

# **HPTN 061 Counseling Manual**

## HPTN 061 Counseling Manual

### Introduction and Use of This Manual:

This manual serves many purposes. It was conceived because the requirements of HPTN 061 for counseling extend beyond providing standard HIV pre-, post- and risk reduction counseling. The counselor for an HPTN 061 visit must also introduce the study, orient the participant to the ACASI questionnaire, introduce peer health navigation, etc. As well she or he must also be prepared to check in with the participant at the end of the ACASI and the end of the visit and make referrals as needed for care. This manual provides a blueprint to complete all of these tasks and more, and could be used by a site almost “as-is” except that an overabundance of probes and questions are included, which each counselor would need to select from to suit their personal style.

It is expected however that most sites will have some of these counseling components in place already, their own way of doing things, and in that case, this manual can serve as a guide or checklist for sites to use to make sure their approach adequately addresses all of the requirements of the study, both in content and in approach. To facilitate this, the scripted part of the manual (not italicized) is presented in either red or blue text, in which **red text** are items we think a counselor must address, or even use from this manual verbatim, whereas **blue text** indicates where sites may want to do things in their own way, or to select some items for use and not others. Italicized components are meant as notes to the counselor, not to be read aloud to the participant

The population being enrolled in HPTN 061 is diverse in their HIV status, experiences, and knowledge-level of sexuality and practices. Not all participants enrolled in HPTN 061 will complete all portions of the manual, and it is therefore laid out in a modular fashion so that counselors can refer to only those sections that apply to the participant they are working with at that moment.

Suggestions for improving this manual are welcomed and should be sent to Krista Goodman or Sam Griffith.

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# Enrollment Visit

## Introduction and Orientation

ALL  
PARTICIPANTS

### **Goals:**

- *Establish initial rapport with participant. Help participant feel comfortable by conveying positive regard, genuine concern and an empathic response toward the participant.*
- *Help participant to feel comfortable with the clinic procedures, understand the role of the counselor, and be clear about the content and purpose of the session.*
- *Explain the activities/components of the counseling sessions: post-ACASI; pre-HIV/STI testing; post-HIV test; post-STI test*

Hi, my name is \_\_\_\_\_. I am the counselor who will be working with you today.

There are a number of things we are going to do today:

- discuss the Informed Consent document
- collect locator information so that we can keep in touch with you
- complete some study questionnaires with a counselor
- collect Medical Provider contact information
- you will complete a questionnaire on the computer
- we will then discuss your sexual behaviors, and how you feel about getting tested for HIV and STIs today (if you agree to get tested).
- An HIV rapid test will be done (if agreed), and you will get your test results about 20 minutes later; (if agreed) you'll also be tested for Chlamydia, gonorrhea and syphilis with blood drawn today.
- *If applicable:* Depending on your eligibility, we may ask if you would like to work with a Peer Health Navigator as a part of this study. The peer health navigator is like a personal coach to help people find and keep appointments with their doctor or other kinds of services they need. If you are eligible and interested in working with a Peer Health Navigator, I can introduce you to one before you leave today, or some other time if that works out better.

My role as your counselor is to work with you to explore issues related to your HIV risk. I will also be available to help you if you have other issues that come up in the course of today's visit, and to refer you to available services for these issues, if available.

### **ACASI overview:**

The questionnaire that you will be completing is on a computer and your answers will be kept private so that not even the people here at the clinic will see them. You may quit the questionnaire at any time, or skip questions that you do not want to answer, but I do request that you complete all questions if you can. Your experiences and feelings will be used to help build interventions to slow down the HIV epidemic in Black men.

Some questions will touch on personal topics like what kind of sexual practices you engage in, whether you use drugs, etc. Please remember that your answers

to these questions on the computer will not be seen by site staff at all and will only be linked to your study ID number, not your name.

Some of these personal questions may raise uncomfortable feelings for you. When you're done with the questionnaire on the computer, I'll check in with you to talk about these feelings. At that time we will also talk about your personal level of risk for HIV and what you can do to lower your risk.

***Clinician interaction:***

You will also meet with a Clinician who will examine you to determine your circumcision status, and collect a rectal swab from you to test for gonorrhea and Chlamydia. Please know that you can collect the rectal swab yourself if you prefer.

## **Post-ACASI brief check-in**

### **Goals:**

- *Immediately check-in after completion of the ACASI, while the participant is still in the “open” state, to give the participant the opportunity to talk about his feelings. After being asked so many closed ended, personal, potentially upsetting questions by a machine, give him a chance to feel “human” again, to connect with another person, and to talk about the ACASI experience, and about what he was upset by, curious about, wanting help with.*
- *To provide the participant with information about issues of concern, including information on what help is available for those issues in the local area*
- *To begin discussion of risk*

**Thank you for completing the questionnaire. How was it for you going through the questionnaire? What concerns or questions did it bring up for you?**

*Don't be surprised if participant expresses frustration at length/questions/issues and close-ended nature of the questionnaire. If participant wants to discuss questions they were not able to answer as they might have liked, acknowledge and allow; check-in before moving to next section if there is anything of personal nature that want to discuss – such as, see below:*

*Participant may disclose that it made them realize/think about:*

- *Feel a bit sad from putting together your life events in a new way*
- *Recognition of extent of use of alcohol/drugs*
- *Feeling vulnerable from violence experienced because of attraction to men, or have a violent partner*
- *Feeling a bit raw from abuse experienced either as a child or as an adult*

*Counselor should take note of issues for which it might be possible to provide a referral, including counseling for depression, abuse, PTSD, etc., substance use program, non-psychological health care.*

**Thank you for sharing. We'll be talking about a number of things that the questionnaire may have brought up for you.**

## Risk Reduction Counseling

### *For Participants Who Are HIV Negative or Unknown Status at Start of Enrollment Visit and Participants Refusing HIV Testing*

*The counselor should have an open and inquisitive approach to this portion of the session. This approach will stimulate the participant's curiosity and encourage self-reflection and examination of his own behaviors. The exploration of the risk behavior should be specific. A thorough discussion of the most recent risk behavior may help the participant clarify how the risk behavior occurred. What may have initially seemed like an accident or an unusual incident begins to have concrete circumstances that contributed to the participant's decision to engage in high-risk behavior. This process can demystify the risk behavior for the participant. The questions asked by the counselor are directed at eliciting the entire range of factors that may have contributed to the risk behavior. The counselor should be aware that emotions, recent life events, substance use, self-esteem, and other participant characteristics and issues may influence a particular risk incident or pattern of risk behavior. The counselor and participant should be working together to understand the context of the risk behavior. If the participant's risk behavior is episodic or chronic, the counselor is attempting to discover the factors that contribute to this pattern of risk behavior.*

Now we're going to talk about what you've been doing sexually, and how you feel about it. We're also going to discuss your experiences with condoms, drug and alcohol use, and how that might affect your sexual practices; and how you deal with stress.

(If applicable) We'll also talk about how you feel about getting tested for HIV and STIs. I [or another staff member here] will be drawing some blood from you, and a rapid HIV test will be done. I will talk about what is involved with that in a little bit.

Tell me about the last time you had sex...

- What was your partner like? Male? Female? Older? Younger?
- Do you have a primary partner? Tell me about that relationship.
- How many guys/men did you have sex with in the last 6 months?
- Where do you meet casual partners you have sex with?
- How do you find out about the HIV status of your sex partner?
  - How does your partner's HIV status determine what you'll do sexually with him or her?

Thinking about the last time you had sex without a condom what types of sex did you have? ...

***Anal sex:***

- Are you typically a top, typically a bottom? Both?
- How do you determine who you'll do what with?
- Do you think it's less risky for HIV to be a bottom/top?
- Do you ejaculate/cum in guys?
- Do guys ejaculate/cum in you?
  - *If no, encourage that's a good risk reduction strategy*
  - *If yes, How do you feel about that?*

***Oral sex:***

- What do you do in terms of oral sex?
- Do guys ejaculate/cum in your mouth?
  
- How was this last sex encounter typical of your sexual behavior? What was different?

***Safer Sex:***

**What does safer sex mean for you?**

- How often do you have anal sex with a condom?
- What are your thoughts about using condoms in general?
- What's happening differently in those times when you're using condoms compared to when you don't use condoms?
- Think about times when you have discussed HIV with a sex partner and times when you haven't. How does that discussion affect how likely you are to use condoms?

***Sex with women:***

- Do you have sex with women? Do they know you also have sex with men?
- If/when you have sex with women how does your willingness to use a condom change compared to when you have sex with men?
- Tell me about any concerns you have when thinking about using condoms with women. Are there any that are the same as having sex with men? Different?

Probes:

Pregnancy

Overall, how do you feel about the safety of what you're doing sexually?

*Offer thoughts of level of risk based on behavior/habits reported*

### ***Substance Use***

How do drugs and alcohol affect you being able to have safer sex?

- How often do you drink or use drugs?
- How often do sex and drug use or drinking alcohol go together for you?
- Alcohol – drink at home, go out?
- Marijuana – how does smoking pot change your sexual behavior?
- Cocaine/Crack – what happens to your sexual behaviors when you combine cocaine/crack with sex?
- Inject drugs? (If yes, discuss how use changes behavior & assess for sharing of needles)

### ***Stress and Depression***

- What are some of the stressful things in your life?
- How do you deal with stress?
- Do you have friends you can talk to if you're feeling down?
  - If no, who do you talk to or what do you do when you're feeling down?
- Have you ever thought about talking to a therapist or counselor?
- *(If yes and they haven't seen one, ask them what has stopped them)*
  
- How do you feel today?
- How does feeling down or stressed affect your sexual safety?
  - *If feeling depressed or stressed out* – Is sex one way to deal with it?
- Tell me about the sexual encounters you have when you're stressed or down. How do you think they're different or the same as when you're not stressed or down?
  - *Probe:* sex more likely to be without a condom?

### ***Action Plan- Next Steps***

- After talking about all of this, are there some ideas you can come up with for changes you might like to make in terms of your sexual safety?
  - Probes:
    - What do you think are the most important things you can do to lower your sex risk behaviors?
    - What are some things you would be willing to do to reduce the number of sex partners you have at the same time?
    - What are some ideas to make using condoms a bit more realistic?

## HIV/STI Pre-Test Counseling

### *For Participants Refusing All Testing*

#### *HIV Testing*

So you've decided not to get tested today for HIV or other sexually transmitted diseases. People have a lot of different reasons for not wanting to get tested; can you tell me what some of yours are?

