Counselor is also a PHN. Depending on site decisions, a single person may serve as the Counselor and PHN for an individual participant, or a participant may have different people serving him as Counselor and PHN, to keep the roles distinct, even though all staff will be capable of serving either role.
- **Option 3**: Some sites will use a hybrid approach, in which individual staff members will be assessed for their particular skills, and will subsequently be used as a Counselor, PHN or both.

All of these approaches are allowed for HPTN 061, however, sites must make it clear in their SOPs and study documentation which approach they are using, what their rationale is for using that approach, and how the roles of the counselor and navigator will be defined and maintained, even if the same person is serving as Counselor and PHN. Both PHNs and Counselors should be careful not to provide mental health or substance abuse counseling above their level of training.

At sites where the Counselor and navigator roles are being performed by the same person (options 2 and 3), additional concerns must be addressed by site staff:

- Skills- Finding personnel who can perform both Counselor and PHN roles, since the skill sets and personal characteristics for the two roles, while not mutually exclusive, are not the same.
- Scheduling- Counselors work at the site and need to keep fixed hours at least some of the time, whereas PHNs typically work in the field much of the time and need to be more responsive to the schedules of the participants.
- Participant Dissatisfaction- When different people perform the Counselor and PHN roles, a participant who is dissatisfied with one can discuss it with the other and be reassigned. However when one person is both Counselor and PHN for a participant, the participant may feel uncomfortable requesting a switch since the person they have

the most interaction with will be the person they would be asking to transition away from. And so they may choose instead not to participate.
- Association of Counselor with Positive HIV Result: In previous health navigation programs, participants who received a first-time positive HIV test associated that traumatic event with the counselor who provided the pre- and post-test counseling to them, making it hard for them to work with that person in future. Sites should consider having HIV test counseling and provision of results performed by someone other than their assigned navigator.

Sites planning on having personnel perform both roles should note in their SOPs how they will address/mitigate the relevant concerns listed above.

The site specific SOP (regardless of PHN approach) should also describe the mechanisms for encouraging participant feedback on their navigator to allow for reassignment.

13.2.5 Local Services inventory

- Both PHNs and Counselors will need to reference an up-to-date inventory of locally-available services, with an emphasis on cultural competence for Black MSM clients, when making referrals for 061 participants with health care or other needs. It is the responsibility of site staff, particularly PHNs and Counselors, to determine the types of services that will be needed by participants and to identify providers of these services in the study area prior to initiation of the study. Each site's list of services will be tailored to local needs but the following should be considered:
- Case Management
- Financial Assistance
- Housing Services, Rehabilitation Services
- Crisis Counseling
- HIV Prevention Services (testing, prevention case management, free condoms)
- Domestic violence Services
- Substance Abuse Counseling and Services
- Primary Health Care
- HIV Care and Treatment
- Mental Health Care
- Black MSM specific services
- Black Male specific services
- LGBTQ specific services
- Gay men specific services

Staff should not only identify which services are provided where, but collect detailed information, such as hours of operation, when particular services are offered, which staff are preferred by Black MSM (and when these providers are available), how to get there, etc. Wherever possible and practical, site staff should visit the local service provider to

get a sense of the place, to establish relationships with the staff there and to build positive regard for the study. An example of such an inventory is provided in the appendix of the HPTN 061 PHN Operations Manual. All participant referrals should be noted in the participant's file and Referral Log.

Study staff should solicit feedback from participants about local services during the study and should update the inventory on an ongoing basis (at a minimum of every 6 months) based on this information. The site should periodically conduct a formal review of the list by all knowledgeable staff (PHNs, Counselors, community educators, CAB representatives, etc.).

14.1 Counselor, PHN and Qualitative Oversight and Supervision

Counselors, navigators and personnel performing qualitative research require two different types of oversight and supervision: clinical and operational.

Clinical Oversight: Counselors, PHNs, qualitative interviewers and focus group facilitators will require clinical oversight throughout the implementation of HPTN 061. The overseeing clinician must be a licensed mental health provider (masters-level social worker, clinical psychologist or psychiatrist). Clinical oversight activities, which should be described in detail in the site SOPs, are enumerated below.

Operational Oversight: Operational oversight of the Counselors, PHNs, qualitative interviewers and focus group facilitators may be addressed in site SOPs generally addressing personnel management of staff, or may be found in SOPs regarding Counselors, PHNs, qualitative interviewers and focus group facilitators specifically. Regular operational oversight meetings will focus on the administrative requirements and challenges of counseling, health navigation, in-depth interviews and focus groups.

<u>Clinical Oversight</u>
Goals of clinical oversight are:

1. To ensure that Counselors, PHNs, qualitative interviewers and focus group facilitators have a real-time resource available when they are meeting with a participant in case a participant needs to talk to a licensed mental health professional for evaluation and/or triage.
2. To provide continuous training to Counselors, PHNs, qualitative interviewers and focus group facilitators on how to evaluate the needs of a participant and how to respond appropriately.
3. To review the work of the Counselors, PHNs, qualitative interviewers and focus group facilitators and assess their performance/responses from a clinical perspective during regular supervisory sessions
4. To provide support and counseling to individual Counselors, PHNs, qualitative interviewers and focus group facilitators as they process the stress of working with clients

5. To provide a regular opportunity for Counselors, PHNs, qualitative interviewers and focus group facilitators to collectively discuss cases, challenges, procedures, or job-related stress during regular supervisory sessions.