*Probes: confidentiality, not ready for results, don't want to tell people about results, worried about likely reactive result.*

*At this point the counselor should do her/his best to provide the participant with information to help clear any possible misconceptions regarding testing, and ask if they can do anything that would help them get tested today, but without being forceful or demanding. If the participant changes his mind and agrees to testing then proceed as if they had originally wanted an HIV or STI test.*

## HIV/STI Pre-Test Counseling

***For Participants Refusing HIV Testing, Accepting STI Testing***

### ***HIV Testing***

So you've decided not to get an HIV test today. People have a lot of different reasons for not wanting to get an HIV test; can you tell me what some of yours are?

*Probe: confidentiality, not ready for results, don't want to tell people about results, worried about likely reactive result.*

*At this point the counselor should do her/his best to provide the participant with information to help clear any possible misconceptions regarding testing, and ask if they can do anything that would help them get tested today, but without being forceful or demanding. If the participant changes his mind and agrees to testing then proceed as if they had originally wanted an HIV test.*

### ***STI Testing (if agrees to STI testing):***

What do you know about STIs, that is, Sexually Transmitted Infections, also known as STDs?

*Mini overview of Chlamydia/gonorrhea/syphilis? Symptoms, treatment, etc*

Have you ever been tested for STIs? When was the last time?

Do you get tested for STIs regularly, or just when you think you have something?

How do you feel about getting tested for Chlamydia, gonorrhea & syphilis today?

*(If applicable) I want to let you know that in (State) named reporting is required for HIV/Syphilis, etc. If you should test positive for (reportable STIs) we will report your name to the local department of health. Outline local procedures that participant may experience should this occur.*

Partner notification is one component of named reporting. The department of health will notify partners identified by you that someone they have been with sexually has recently tested positive for either HIV or STIs, and recommend that they get tested. The department of health does not tell partners your name, it is kept anonymous. This is an important process in order to make sure your partners are tested and treated as quickly as possible.

*Specimen Collection*

With the blood I draw you'll also be tested for syphilis. We're also going to collect urine from you for Chlamydia and gonorrhea testing. We will also collect a swab from your rectum/butt for Chlamydia and gonorrhea testing, since these diseases can infect both your penis and your butt.

*If treatment being offered on-site:*

Once we get your results, if you are positive for any of the STIs tested for, we will be able to offer treatment at our office.

*Each site to develop own language/plan of how treatment to be handled.*

*If no treatment available on-site; referring out:*

If you test positive for gonorrhea, Chlamydia or syphilis we will refer you to a doctor/facility for treatment. It's really important that you follow-up on the referral so that you can be treated. These STIs are all curable, and when cured, may lower your risk for HIV. We will check-in with you to see how it went or any problems experienced.

## HIV/STI Pre-Test Counseling

*For Participants Who Are HIV Negative  
or Unknown Status at Start of  
Enrollment Visit*

### **HIV Testing:**

**How do you feel about getting tested today for HIV?**

*Incorporate what was discussed earlier regarding last risk to help formulate how feels about getting tested.*

**What do you know about HIV?**

*To assess knowledge – ask about whether or not they know the 4 fluids that can transmit HIV*

**When was the last time you were tested for HIV?**

*Think of behavior reported and discuss HIV window period (today's test capturing anything up to about a month/3-months previously (site specific timeline & dependent on product insert)– risky behavior since then, getting tested again in a month or so)*

**How often do you get tested?**

*[If not tested regularly] Why don't you get tested on a regular basis?*

**What do you think your test result will be today?**

**What does a negative test result mean to you?**

**How important is being HIV-negative to you?**

**What would an HIV-positive test result mean for you?**

**How do you think you would deal with a positive result?**

*Re-visit support network discussed earlier – any potential to do harm to self or others if were to test HIV-positive?*

### **STI Testing:**

**What do you know about STIs, that is, Sexually Transmitted Infections, also known as STDs?**

*Mini overview of Chlamydia/gonorrhea/syphilis? Symptoms, treatment, etc*

Have you ever been tested for STIs? When was the last time?

Do you get tested for STIs regularly, or just when you think you have something?

How do you feel about getting tested for Chlamydia, gonorrhea & syphilis today?

(If applicable) I want to let you know that in (*State*) named reporting is required for HIV/Syphilis, etc. If you should test positive for (*reportable STIs*) we will report your name to the local department of health. *Outline local procedures that participant may experience should this occur.*

Partner notification is one component of named reporting. The department of health will notify partners identified by you that someone they have been with sexually has recently tested positive for either HIV or STIs, and recommend that they get tested. The department of health does not tell partners your name, it is kept anonymous. This is an important process in order to make sure your partners are tested and treated as quickly as possible.

***Explanation of how/what specimens will be collected:***

Have you ever had an HIV Rapid test – and gotten the result in 20 minutes?

***Explanation of Rapid test:***

We're going to draw some blood and in 20 minutes we'll have results. There are three potential outcomes of the Rapid test: HIV negative, preliminary positive, or invalid. Invalid is usually a problem with the test kit and not the person, and we would do the test again. HIV negative results show that as of about a month ago, you hadn't gotten infected. Preliminary positive is the result when it looks like you are probably HIV-positive. The rapid test is not a definitive test – if we get a preliminary positive result, I will then send out a tube of blood to the lab for confirmatory testing. The lab will do a much more accurate test, and we would get those results back in about a week and would draw more blood to re-confirm the results.

*\*\*in lab when doing test show illustration (Rapid test placard) of what different results look like\*\**

***STI testing (if agrees to STI testing):***

With the blood I draw you'll also be tested for syphilis. We're also going to collect urine from you for Chlamydia and gonorrhea testing. We will also collect a swab from your rectum/butt for Chlamydia and gonorrhea testing, since these diseases can infect both your penis and your butt.

- ***If treatment being offered on-site:***

Once we get your results if you are positive for any of the STIs tested for, we will be able to offer treatment at our office.

*Each site to develop own language/plan of how treatment to be handled.*

- ***If no treatment available on-site; referring out:***

If you test positive for gonorrhea, Chlamydia or syphilis we will refer you to a doctor/facility for treatment. It's really important that you follow-up on the referral so that you can be treated. These STIs are all curable, and when cured, may lower your risk for HIV. We will check-in with you to see how it went or any problems experienced.

## Risk Reduction Counseling

### *For Participants Who Know They Are HIV Positive at the Start of Enrollment Visit*

*The counselor should be aware that many components of prevention with positives is similar to the more typical HIV test counseling that they are likely used to, such as goal-setting and risk reduction plans. However, counselors need to be sure to be mindful that people living with HIV may have a variety of different perspectives approaching sexual behavior after diagnosis, and that those perspectives may change over time. The goal of prevention with positives is to help the client change their behavior so that it values their sexual activity, their health, and the health of their partners.*

### **HIV Experience**

How long have you been HIV+?

Have you ever taken any HIV medications?

*If yes, How long have you been taking HIV meds? How has that been?*

*How many different regimens have you been on?*

*What are some strategies are helpful in adhering to your meds?*

*Can you think others of that would be helpful in adhering to your meds?*

Do you have a regular doctor you go to?

*If no, what do you do when you're not feeling well?*

*We'll talk about some ideas or referrals we have to get you hooked up with a doctor.*

*If yes, how often do you go to the doctor?*

*What are some of the reasons you don't go very often?*

### **Overview of super-HIV infection**

*HIV-infected people can be re-infected or co-infected with another strain of HIV. This can occur when they are exposed to a different strain of HIV than what they already have. Being infected with two strains of HIV can make it hard find the right medicines to treat the infection and can even speed the progress of HIV disease for some.*

### **Prevention for Positives**

*We talk to everyone about safer sex for positive men and how they can keep themselves as healthy as possible. I understand that this might be an*

uncomfortable topic, but I want to talk a little bit more about safer sex so you can stay healthy living with HIV.

Some people who live with HIV don't engage in safer sex, while others try to be as safe as they can. **Can you tell me about your experiences with safer sex after you found out you were HIV-positive?**

Has who you're having sex with changed?

Have the types of sex you're having changed?

**Tell me about the last time you had sex...**

- What was your partner like? Male? Female? Older? Younger?
- Who did you have sex with?
- Do you have a primary partner? Tell me about that relationship.
- How many guys/men did you have sex with in the last 6 months?
- Where do you meet casual partners you have sex with?
- How do you find out about the HIV status of your sex partner?
  - How does your partner's HIV status determine what you'll do sexually with him or her?

**Thinking about the last time you had sex without a condom what types of sex did you have? ...**

***Anal sex:***

- Are you typically a top, typically a bottom? Both?
- How do you determine who you'll do what with?
- Do you think it's less risky for HIV to be a bottom/top?
- Do you ejaculate/cum in guys?
  - *If no, encourage that's a good risk reduction strategy*
  - *If yes, How do you feel about that?*
- Do guys ejaculate/cum in you?
  - *If no, encourage that's a good risk reduction strategy*
  - *If yes, How do you feel about that?*

***Oral sex:***

- What do you do in terms of oral sex?
- Do guys ejaculate/cum in your mouth?
- How was this last sex encounter typical of your usual sexual behavior?  
What was different?

*Safer Sex:*

What does safer sex mean for you?

- How often do you have anal sex with a condom?
- What are your thoughts about using condoms in general?
- What's happening differently in those times when you're using condoms compared to when you don't use condoms?
- Think about times when you have discussed HIV with a partner and times when you haven't. How does that affect how likely you are to use condoms?

*Sex with women:*

- Do you have sex with women? Do they know you also have sex with men?
- If/when you have sex with women – are you more likely to use condoms than when you have sex with men?
- Tell me about any concerns you have when thinking about using condoms with women. Are there any that are the same as having sex with men? Different?

Probes:

Pregnancy

Birth Control – protects against pregnancy, not STIs

Who have you told about your HIV status?

Are there people you want to tell but haven't said anything yet?

What's made it difficult to tell them?

Since your diagnosis, what reasons have become important to you when thinking about safer sex?

How important is it to you that you have safer sex?

*-Probe: Provide reasons if they have difficulty thinking of them: protecting from STIs, other HIV strains, transmitting virus to other people*

*The counselor should acknowledge and summarize difficulties the participant is having with safer sex, and then reiterate reasons they identified as why safer sex is important.*

So after discussing this, are there ideas that you can think of so that you can stay safe when having sex?

*-Possible suggestions involve disclosure, less sex partners, always using a condom for anal intercourse, not engaging in penetrative sex*

### ***Substance Use***

How do drugs and alcohol affect your being able to have safer sex?

- How often do you drink or use drugs?
- How often do sex and taking drugs or drinking alcohol go together for you?
- Alcohol – drink at home, go out?
- Marijuana – how does smoking pot change your sexual behavior?
- Cocaine/Crack – what happens to your sexual behaviors when you combine cocaine/crack with sex?
- Inject drugs? (If yes, discuss how use changes behavior & assess for sharing of needles)

### ***Stress and Depression***

- What are some of the stressful things in your life?
- How do you deal with stress?
- Do you have friends you can talk to if you're feeling down?
  - If no, who do you talk to or what do you do when you're feeling down?
- Have you ever thought about talking to a therapist or counselor?
- *(If yes and they haven't seen one, ask them what has stopped them)*
- How do you feel today?

- How does feeling down or stressed affect the safety of your sexual behaviors?

*If feeling depressed or stressed out – Is sex one way to deal with it?*

- Tell me about the sexual encounters you have when you're stressed or down. How do you think they're different or the same as when you're not stressed or down?
  - *Probe:* sex more likely to be without a condom?

### ***STI co-infection with HIV***

STI testing is important for HIV-infected people because syphilis, gonorrhea and Chlamydia infections increase the burden to the immune system, increase the viral load and make men more infectious to others when having unprotected sex with HIV-negative partners. Getting treatment for STIs helps HIV infected people stay healthy and stay less likely to transmit their infection to others.

### ***Action Plan- Next Steps***

- After talking about all of this, are there some ideas you can come up with for changes you might like to make in terms of your sexual safety?
  - Probes:
    - What do you think are the most important things you can do to lower your sex risk behaviors?
    - What are some things you would be willing to do to reduce the sexual risk to yourself and your partners?
    - What are some ideas to make using condoms a bit more realistic?

## HIV/STI Pre-Test Counseling

***For Participants Who Know They Are HIV Positive at the Start of Enrollment Visit***

### ***STI Testing (if agrees to STI testing)***

What do you know about STIs, that is, Sexually Transmitted Infections, also known as STDs?

*Mini overview of Chlamydia/gonorrhea/syphilis? Symptoms, treatment, etc*

Have you ever been tested for STIs? When was the last time?

Do you get tested for STIs regularly, or just when you think you have something?

How do you feel about getting tested for Chlamydia, gonorrhea & syphilis today?

(If applicable) I want to let you know that in (*State*) named reporting is required for HIV/Syphilis, etc. If you should test positive for (*reportable STIs*) we will report your name to the local department of health. *Outline local procedures that participant may experience should this occur.*

Partner notification is one component of named reporting. The department of health will notify partners identified by you that someone they have been with sexually has recently tested positive for either HIV or STIs, and recommend that they get tested. The department of health does not tell partners your name, it is kept anonymous. This is an important process in order to make sure your partners are tested and treated as quickly as possible.

### ***Explanation of how/what specimens will be collected:***

I will draw some blood from you today that we will be using to test you for a few things, including confirming your HIV status. This blood test will be used to test your CD4 T-cell count and viral load measures. You will also be tested for syphilis, and we'll get those results back in about XX (*local lab time*). We're also going to collect urine from you for Chlamydia and gonorrhea testing. Chlamydia and gonorrhea will also be tested for by collecting a swab from your rectum/butt – the reason for the rectal swab test is that these STIs can cause infection in both your penis and your butt.

### ***If treatment being offered on-site:***

Once we get your results if you are positive for any of the STIs tested for, we will be able to offer some treatment at our office or make a referral to an agency for care.

*Each site to develop own language/plan of how treatment to be handled.*

***If no treatment available on-site; referring out:***

If you test positive for gonorrhea, Chlamydia or syphilis we will refer you to a doctor/facility for treatment. It's really important that you follow-up on the referral so that you can be treated. These STIs are all curable, and when cured, can help you stay healthy. We will check in with you to see how it went or any problems experienced.

## STI post-test counseling

*All  
Participants*

### *If negative for all STIs:*

Let's take a look at your test results for Chlamydia and gonorrhea and syphilis; the test results are all negative, which means that you are not infected with any of these STIs. *[If participant will be having follow-up visits]* We will be testing you again for Chlamydia, gonorrhea and syphilis at your 6- and 12-month follow-up visits. If you think you may have been exposed to any of those STIs between your study visits we'll want you to come back to our office to get tested.

### *If positive for one/multi-STIs:*

Let's take a look at your test results for Chlamydia and gonorrhea and syphilis. The test results show that you are positive for (one, two or any of them). What this means is that you have had sex with someone who had [Chlamydia, gonorrhea and/or syphilis] and you were exposed, and infected. Exposure may have happened from oral sex or anal sex.

*What sorts of feelings are you having as I tell you about your positive test result? [If person is distressed or upset, take time to talk with him and let him have his reactions. Normalize feelings of upset or embarrassment.]*

*This/These STI(s) is/are easily treated, and we will be treating you (or referring you for treatment) today.*

*(If applicable) As I mentioned earlier in (State) I am required to report your name to the department of health when infection of (STI) is identified. Can we take a minute and collect some information about recent sexual partners who may have been exposed? I have to submit this paperwork to the department of health, and will not be the one notifying your partners. Your name will not be given as how they may have been exposed, only that they should be immediately tested.*

*Let's take a few minutes and talk about the behavior that you think got you exposed to this/these infections. Talk again of risky behavior and also changes discussed that could be made.*

## HIV Post-Test Counseling

### Participants Who Are HIV Negative or Unknown Status at Start of Enrollment Visit

*(Please refer to the Network Lab Western Blot algorithm, can be found in SSP section 11.4.2 for further explanation of HIV testing procedures. HIV+ participants do not undergo HIV post-test counseling so they should proceed directly to the next section)*

#### For negative/non-reactive test results

Thanks for hanging out while waiting for your test - let's take a look at your HIV test result. The test result shows that you are HIV-negative. This means that any behavior you engaged in until about [a month/three months] ago has not infected you with HIV.

What do you think about this test result?

How can you stay HIV-negative?

We will be testing you again at both your 6-month and 12-month study visit. If you think you're exposed to HIV anytime between those 2 visits we'll want you to come back to our office to get tested. *[Inform participant who to contact (counselor vs. PHN) if they think they've been exposed and what to do]*

#### ***PHN Introduction, If Eligible:***

I mentioned earlier the possibility of working with a Peer Health Navigator, to help you identify some needs you might have in your life- like help getting health care, finding stable housing, etc, and getting referred to care for issues like these. You would work with the PHN on a schedule you decide together, and you can meet where it works best for you two...here, on the phone, in your neighborhood, etc., so your time with the PHN would not be tied to the visits you're going to have here with me, six and 12 months from now. The idea with a PHN is that you start out working together often, and then meet less frequently as time goes by and you are getting the care and services you need. If you have on-going health needs when your study participation is ending, the PHN will try to connect you with a resource outside of this study (like a case manager) who can continue to work with you even though your participation here has ended.

Do you think you'd like to work with a PHN?

*[If no, complete “ENR” CRF. Counselor makes referral as discussed in the End of Visit portion of this manual]*

*[If yes, document his decision, then:]* Your PHN and I are both part of the staff here, so I would share with him the referrals and risk reduction plan we’ve put together today, so he knows where to start from. And he’ll let me know what you two are working on from time to time so I’m up to speed when you and I meet six months from now.

Do you have any questions about how PHN works?

Let me introduce you then to \_\_\_\_\_ in a few minutes when we’re finished up, and you two can figure out when you want to get started.

### **For Preliminary HIV Positive Test Results**

Thanks for hanging out while waiting for your test – let’s take a look at your HIV test result. This initial test result is showing as preliminary positive. What this means is that you are probably infected with HIV, and we will send out your blood to the lab before we determine for sure whether you are infected with HIV or not. Given what we’ve discussed about your potential exposures to HIV, today’s result may/may not accurately reflect whether you are infected with HIV.

Take your time to think about what’s going on right now. We have plenty of time to talk about how you’re feeling and what we do from here.

How are you feeling about this initial result?

How will you be for the next few days between now and when we get the confirmatory results?

Do you have any ideas of how to take care of yourself between now and then?

Do you have a friend or someone you would like to call right now to come and meet you, or just talk with?

#### ***Some thoughts of where to go from here:***

*Offer participant opportunity to talk with site clinician about what HIV infection means; participant may not want to discuss anything until confirmatory tests are back.*

## For Confirmed HIV-negative test result following preliminary positive

Thank you for coming back to the office for your confirmatory result, how have you been over the last few days? We have gotten the result from our lab, and the result of the HIV Western Blot test is negative. This means you are not infected with HIV at this time.

This was one of those times, which are rare, when the rapid test result shows HIV positive and the more sensitive and accurate HIV-Western Blot test shows HIV negative. In these cases, it's good to review the commitment to staying HIV-negative and developing a plan to help stay that way.

How are you doing – with this test result?

*Based on behavior reported at Enrollment or follow-up visit:*

I highly recommend that we do another test in XX (*dependent on window behavior of last potential exposure*). Can we make a follow-up appointment for you right now?

### ***PHN Introduction, If Eligible:***

[If eligible] I mentioned earlier the possibility of working with a Peer Health Navigator, to help you identify some needs you might have in your life- like help getting health care, finding stable housing, etc, and getting referred to care for issues like these. You would work with the PHN on a schedule you decide together, and you can meet where it works best for you two...here, on the phone, in your neighborhood, etc., so your time with the PHN would not be tied to the visits you're going to have here with me, six and 12 months from now. The idea with a PHN is that you start out working together often, and then meet less frequently as time goes by and you are getting the care and services you need. If you have on-going health needs when your study participation is ending, the PHN will try to connect you with a resource outside of this study (like a case manager) who can continue to work with you even though your participation here has ended.

Do you think you'd like to work with a PHN?

*[If no, complete "ENR" CRF. Counselor makes referral as discussed in the End of Visit portion of this manual]*

*[If yes, document his decision, then:]* Your PHN and I are both part of the staff here, so I would share with him the referrals and risk reduction plan we've put together today, so he knows where to start from. And he'll let me know what you two are working on from time to time so I'm up to speed when you and I meet six months from now.

Do you have any questions about how PHN works?

Let me introduce you then to \_\_\_\_\_ in a few minutes when we're finished up, and you two can figure out when you want to get started

### **Positive HIV WB Test Result:**

*[Note: it would be a good idea to ensure that a clinician and PHN is scheduled to be available in person whenever a confirmatory result is being given out to a person who's newly diagnosed as positive]*

Thank you for coming back to the office for your confirmatory result, how have you been since the last time I saw you?

We have gotten the result back from our lab, and these results are also HIV positive. The primary test we did was what is called an HIV Western blot test. This was followed up with an HIV viral load test which measures the amount of virus in your blood, and a CD4 test which measures your body's response to the HIV. For your safety and to make absolutely certain we know you are HIV positive, we are going to draw another tube of blood today for another HIV Western Blot test. Once we receive these results, we should have a definitive HIV result, but it is extremely unlikely that those results would be any different from the ones we have now. You will come back to our office in one week for these results.