To meet these goals:

6. During open hours for the clinic, a licensed mental health provider will be available via pager. Also, a licensed mental health provider will be available in person, by phone, or via pager any time a counselor is meeting with a participant for a study visit, when a PHN is meeting with a client for the first time, or when a focus group or qualitative interview is taking place..
7. Because there may be times when a PHN, a focus group leader or qualitative interviewer is working with participants at a time outside of business hours, the site will define in their SOPs what resource these staff should contact in order to assist a participant in distress. It may be the pager number for the daytime study mental health provider, but it may instead be a local helpline, crisis center, or hospital, or another local resource.
8. The clinical supervisor will hold group supervision at least once every two weeks with the counseling and PHN staff together to discuss tough cases, challenges, procedures, etc.
9. The clinical supervisor will provide individual supervision with each Counselor and PHN in person at least once every month and once every two weeks for qualitative interviewers or focus group facilitators to discuss any individual concerns they may be having. The frequency may be greater with a newly hired PHN or at the beginning of the study.
10. The clinical supervisor will individually assess the performance of Counselors, PHNs, qualitative interviewers and focus group facilitators in performing their duties from a clinical perspective. The methods and frequency of completion of clinical performance assessments at each site should be described in the site SOPs.
11. Clinical training is an activity that should be ongoing throughout the study. In particular, clinical supervisors should provide training to Counselors, PHNs, qualitative interviewers and focus group facilitators on how to recognize and respond to participants in emotional distress. This training should include how to triage a participant's needs for either a referral, discussion with an on-call clinician, or activation of the emergency protocol. Site SOPs should describe how this training will be executed and at what frequency.
12. Sites SOPs should describe the standards for clinician availability and response, including what back up arrangements are in place if the regular clinician is not available for any reason.

Operational Oversight

The goals of operational oversight are:

1. To ensure PHNs, Counselors, qualitative interviewers and focus-group leaders adequately fulfill the duties required of their role in the study.
2. To ensure that PHNs, Counselors, qualitative interviewers and focus-group leaders have the training, resources, time and support they need to do their job well.

3. To assign PHNs and Counselors to participants.

To meet these goals, the operational supervisor(s):

1. Will establish expectations for PHN, Counselor, qualitative interviewer and focus-group leader responsibilities, performance and documentation, in accordance with the dictates of the protocol, SSP and applicable guidelines.
2. Will assess the performance of PHNs, Counselors, qualitative interviewers and focus-group leaders through the review of work documents such as CRFs, case notes, participant files etc.
3. Will periodically meet with the PHNs and Counselors, and qualitative interviewers and focus-group leaders, as groups and/or individually to review their performance, to provide constructive feedback, and to hear what operational needs and challenges they are encountering.
4. Will arrange initial and ongoing training of PHNs and Counselors and qualitative interviewers and focus-group leaders.
5. Will assign PHNs and Counselors to participants, or will establish and oversee the mechanism by which assignments are made and changed.
6. Will liaise with the clinical supervisor to maintain awareness of individual and group performance of PHNs, Counselors, and qualitative interviewers and focus-group leaders, to address concerns or needs.

Sites will determine the mechanism, frequency and manner in which operational group and individual supervision will be provided for PHNs, Counselors, qualitative interviewers and focus group leaders.

13.3 Counseling

Except for the following note on the definition of counseling, please refer to the HPTN 061 Counseling Manual for additional guidance on the conduct of counseling in HPTN 061.

13.3.1 Note on "Counseling"

The term "counseling" has many meanings. For HPTN 061, we can identify two categories of "counseling". One of these is counseling that is provided as part of specific study procedures including post-ACASI counseling, and pre- and post- test HIV/STI/risk reduction counseling. All Counselors working on HPTN 061 should be trained and certified to provide the pre/post- test HIV/STI/risk reduction counseling as required by local/state requirements. At sites where Counselors and PHNs are different people, PHNs are not expected to have this training or certification, and should not, therefore, provide this sort of counseling. At sites where PHNs have such training and certification by happenstance or by intent, the site will need to define in their SOPs whether these PHNs should be allowed to provide such counseling, and if so, in what situations.

The second type of counseling is clinical counseling, which is only to be provided by a licensed, masters-level or higher social worker, clinical psychologist or psychiatrist. As described elsewhere in this SSP, the licensed mental health professional at a site may need to provide on-the-spot clinical counseling or triage for participants in distress identified by site staff. Note that long term clinical counseling- what might be called "therapy"- is not the role of site staff of 061, but rather is something a participant may be referred for. Prior navigation projects have shown that there is a risk of PHNs "drifting" into providing counseling to participants, even if they are not trained or that is not part of their role, and sites must proactively work to prevent this from happening. Clinical Supervisors should be sensitive to this possibility and work with PHNs to identify and resist the temptation to "drift" into a counseling role.

A third use of the term "counseling", a colloquial definition, could be used to describe the support that PHNs provide in helping the participant identify their health care needs and barriers, encouraging participants to overcome their barriers, providing support for behavior change, etc. We will not refer to these activities as "counseling" in 061 because of the confusion that that could cause in distinguishing this activity from those described above. In this manual, this type of "counseling" is termed navigation.