*(site plan of how to discuss results with participants – clinician to take charge/counselor able to discuss)*

How are you doing?

*Appropriate post-test counseling stuff including referrals/PHN.*

*(If applicable)* As I mentioned earlier in *(State)* I am required to report your name to the department of health when HIV infection is identified. Can we take a minute and collect some information about recent sexual partners who may have

been exposed. I have to submit this paperwork to the department of health, and will not be notifying and will not be the one notifying your partners. Your name will not be given as how they may have been exposed, only that they should be immediately tested.

***PHN Introduction:***

[If eligible] I mentioned earlier the possibility of working with a Peer Health Navigator, to help you identify some needs you might have in your life- like help getting health care, finding stable housing, etc, and getting referred to care for issues like these. You would work with the PHN on a schedule you decide together, and you can meet where it works best for you two...here, on the phone, in your neighborhood, etc., so your time with the PHN would not be tied to the visits you're going to have here with me, six and 12 months from now. The idea with a PHN is that you start out working together often, and then meet less frequently as time goes by and you are getting the care and services you need. If you have on-going health needs when your study participation is ending, the PHN will try to connect you with a resource outside of this study (like a case manager) who can continue to work with you even though your participation here has ended.

Do you think you'd like to work with a PHN?

*[If no, complete "ENR" CRF. Counselor makes referral as discussed in the End of Visit portion of this manual]*

*[If yes, document his decision, then:]* Your PHN and I are both part of the staff here, so I would share with him the referrals and risk reduction plan we've put together today, so he knows where to start from. And he'll let me know what you two are working on from time to time so I'm up to speed when you and I meet six months from now.

Do you have any questions about how PHN works?

Let me introduce you then to \_\_\_\_\_ in a few minutes when we're finished up, and you two can figure out when you want to get started

## End of visit check-in

### All Participants

*The counselor will complete the check-in below, and the PHN will also do a check-in if the participant has a PHN and if this is his first meeting with the PHN*

#### **Between counselor and participant**

We're nearly done with the visit. Before we finish up, I wanted to talk with you about a couple of things. First, as we have talked, you've mentioned some issues about \_\_\_\_\_ [substance use, depression, desire for primary health care, housing assistance, etc.]. If you would like, I can help you [get an appointment, find a program, etc.].

*[If working with a PHN]* You can also wait if you'd like and the PHN can help you with that appointment, since you will be working with him/her on these issues.

Would you like me to make a referral or appointment for you?

*[Whether participant agrees to referral or not]* I also have this list that has resources you could use if at a later time you decide that you would like to get help with something. Can I give you a copy to hold on to?

The other thing I wanted to do is check in with you before you leave. Between the computer questionnaire and our conversation, we've covered a lot of topics that people can find painful or difficult. Some experience emotional reactions that can be unexpected and strong – now or even after you leave here. After all involved in this visit, are you having ANY feelings that you might harm yourself or someone else? To make sure, I'd like to hear from you how intense your feelings have been to today's visit on a scale of 1 to 10, with "1" being "no reaction" and "10" being "most intense feelings ever."

*Depending on response, may go something like this.*

(1-2) Okay, so it wasn't too intense an experience for you. Even so, we're here for you and are available to you to talk with about any difficult or painful feelings that may come up. Would you like to talk with me or a professional therapist about your feelings? *Depending on response, can talk more, provide a referral, or call on-site clinician.*

(3-5) Okay, so it sounds like this visit brought up some stuff for you. Would you like to talk with me or a professional therapist about your experience? *Depending on response, can talk more, provide a referral, or call on-site clinician.*

(>5) Today's visit was pretty intense for you. It might be a good idea for us to talk some more about how you're feeling or if you would like, you could talk with a professional therapist. *Depending on response, can talk more, provide a referral, or call on-site clinician.*

*[Be sure to document any explicit decline of option for speaking to therapist in progress notes.]*

*[If the participant has any inclination toward killing himself or hurting someone else, activate the emergency protocol. ]*

# 6 Month Follow-up Visit

## Reintroduction and Orientation

ALL  
PARTICIPANTS

### Goals:

- *Establish/re-establish initial rapport with participant. Help participant feel comfortable by conveying positive regard, genuine concern and an empathic response toward the participant. Make sure the participant understands why they have returned for the 6-month follow-up visit and how it will differ and be similar to their enrollment visit.*
- *Help participant to feel comfortable with the clinic procedures, understand the role of the counselor, and be clear about the content and purpose of the 6-month follow up session*
- *Explain the activities/components of the follow-up counseling sessions: post-ACASI; pre-STI testing; post-STI test, and pre-HIV testing and post-HIV test (if the participant is not HIV-positive)*

Hi, my name is \_\_\_\_\_. I am the counselor who will be working with you today.

There are a number of things we are going to do today:

- review the procedures to be covered today; update locator information
- have you complete a similar questionnaire on the computer to what you did 6-months ago
- discuss your sexual behaviors and your risk reduction plan for the last 6-months
- HIV/STD testing (if agreed)
- discuss how your experiences with the peer health navigator are going

My role as your counselor is to work with you to explore issues related to your HIV risk. I will also be available to help you if you have other issues that come up in the course of today's visit, and to refer you to available services for these issues, if available.

### ***Clinician interaction:***

You will also meet with a Clinician who will examine you to determine your circumcision status, and collect a rectal swab from you to test for gonorrhea and Chlamydia. Please know that you can collect the rectal swab yourself if you prefer.

### ***ACASI overview:***

I think you remember the questionnaire you completed during the first visit. Today's questionnaire is a bit shorter, but will ask many of the same questions as the first one. As with the first questionnaire, your answers on the computer will be kept private so that not even the people here at the clinic will see them. Please answer the questions as they relate to you today; we understand that some things may have changed and that some things may not have changed in the last 6 months. You may quit the questionnaire at any time, or skip questions that you

do not want to answer, but I do request that you complete all questions if you can. Your experiences and feelings will be used to help build interventions to slow down the HIV epidemic in Black men.

Some questions will touch on personal topics like what kind of sexual practices you engage in, whether you use drugs, etc. Please remember that your answers to these questions on the computer will not be seen by site staff at all and will only be linked to your study ID number, not your name.

Some of these personal questions may raise uncomfortable feelings for you. When you're done with the questionnaire on the computer, I'll check in with you to talk about these feelings. At that time we will also talk about your personal level of risk for HIV and what you can do to lower your risk.

## Post-ACASI brief check-in

**ALL  
PARTICIPANTS**

### **Goals:**

- *Immediately check-in after completion of the ACASI, while the participant is still in the “open” state, to give the participant the opportunity to talk about his feelings. After being asked so many closed ended, personal, potentially upsetting questions by a machine, give him a chance to feel “human” again, to connect with another person, and to talk about the ACASI experience, and about what he was upset by, curious about, wanting help with.*
- *To provide the participant with information about issues of concern, including information on what help is available for those issues in the local area*
- *To begin discussion of risk*

**Thank you for completing the questionnaire. How was it for you going through the questionnaire? What concerns or questions did it bring up for you?**

*Don't be surprised if participant expresses frustration at length/questions/issues and close-endedness of the questionnaire. If participant wants to discuss questions they were not able to answer as they might have liked, acknowledge and allow; check-in before moving to next section if there is anything of personal nature that want to discuss – such as, see below:*

*Participant may disclose that it made them realize/think about:*

- *Feel a bit sad from putting together your life events in a new way*
- *Recognition of extent of use of alcohol/drugs*
- *Feeling vulnerable from violence experienced because of attraction to men, or have a violent partner*
- *Feeling a bit raw from abuse experienced either as a child or as an adult*  
*Counselor should take note of issues for which it might be possible to provide a referral, including counseling for depression, abuse, PTSD, etc., substance use program, non-psychological health care.*

**Thank you for sharing. We'll be talking about a number of things that the questionnaire may have brought up for you.**

## Risk reduction counseling

### *For Participants Who Are HIV Negative or Unknown Status at Start of 6-Month Visit and Participants Refusing HIV Testing*

*The counselor should have an open and inquisitive approach to this portion of the session. This approach will stimulate the participant's curiosity and encourage self-reflection and examination of his own behaviors. The exploration of the risk behavior should be specific. A thorough discussion of the most recent risk behavior may help the participant clarify how the risk behavior occurred. What may have initially seemed like an accident or an unusual incident begins to have concrete circumstances that contributed to the participant's decision to engage in high-risk behavior. This process can demystify the risk behavior for the participant. The questions asked by the counselor are directed at eliciting the entire range of factors that may have contributed to the risk behavior. The counselor should be aware that emotions, recent life events, substance use, self-esteem, and other participant characteristics and issues may influence a particular risk incident or pattern of risk behavior. The counselor and participant should be working together to understand the context of the risk behavior. If the participant's risk behavior is episodic or chronic, the counselor is attempting to discover the factors that contribute to this pattern of risk behavior.*

Now we're going to talk about what you've been doing sexually, and how you feel about it. We're also going to discuss your experiences with condoms, drug and alcohol use, and how that might affect your sexual practices; and how you deal with stress.

(If applicable) We'll also talk about how you feel about getting tested for HIV and STIs. I [or another staff member here] will be drawing some blood from you, and a rapid HIV test will be done. I will talk about what is involved with that in a little bit.

Tell me about the last time you had sex...

- What was your partner like? Male? Female? Older? Younger?
- Do you have a primary partner? Tell me about that relationship.
- How many guys/men did you have sex with in the last 6 months?
- Where do you meet casual partners you have sex with?
- How do you find out about the HIV status of your sex partner?

How does your partner's HIV status determine what you'll do sexually with him or her?

Thinking about the last time you had sex without a condom what types of sex did you have? ...

### ***Anal sex:***

- Are you typically a top, typically a bottom? Both?
- How do you determine who you'll do what with?
- Do you think it's less risky for HIV to be a bottom/top?
- Do you ejaculate/cum in guys?
- Do guys ejaculate/cum in you?
  - *If no, encourage that's a good risk reduction strategy*
  - *If yes, How do you feel about that?*

### ***Oral sex:***

- What do you do in terms of oral sex?
- Do guys ejaculate/cum in your mouth?
  
- How was this last sex encounter typical of your sexual behavior? What was different?

### ***Safer Sex:***

#### ***What does safer sex mean for you?***

- How often do you have anal sex with a condom?
- What are your thoughts about using condoms in general?
- What's happening differently in those times when you're using condoms compared to when you don't use condoms?
  
- Think about times when you have discussed HIV with a sex partner and times when you haven't. How does that discussion affect how likely you are to use condoms?

### ***Sex with women:***

- Do you have sex with women? Do they know you also have sex with men?
- If/when you have sex with women how does your willingness to use a condom change compared to when you have sex with men?
- Tell me about any concerns you have when thinking about using condoms with women. Are there any that are the same as having sex with men? Different?

Probes:

## Pregnancy

Birth Control – protects against pregnancy, not STIs

Overall, how do you feel about the safety of your sexual behaviors?

*Offer thoughts of level of risk based on behavior/habits reported*

### ***Substance Use***

How do drugs and alcohol affect you being able to have safer sex?

- How often do you drink or use drugs?
- How often do sex and drug use or drinking alcohol go together for you?
- Alcohol – do you drink at home, do you go out?
- Marijuana – how does smoking pot change your sexual behavior?
- Cocaine/Crack – what happens to your sexual behaviors when you combine cocaine/crack with sex?
- Inject drugs? (If yes, discuss how use changes behavior & assess for sharing of needles)

### ***Stress and Depression***

- What are some of the stressful things in your life?
- How do you deal with stress?
- Do you have friends you can talk to if you're feeling down?
  - If no, who do you talk to or what do you do when you're feeling down?
- Have you ever thought about talking to a therapist or counselor?
- *(If yes and they haven't seen one, ask them what has stopped them)*
  
- How do you feel today?
- How does feeling down or stressed affect your safe sexual behaviors?
  - *If feeling depressed or stressed out* – Is sex one way to deal with it?
- Tell me about the sexual encounters you have when you're stressed or down. How do you think they're different or the same as when you're not stressed or down?
  - *Probe:* sex more likely to be without a condom?

### *Action Plan- Next Steps*

- After talking about all of this, are there some ideas you can come up with for changes you might like to make in terms of your sexual safety?
  - Probes:
    - What do you think are the most important things you can do to lower your sex risk behaviors?
    - What are some things you would be willing to do to reduce the number of sex partners you have at the same time?
    - What are some ideas to make using condoms a bit more realistic?

## HIV/STI Pre-test counseling

***For Participants Refusing HIV Testing, Accepting STI Testing***

### ***HIV Testing***

So you've decided not to get an HIV test today. People have a lot of different reasons for not wanting to get an HIV test, can you tell me what some of yours are?

*Probe: confidentiality, think they may be infected but are not ready for results, don't want to tell people about results, worried about likely reactive result.*

*At this point the counselor should do her/his best to provide the participant with information to help clear any possible misconceptions regarding testing, and ask if they can do anything that would help them get tested today, but without being forceful or demanding. If the participant changes his mind and agrees to testing then proceed as if they had originally wanted an HIV test.*

### ***STI Testing (if agrees to STI testing):***

What do you know about STIs, that is, Sexually Transmitted Infections, also known as STDs?

*Mini overview of Chlamydia/gonorrhea/syphilis? Symptoms, treatment, etc*

Have you ever been tested for STIs? [skip this question if you know participant tested for STIs at baseline visit]

When was the last time you tested for STIs?

How do you feel about getting tested for Chlamydia, gonorrhea & syphilis today?

(If applicable) I want to let you know that in (State) named reporting is required for HIV/Syphilis, etc. If you should test positive for (reportable STIs) we will report your name to the local department of health. *Outline local procedures that participant may experience should this occur.*

Partner notification is one component of named reporting. The department of health will notify partners identified by you that someone they have been with sexually has recently tested positive for either HIV or STIs, and recommend that they get tested. The department of health does not tell partners your name, it is kept anonymous. This is an important process in order to make sure your partners are tested and treated as quickly as possible.

### ***Explanation of how/what specimens will be collected:***

I will draw some blood from you today that we will be using to test for only syphilis (not HIV), and we'll get that result back in about XX (local lab time). We're also going to

collect urine from you for Chlamydia and gonorrhea testing. Chlamydia and gonorrhea will also be tested for by collecting a swab from your rectum/butt – the reason for the rectal swab test is that these STIs can cause infection in both your penis and your butt.

***If treatment being offered on-site:***

Once we get your results if you are positive for any of the STIs tested for, we will be able to offer some treatment at our office.

*Each site to develop own language/plan of how treatment to be handled.*

***If no treatment available on-site; referring out:***

If you test positive for gonorrhea, Chlamydia or syphilis we will refer you to a doctor/facility for treatment. It's really important that you follow-up on the referral so that you can be treated. These STIs are all curable, and when cured, may lower your risk for HIV. We will check-in with you to see how it went or any problems experienced.

## HIV/STI Pre-Test Counseling

*For Participants Who Are HIV Negative or Unknown Status at Start of 6-Month Visit*

### *HIV Testing:*

How do you feel about getting tested today for HIV?

*Incorporate what was discussed earlier regarding last risk to help formulate how feels about getting tested.*

What do you know about HIV?

*To assess knowledge – ask about whether or not they know the 4 fluids that can transmit HIV*

When was the last time you were tested for HIV?

*Think of behavior reported and discuss HIV window period (today's test capturing anything up to about a month/3-months pror (site specific timeline & dependent on product insert)– risky behavior since then, getting tested again in a month or so)*

How often do you get tested?

*[If not tested regularly] Why don't you get tested on a regular basis?*

What do you think your test result will be today?

What does a negative test result mean to you?

How important is being HIV-negative to you?

What would an HIV-positive test result mean for you?

How do you think you would deal with a positive result?

*Re-visit support network discussed earlier – any potential to do harm to self or others if were to test HIV-positive?*

### *STI Testing:*

What do you know about STIs, that is, Sexually Transmitted Infections, also known as STDs?

*Mini overview of Chlamydia/gonorrhea/syphilis? Symptoms, treatment, etc*

Have you ever been tested for STIs? [skip this question if participant tested for STIs at baseline]

When was the last time?

How do you feel about getting tested for Chlamydia, gonorrhea & syphilis today?

(If applicable) I want to let you know that in *(State)* named reporting is required for HIV/Syphilis, etc. If you should test positive for *(reportable STIs)* we will report your name to the local department of health. *Outline local procedures that participant may experience should this occur.*

Partner notification is one component of named reporting. The department of health will notify partners identified by you that someone they have been with sexually has recently tested positive for either HIV or STIs, and recommend that they get tested. The department of health does not tell partners your name, it is kept anonymous. This is an important process in order to make sure your partners are tested and treated as quickly as possible.

***Explanation of how/what specimens will be collected:***

Have you ever had an HIV Rapid test – and gotten the result in 20 minutes?

***Explanation of Rapid test:***

We're going to draw some blood and in 20 minutes we'll have results. There are three potential outcomes of the Rapid test: HIV negative, preliminary positive, or invalid. Invalid is usually a problem with the test kit and not the person, and we would do the test again. HIV negative results show that as of about a month ago, you hadn't gotten infected. Preliminary positive is the result when it looks like you are probably HIV-positive. The rapid test is not a definitive test – if we get a preliminary positive result, I will then send out a tube of blood to the lab for confirmatory testing. The lab will do a much more accurate test, and we would get those results back in about a week and would draw more blood to re-confirm the results.

*\*\*in lab when doing test show illustration (Rapid test placard) of what different results look like\*\**

***STI testing (if agrees to STI testing):***

With the blood I draw you'll also be tested for syphilis. We're also going to collect urine from you for Chlamydia and gonorrhea testing. We will also collect a swab from your rectum/butt for Chlamydia and gonorrhea testing, since these diseases can infect both your penis and your butt.

- ***If treatment being offered on-site:***

Once we get your results if you are positive for any of the STIs tested for, we will be able to offer treatment at our office.

*Each site to develop own language/plan of how treatment to be handled.*

- ***If no treatment available on-site; referring out:***

If you test positive for gonorrhea, Chlamydia or syphilis we will refer you to a doctor/facility for treatment. It's really important that you follow-up on the referral so that you can be treated. These STIs are all curable, and when cured, may lower your risk for HIV. We will check-in with you to see how it went or any problems experienced.

## Risk Reduction Counseling

***For Participants Who Know They Are HIV Positive at the Start of 6-Month Visit***

*The counselor should be aware that many components of prevention with positives is similar to the more typical HIV test counseling that they are likely used to, such as goal-setting and risk reduction plans. However, counselors need to be sure to be mindful that people living with HIV may have a variety of different perspectives approaching sexual behavior after diagnosis, and that those perspectives may change over time. The goal of prevention with positives is to help the client change their behavior so that it values their sexual activity, their health, and the health of their partners.*

### ***HIV Experience***

How long have you been HIV+?

[skip this question if participant was HIV+ at baseline]

Are you taking HIV medications?

*If yes, How long have you been taking HIV meds? How has that been?*

*How many different regimens have you been on?*

*What are some strategies are helpful in adhering to your meds?*

*Can you think others of that would be helpful in adhering to your meds?*

Do you have a regular doctor you go to?

*If no, what do you do when you're not feeling well?*

*We'll talk about some ideas or referrals we have to get you hooked up with a doctor.*

*If yes, how often do you go to the doctor?*

*What are some of the reasons you don't go very often?*

### ***Overview of super-HIV infection***

*HIV-infected people can be re-infected or co-infected with another strain of HIV. This can occur when a person is exposed to a different strain of HIV than what they already have. Being infected with two strains of HIV can make it hard find the right medicines to treat the infection and can even speed the progress of HIV disease for some.*

### ***Prevention for Positives***

*We talk to everyone about safer sex for positive men and how they can keep themselves as healthy as possible. I understand that this might be an*

uncomfortable topic, but I want to talk a little bit more about safer sex so you can stay healthy living with HIV.

Some people who live with HIV don't engage in safer sex, while others try to be as safe as they can. **Can you tell me about your experiences with safer sex after you found out you were HIV-positive?**

How often do you have partners who are HIV-negative or who say they don't know their status (presumed positive)?

Has who you're having sex with changed?

Has the types of sex you're having changed?

**Tell me about the last time you had sex...**

- What was your partner like? Male? Female? Older? Younger?
- Who did you have sex with?
- Do you have a primary partner? Tell me about that relationship.
- How many guys/men did you have sex with in the last 6 months?
- Where do you meet casual partners you have sex with?
- How do you find out about the HIV status of your sex partner?
  - How does your partner's HIV status determine what you'll do sexually with him or her?

**Thinking about the last time you had sex without a condom what types of sex did you have? ...**

***Anal sex:***

- Are you typically a top, typically a bottom? Both?
- How do you determine who you'll do what with?
- Do you think it's less risky for HIV to be a bottom/top?
- Do you ejaculate/cum in guys?
  - *If no, encourage that's a good risk reduction strategy*
  - *If yes, How do you feel about that?*
- Do guys ejaculate/cum in you?
  - *If no, encourage that's a good risk reduction strategy*
  - *If yes, How do you feel about that?*

***Oral sex:***

- What do you do in terms of oral sex?
- Do guys ejaculate/cum in your mouth?
- How was this last sex encounter typical of your usual sexual behavior?  
What was different?

***Safer Sex:***

**What does safer sex mean for you?**

- How often do you have anal sex with a condom?
- What are your thoughts about using condoms in general?
- What's happening differently in those times when you're using condoms compared to when you don't use condoms?
- Think about times when you have discussed HIV with a partner and times when you haven't. How does that affect how likely you are to use condoms?

***Sex with women:***

- Do you have sex with women? Do they know you also have sex with men?
- If/when you have sex with women – are you more likely to use condoms than when you have sex with men?
- Tell me about any concerns you have when thinking about using condoms with women. Are there any that are the same as having sex with men? Different?

Probes:

Pregnancy

Birth Control – protects against pregnancy, not STIs

Who have you told about your HIV status?

Are there people you want to tell but haven't said anything yet?

What's made it difficult to tell them?

Since your diagnosis, what reasons have become important to you when thinking about safer sex?

How important is it to you that you have safer sex?

*-Probe: Provide reasons if they have difficulty thinking of them: protecting from STIs, other HIV strains, transmitting virus to other people*

*The counselor should acknowledge and summarize difficulties the participant is having with safer sex, and then reiterate reasons they identified as why safer sex is important.*

So after discussing this, are there ideas that you can think of so that you can stay safe when having sex?

*-Possible suggestions involve disclosure, less sex partners, always using a condom for anal intercourse, not engaging in penetrative sex*

### ***Substance Use***

How do drugs and alcohol affect your being able to have safer sex?

- How often do you drink or use drugs?
- How often do sex and taking drugs or drinking alcohol go together for you?
- Alcohol – drink at home, go out?
- Marijuana – how does smoking pot change your sexual behavior?
- Cocaine/Crack – what happens to your sexual behaviors when you combine cocaine/crack with sex?
- Inject drugs? (If yes, discuss how use changes behavior & assess for sharing of needles)

### ***Stress and Depression***

- What are some of the stressful things in your life?
- How do you deal with stress?
- Do you have friends you can talk to if you're feeling down?
  - If no, who do you talk to or what do you do when you're feeling down?
- Have you ever thought about talking to a therapist or counselor?
- *(If yes and they haven't seen one, ask them what has stopped them)*
- How do you feel today?
- How does feeling down or stressed affect your safe sexual behavior?

*If feeling depressed or stressed out – Is sex one way to deal with it?*

- Tell me about the sexual encounters you have when you're stressed or down. How do you think they're different or the same as when you're not stressed or down?
  - *Probe:* sex more likely to be without a condom?

### ***STI co-infection with HIV***

STI testing is important for HIV-infected people because syphilis, gonorrhea and Chlamydia infections increase the burden to the immune system, increase the viral load and make men more infectious to others when having unprotected sex with HIV-negative partners. Getting treatment for STIs helps HIV infected people stay healthy and stay less likely to transmit their infection to others.

### ***Action Plan- Next Steps***

- After talking about all of this, are there some ideas you can come up with for changes you might like to make in terms of your sexual safety?
  - Probes:
    - What do you think are the most important things you can do to lower your sex risk behaviors?
    - What are some things you would be willing to do to reduce the sexual risk to yourself and your partners?
    - What are some ideas to make using condoms a bit more realistic?

## HIV/STI Pre-Test Counseling

*For Participants Who Know They Are HIV Positive at the Start of 6-Month Visit*

### *STI Testing (if agrees to STI testing)*

What do you know about STIs, that is, Sexually Transmitted Infections, also known as STDs?

*Mini overview of Chlamydia/gonorrhea/syphilis? Symptoms, treatment, etc*

Have you ever been tested for STIs? [skip this question if they were tested for stis at baseline]

When was the last time you were tested for STIs?

How do you feel about getting tested for Chlamydia, gonorrhea & syphilis today?

(If applicable) I want to let you know that in (State) named reporting is required for HIV/Syphilis, etc. If you should test positive for (reportable STIs) we will report your name to the local department of health. *Outline local procedures that participant may experience should this occur.*

Partner notification is one component of named reporting. The department of health will notify partners identified by you that someone they have been with sexually has recently tested positive for either HIV or STIs, and recommend that they get tested. The department of health does not tell partners your name, it is kept anonymous. This is an important process in order to make sure your partners are tested and treated as quickly as possible.

### *Explanation of how/what specimens will be collected:*

I will draw some blood from you today that we will be using to test you for a few things, including confirming your HIV status. This blood test will be used to test your CD4 T-cell count and viral load measures. You will also be tested for syphilis, and we'll get those results back in about XX (local lab time). We're also going to collect urine from you for Chlamydia and gonorrhea testing. Chlamydia and gonorrhea will also be tested for by collecting a swab from your rectum/butt – the reason for the rectal swab test is that these STIs can cause infection in both your penis and your butt.

### *If treatment being offered on-site:*

Once we get your results if you are positive for any of the STIs tested for, we will be able to offer some treatment at our office or make a referral to an agency for care.

*Each site to develop own language/plan of how treatment to be handled.*

***If no treatment available on-site; referring out:***

If you test positive for gonorrhea, Chlamydia or syphilis we will refer you to a doctor/facility for treatment. It's really important that you follow-up on the referral so that you can be treated. These STIs are all curable, and when cured, can help you stay healthy. We will check-in with you to see how it went or any problems experienced.

## STI post-test counseling

*All  
Participants*

### *If negative for all STIs:*

Let's take a look at your test results for Chlamydia and gonorrhea and syphilis; the test results are all negative, which means that you are not infected with any of these STIs. *[If participant will be having follow-up visits]* We will be testing you again for Chlamydia, gonorrhea and syphilis at your 6- and 12-month follow-up visits. If you think you may have been exposed to any of those STIs between your study visits we'll want you to come back to our office to get tested.

### *If positive for one/multi-STIs:*

Let's take a look at your test results for Chlamydia and gonorrhea and syphilis. The test results show that you are positive for (one, two or any of them). What this means is that you have had sex with someone who had [Chlamydia, gonorrhea and/or syphilis] and you were exposed, and infected. Exposure may have happened from oral sex or anal sex.

*What sorts of feelings are you having as I tell you about your positive test result? [If person is distressed or upset, take time to talk with him and let him have his reactions. Normalize feelings of upset or embarrassment.]*

*This/these STI(s) is/are easily treated, and we will be treating you (or referring you for treatment) today.*

*(If applicable) As I mentioned earlier in (State) I am required to report your name to the department of health when infection of (STI) is identified. Can we take a minute and collect some information about recent sexual partners who may have been exposed? I have to submit this paperwork to the department of health, and will not be the one notifying your partners. Your name will not be given as how they may have been exposed, only that they should be immediately tested.*

*Let's take a few minutes and talk about the behavior that you think got you exposed to this/these infections. Talk again of risky behavior and also changes discussed that could be made.*

## HIV Post-Test Counseling

### Participants Who Are HIV Negative or Unknown Status at Start of 6-Month Visit

*(Please refer to the Network Lab Western Blot algorithm, can be found in SSP section 11.4.2 for further explanation of HIV testing procedures. HIV+ participants do not undergo HIV post-test counseling so they should proceed directly to the next section)*

#### For negative/non-reactive test results

Thanks for hanging out while waiting for your test - let's take a look at your HIV test result. The test result shows that you are HIV-negative. This means that any behavior you engaged in until about [a month/three months] ago has not infected you with HIV.

What do you think about this test result?

How can you stay HIV-negative?

We will be testing you again at your 12-month study visit. If you think you're exposed to HIV anytime between now and your next visit we'll want you to come back to our office to get tested. *[Inform participant who to contact (counselor vs. PHN) if they think they've been exposed and what to do]*

#### ***PHN Introduction (if not already working with a PHN):***

I mentioned earlier the possibility of working with a Peer Health Navigator, to help you identify some needs you might have in your life- like help getting health care, finding stable housing, etc, and getting referred to care for issues like these. You would work with the PHN on a schedule you decide together, and you can meet where it works best for you two...here, on the phone, in your neighborhood, etc., so your time with the PHN would not be tied to the visits you're going to have here with me, six and 12 months from now. The idea with a PHN is that you start out working together often, and then meet less frequently as time goes by and you are getting the care and services you need. If you have on-going health needs when your study participation is ending, the PHN will try to connect you with a resource outside of this study (like a case manager) who can continue to work with you even though your participation here has ended.

Do you think you'd like to work with a PHN?

*[If no, complete "FUV" CRF. Counselor makes referral as discussed in the End of Visit portion of this manual]*

*[If yes, document his decision, then:]* Your PHN and I are both part of the staff here, so I would share with him the referrals and risk reduction plan we've put together today, so he knows where to start from. And he'll let me know what you two are working on from time to time so I'm up to speed when you and I meet six months from now.

Do you have any questions about how PHN works?

Let me introduce you then to \_\_\_\_\_, and you two can figure out when you want to get started.

## **For Preliminary HIV Positive Test Results**

Thanks for hanging out while waiting for your test – let's take a look at your HIV test result. This initial test result is showing as preliminary positive. What this means is that you are probably infected with HIV, and we will send out your blood to the lab before we determine for sure whether you are infected with HIV or not. Given what we've discussed about your potential exposures to HIV, today's result may/may not accurately reflect whether you are infected with HIV.

Take your time to think about what's going on right now. We have plenty of time to talk about how you're feeling and what we do from here.

How are you feeling about this initial result?

How will you be for the next few days between now and when we get the confirmatory results?

Do you have any ideas of how to take care of yourself between now and then?

Do you have a friend or someone you would like to call right now to come and meet you, or just talk with?

***Some thoughts of where to go from here:***

*Offer participant opportunity to talk with site clinician about what HIV infection means; participant may not want to discuss anything until confirmatory tests are back.*

### **For Confirmed HIV-negative test result following preliminary positive**

Thank you for coming back to the office for your confirmatory result, how have you been over the last few days? We have gotten the result from our lab, and the result of the HIV Western Blot test is negative. This means you are not infected with HIV at this time.

This was one of those times, which are rare, when the rapid test result shows HIV positive and the more sensitive and accurate HIV-Western Blot test shows HIV negative. In these cases, it's good to review the commitment to staying HIV-negative and developing a plan to help stay that way.

How are you doing – with this test result?

*Based on behavior reported at Enrollment or follow-up visit:*

I highly recommend that we do another test in XX (*dependent on window behavior of last potential exposure*). Can we make a follow-up appointment for you right now?

### ***PHN Introduction (if not already working with a PHN):***

I mentioned earlier the possibility of working with a Peer Health Navigator, to help you identify some needs you might have in your life- like help getting health care, finding stable housing, etc, and getting referred to care for issues like these. You would work with the PHN on a schedule you decide together, and you can meet where it works best for you two...here, on the phone, in your neighborhood, etc., so your time with the PHN would not be tied to the visits you're going to have here with me, six and 12 months from now. The idea with a PHN is that you start out working together often, and then meet less frequently as time goes by and you are getting the care and services you need. If you have on-going health needs when your study participation is ending, the PHN will try to connect you with a resource outside of this study (like a case manager) who can continue to work with you even though your participation here has ended.

Do you think you'd like to work with a PHN?

*[If no, complete “FUV” CRF. Counselor makes referral as discussed in the End of Visit portion of this manual]*

*[If yes, document his decision, then:]* Your PHN and I are both part of the staff here, so I would share with him the referrals and risk reduction plan we’ve put together today, so he knows where to start from. And he’ll let me know what you two are working on from time to time so I’m up to speed when you and I meet six months from now.

Do you have any questions about how PHN works?

Let me introduce you then to \_\_\_\_\_, and you two can figure out when you want to get started.

### **Positive HIV WB Test Result:**

*[Note: it would be a good idea to ensure that a clinician and PHN is scheduled to be available in person whenever a confirmatory result is being given out to a person who’s newly diagnosed as positive]*

Thank you for coming back to the office for your confirmatory result, how have you been since the last time I saw you?

We have gotten the result back from our lab, and these results are also HIV positive. The primary test we did was what is called an HIV Western blot test. This was followed up with an HIV viral load test which measures the amount of virus in your blood, and a CD4 test which measures your body’s response to the HIV. For your safety and to make absolutely certain we know you are HIV positive, we are going to draw another tube of blood today for another HIV Western Blot test. Once we receive these results, we should have a definitive HIV result, but it is extremely unlikely that those results would be any different from the ones we have now. You will come back to our office in one week for these results.

*(site plan of how to discuss results with participants – clinician to take charge/counselor able to discuss)*

How are you doing?

*Appropriate post-test counseling stuff including referrals/PHN.*

*(If applicable)* As I mentioned earlier in *(State)* I am required to report your name to the department of health when HIV infection is identified. Can we take a minute and collect some information about recent sexual partners who may have been exposed. I have to submit this paperwork to the department of health, and will not be notifying and will not be the one notifying your partners. Your name will not be given as how they may have been exposed, only that they should be immediately tested.

***PHN Introduction (if not already working with a PHN):***

I mentioned earlier the possibility of working with a Peer Health Navigator, to help you identify some needs you might have in your life- like help getting health care, finding stable housing, etc, and getting referred to care for issues like these. You would work with the PHN on a schedule you decide together, and you can meet where it works best for you two...here, on the phone, in your neighborhood, etc., so your time with the PHN would not be tied to the visits you're going to have here with me, six and 12 months from now. The idea with a PHN is that you start out working together often, and then meet less frequently as time goes by and you are getting the care and services you need. If you have on-going health needs when your study participation is ending, the PHN will try to connect you with a resource outside of this study (like a case manager) who can continue to work with you even though your participation here has ended.

Do you think you'd like to work with a PHN?

*[If no, complete "FUV" CRF. Counselor makes referral as discussed in the End of Visit portion of this manual]*

*[If yes, document his decision, then:]* Your PHN and I are both part of the staff here, so I would share with him the referrals and risk reduction plan we've put together today, so he knows where to start from. And he'll let me know what you two are working on from time to time so I'm up to speed when you and I meet six months from now.

Do you have any questions about how PHN works?

Let me introduce you then to \_\_\_\_\_, and you two can figure out when you want to get started.

## End of visit check-in

All  
Participants

*The counselor will complete the check-in below, and the PHN will also do a check-in if the participant has a PHN and if this is his first meeting with the PHN*

### **Between counselor and participant**

We're nearly done with the visit. Before we finish up, I wanted to talk with you about a couple of things. First, as we have talked, you've mentioned some issues about \_\_\_\_\_ [substance use, depression, desire for primary health care, housing assistance, etc.]. If you would like, I can help you [get an appointment, find a program, etc.].

*[If working with a PHN]* You can also wait if you'd like and the PHN can help you with that appointment, since you will be working with him/her on these issues.

Would you like me to make a referral or appointment for you?

*[Whether participant agrees to referral or not]* I also have this list that has resources you could use if at a later time you decide that you would like to get help with something. Can I give you a copy to hold on to?

The other thing I wanted to do is check in with you before you leave. Between the computer questionnaire and our conversation, we've covered a lot of topics that people can find painful or difficult. Some experience emotional reactions that can be unexpected and strong – now or even after you leave here. After all involved in this visit, are you having ANY feelings that you might harm yourself or someone else? To make sure, I'd like to hear from you how intense your feelings have been to today's visit on a scale of 1 to 10, with "1" being "no reaction" and "10" being "most intense feelings ever."

*Depending on response, may go something like this.*

(1-2) Okay, so it sounds like this wasn't too intense an experience for you. Even so, we're here for you and are available to you to talk with about any difficult or painful feelings that may come up. Would you like to talk with me or a professional therapist about your feelings? *Depending on response, can talk more, provide a referral, or call on-site clinician.*

(3-5) Okay, so it sounds like this visit brought up some stuff for you. Would you like to talk with me or a professional therapist about your experience? *Depending on response, can talk more, provide a referral, or call on-site clinician.*

(>5) Today's visit was pretty intense for you. It might be a good idea for us to talk some more about how you're feeling or if you would like, you could talk with a professional therapist. *Depending on response, can talk more, provide a referral, or call on-site clinician.*

*[Be sure to document any explicit decline of option for speaking to therapist in progress notes.]*

*[If the participant has any inclination toward killing himself or hurting someone else, activate the emergency protocol.]*

# 12 Month Follow-up Visit

## Reintroduction and Orientation

**ALL  
PARTICIPANTS**

### **Goals:**

- *Establish/re-establish initial rapport with participant Help participant feel comfortable by conveying positive regard, genuine concern and an empathic response toward the participant. Make sure the participant understands why they have returned for the 6-month follow-up visit and how it will differ and be similar to their enrollment visit.*
- *Help participant to feel comfortable with the clinic procedures, understand the role of the counselor, and be clear about the content and purpose of the 12-month follow up session*
- *Explain the activities/components of the follow-up counseling sessions: post-ACASI; pre-STI testing; post-STI test, and pre-HIV testing and post-HIV test (if the participant is not HIV-positive)*

Hi, my name is \_\_\_\_\_. I am the counselor who will be working with you today.

There are a number of things we are going to do today:

- review the procedures to be covered today; update locator information
- have you complete a similar questionnaire on the computer to what you did 6-months ago
- discuss your sexual behaviors and your risk reduction plan for the last 6-months
- HIV/STD testing (if agreed)
- discuss how your experiences with the peer health navigator was

My role as your counselor is to work with you to explore issues related to your HIV risk. I will also be available to help you if you have other issues that come up in the course of today's visit, and to refer you to available services for these issues, if available.

### **ACASI overview:**

I think you remember the questionnaires you completed the first and second visits. Today's questionnaire will ask many of the same questions as the other ones. You may quit the questionnaire at any time, or skip questions that you do not want to answer, but I do request that you complete all questions if you can. Your experiences and feelings will be used to help build interventions to slow down the HIV epidemic in Black men.

Some questions will touch on personal topics like what kind of sexual practices you engage in, whether you use drugs, etc. Please remember that your answers to these questions on the computer will not be seen by site staff at all and will only be linked to your study ID number, not your name.

Some of these personal questions may raise uncomfortable feelings for you. When you're done with the questionnaire on the computer, I'll check in with you

to talk about these feelings. At that time we will also talk about your personal level of risk for HIV and what you can do to lower your risk. We will also talk about your personal level of risk for HIV and what you can do to lower your risk, and how the last 6-months have been working for you.

***Clinician interaction:***

You will also meet with a Clinician collect a rectal swab from you to test for gonorrhea and Chlamydia. Please know that you can collect the rectal swab yourself if you prefer. They will also be collecting urine to test for Chlamydia and gonorrhea. *If participant is known HIV+ at the start of this visit, they will also receive a blood draw to test for viral load.*

## **Post-ACASI brief check-in**

### **Goals:**

- *Immediately check-in after completion of the ACASI, while the participant is still in the “open” state, to give the participant the opportunity to talk about his feelings. After being asked so many closed ended, personal, potentially upsetting questions by a machine, give him a chance to feel “human” again, to connect with another person, and to talk about the ACASI experience, and about what he was upset by, curious about, wanting help with.*
- *To provide the participant with information about issues of concern, including information on what help is available for those issues in the local area*
- *To begin discussion of risk*

**Thank you for completing the questionnaire. How was it for you going through the questionnaire? What concerns or questions did it bring up for you?**

*Don't be surprised if participant expresses frustration at length/questions/issues and close-ended nature of the questionnaire. If participant wants to discuss questions they were not able to answer as they might have liked, acknowledge and allow; check-in before moving to next section if there is anything of personal nature that want to discuss – such as, see below:*

*Participant may disclose that it made them realize/think about:*

- *Feel a bit sad from putting together your life events in a new way*
- *Recognition of extent of use of alcohol/drugs*
- *Feeling vulnerable from violence experienced because of attraction to men, or have a violent partner*
- *Feeling a bit raw from abuse experienced either as a child or as an adult*  
*Counselor should take note of issues for which it might be possible to provide a referral, including counseling for depression, abuse, PTSD, etc., substance use program, non-psychological health care.*

**Thank you for sharing. We'll be talking about a number of things that the questionnaire may have brought up for you.**

## Risk reduction counseling

### *For Participants Who Are HIV Negative or Unknown Status at Start of 12-Month Visit and Participants Refusing HIV Testing*

*The counselor should have an open and inquisitive approach to this portion of the session. This approach will stimulate the participant's curiosity and encourage self-reflection and examination of his own behaviors. The exploration of the risk behavior should be specific. A thorough discussion of the most recent risk behavior may help the participant clarify how the risk behavior occurred. What may have initially seemed like an accident or an unusual incident begins to have concrete circumstances that contributed to the participant's decision to engage in high-risk behavior. This process can demystify the risk behavior for the participant. The questions asked by the counselor are directed at eliciting the entire range of factors that may have contributed to the risk behavior. The counselor should be aware that emotions, recent life events, substance use, self-esteem, and other participant characteristics and issues may influence a particular risk incident or pattern of risk behavior. The counselor and participant should be working together to understand the context of the risk behavior. If the participant's risk behavior is episodic or chronic, the counselor is attempting to discover the factors that contribute to this pattern of risk behavior.*

Now we're going to talk about your sexual behaviors, and how you feel about them. We're also going to discuss your experiences with condoms, drug and alcohol use, and how that might affect your sexual practices; and how you deal with stress.

(If applicable) We'll also talk about how you feel about getting tested for HIV and STIs. I [or another staff member here] will be drawing some blood from you, and a rapid HIV test will be done. I will talk about what is involved with that in a little bit.

Tell me about the last time you had sex...

- What was your partner like? Male? Female? Older? Younger?
- Do you have a primary partner? Tell me about that relationship.
- How many guys/men did you have sex with in the last 6 months?
- Where do you meet casual partners you have sex with?
- How do you find out about the HIV status of your sex partner?
  - How does your partner's HIV status determine what you'll do sexually with him or her?

Thinking about the last time you had sex without a condom what types of sex did you have? ...

***Anal sex:***

- Are you typically a top, typically a bottom? Both?
- How do you determine who you'll do what with?
- Do you think it's less risky for HIV to be a bottom/top?
- Do you ejaculate/cum in guys?
- Do guys ejaculate/cum in you?
  - *If no, encourage that's a good risk reduction strategy*
  - *If yes, How do you feel about that?*

***Oral sex:***

- What do you do in terms of oral sex?
- Do guys ejaculate/cum in your mouth?
- How was this last sex encounter typical of your sexual behavior? What was different?

***Safer Sex:***

**What does safer sex mean for you?**

- How often do you have anal sex with a condom?
- What are your thoughts about using condoms in general?
- What's happening differently in those times when you're using condoms compared to when you don't use condoms?
- Think about times when you have discussed HIV with a sex partner and times when you haven't. How does that discussion affect how likely you are to use condoms?

***Sex with women:***

- Do you have sex with women? Do they know you also have sex with men?
- If/when you have sex with women how does your willingness to use a condom change compared to when you have sex with men?
- Tell me about any concerns you have when thinking about using condoms with women. Are there any that are the same as having sex with men? Different?

Probes:

Pregnancy

Birth Control – protects against pregnancy, not STIs

Overall, how do you feel about the safety of your sexual behaviors?

*Offer thoughts of level of risk based on behavior/habits reported*

### ***Substance Use***

How do drugs and alcohol affect you being able to have safer sex?

- How often do you drink or use drugs?
- How often do sex and drug use or drinking alcohol go together for you?
- Alcohol – drink at home, go out?
- Marijuana – how does smoking pot change your sexual behavior?
- Cocaine/Crack – what happens to your sexual behaviors when you combine cocaine/crack with sex?
- Inject drugs? (If yes, discuss how use changes behavior & assess for sharing of needles)

### ***Stress and Depression***

- What are some of the stressful things in your life?
- How do you deal with stress?
- Do you have friends you can talk to if you're feeling down?
  - If no, who do you talk to or what do you do when you're feeling down?
- Have you ever thought about talking to a therapist or counselor?
- *(If yes and they haven't seen one, ask them what has stopped them)*
  
- How do you feel today?
- How does feeling down or stressed affect your safe sexual behavior?
  - *If feeling depressed or stressed out – Is sex one way to deal with it?*
- Tell me about the sexual encounters you have when you're stressed or down. How do you think they're different or the same as when you're not stressed or down?
  - *Probe: sex more likely to be without a condom?*

### ***Action Plan- Next Steps***

- After talking about all of this, are there some ideas you can come up with for changes you might like to make in terms of your sexual safety?

- Probes:
  - What do you think are the most important things you can do to lower your sex risk behaviors?
  - What are some things you would be willing to do to reduce the number of sex partners you have at the same time?
  - What are some ideas to make using condoms a bit more realistic?

## HIV/STI Pre-test counseling

***For Participants Refusing HIV Testing/Accepting STI testing***

### ***HIV Testing***

So you've decided not to get an HIV test today. People have a lot of different reasons for not wanting to get an HIV test, can you tell me what some of yours are?

*Probe: confidentiality, think they are infected but not ready for results, don't want to tell people about results, worried about likely reactive result.*

*At this point the counselor should do her/his best to provide the participant with information to help clear any possible misconceptions regarding testing, and ask if they can do anything that would help them get tested today, but without being forceful or demanding. If the participant changes his mind and agrees to testing then proceed as if they had originally wanted an HIV test.*

### ***STI Testing (if agrees to STI testing):***

What do you know about STIs, that is, Sexually Transmitted Infections, also known as STDs?

*Mini overview of Chlamydia/gonorrhea/syphilis? Symptoms, treatment, etc*

Have you ever been tested for STIs? [skip this question if participant tested for STIs at previous visits]

When was the last time you tested for STIs?

How do you feel about getting tested for Chlamydia, gonorrhea & syphilis today?

(If applicable) I want to let you know that in (State) named reporting is required for HIV/Syphilis, etc. If you should test positive for (reportable STIs) we will report your name to the local department of health. *Outline local procedures that participant may experience should this occur.*

Partner notification is one component of named reporting. The department of health will notify partners identified by you that someone they have been with sexually has recently tested positive for either HIV or STIs, and recommend that they get tested. The department of health does not tell partners your name, it is kept anonymous. This is an important process in order to make sure your partners are tested and treated as quickly as possible.

### ***Explanation of how/what specimens will be collected:***

I will draw some blood from you today that we will be using to test you for syphilis, and we'll get that result back in about XX (local lab time). We're also going to collect urine

from you for Chlamydia and gonorrhea testing. Chlamydia and gonorrhea will also be tested for by collecting a swab from your rectum/butt – the reason for the rectal swab test is that these STIs can cause infection in both your penis and your butt.

***If treatment being offered on-site:***

Once we get your results, if you are positive for any of the STIs tested for, we will be able to offer some treatment at our office.

*Each site to develop own language/plan of how treatment to be handled.*

***If no treatment available on-site; referring out:***

If you test positive for gonorrhea, Chlamydia or syphilis we will refer you to a doctor/facility for treatment. It's really important that you follow-up on the referral so that you can be treated. These STIs are all curable, and when cured, may lower your risk for HIV. We will check-in with you to see how it went or any problems experienced.

## HIV/STI Pre-Test Counseling

*For Participants Who Are HIV Negative or Unknown Status at Start of 12-Month Visit*

### **HIV Testing:**

How do you feel about getting tested today for HIV?

*Incorporate what was discussed earlier regarding last risk to help formulate how feels about getting tested.*

What do you know about HIV?

*To assess knowledge – ask about whether or not they know the 4 fluids that can transmit HIV*

When was the last time you were tested for HIV?

*Think of behavior reported and discuss HIV window period (today's test capturing anything up to about a month/3-months prior (site specific timeline & dependent on product insert)– risky behavior since then, getting tested again in a month or so)*

How often do you plan on getting tested now that your study participation is ending?

*[If not planning on testing regularly] Why don't you plan on getting tested on a regular basis? Can study site offer on-going HIV post-study testing?*

What do you think your test result will be today?

What does a negative test result mean to you?

How important is being HIV-negative to you?

What would an HIV-positive test result mean for you?

How do you think you would deal with a positive result?

*Re-visit support network discussed earlier – any potential to do harm to self or others if were to test HIV-positive?*

### **STI Testing:**

What do you know about STIs, that is, Sexually Transmitted Infections, also known as STDs?

*Mini overview of Chlamydia/gonorrhea/syphilis? Symptoms, treatment, etc*

When was the last time you were tested for STIs?

How do you feel about getting tested for Chlamydia, gonorrhea & syphilis today?

(If applicable) I want to let you know that in (State) named reporting is required for HIV/Syphilis, etc. If you should test positive for (reportable STIs) we will report your name to the local department of health. *Outline local procedures that participant may experience should this occur.*

Partner notification is one component of named reporting. The department of health will notify partners identified by you that someone they have been with sexually has recently tested positive for either HIV or STIs, and recommend that they get tested. The department of health does not tell partners your name, it is kept anonymous. This is an important process in order to make sure your partners are tested and treated as quickly as possible.

***Explanation of how/what specimens will be collected:***

Have you ever had an HIV Rapid test – and gotten the result in 20 minutes?

***Explanation of Rapid test:***

We're going to draw some blood and in 20 minutes we'll have results. There are three potential outcomes of the Rapid test: HIV negative, preliminary positive, or invalid. Invalid is usually a problem with the test kit and not the person, and we would do the test again. HIV negative results show that as of about a month ago, you hadn't gotten infected. Preliminary positive is the result when it looks like you are probably HIV-positive. The rapid test is not a definitive test – if we get a preliminary positive result, I will then send out a tube of blood to the lab for confirmatory testing. The lab will do a much more accurate test, and we would get those results back in about a week and would draw more blood to re-confirm the results.

*\*\*in lab when doing test show illustration (Rapid test placard) of what different results look like\*\**

***STI testing (if agrees to STI testing):***

With the blood I draw you'll also be tested for syphilis. We're also going to collect urine from you for Chlamydia and gonorrhea testing. We will also collect a swab from your rectum/butt for Chlamydia and gonorrhea testing, since these diseases can infect both your penis and your butt.

- ***If treatment being offered on-site:***

Once we get your results if you are positive for any of the STIs tested for, we will be able to offer treatment at our office.

*Each site to develop own language/plan of how treatment to be handled.*

- ***If no treatment available on-site; referring out:***

If you test positive for gonorrhea, Chlamydia or syphilis we will refer you to a doctor/facility for treatment. It's really important that you follow-up on the referral so that you can be treated. These STIs are all curable, and when cured, may lower your risk for HIV. We will check-in with you to see how it went or any problems experienced.

## Risk Reduction Counseling

***For Participants Who Know They Are HIV Positive at the Start of 12-Month Visit***

*The counselor should be aware that many components of prevention with positives is similar to the more typical HIV test counseling that they are likely used to, such as goal-setting and risk reduction plans. However, counselors need to be sure to be mindful that people living with HIV may have a variety of different perspectives approaching sexual behavior after diagnosis, and that those perspectives may change over time. The goal of prevention with positives is to help the client change their behavior so that it values their sexual activity, their health, and the health of their partners.*

### ***HIV Experience***

**Are you taking HIV medications?**

*If yes, How long have you been taking HIV meds? How has that been?*

*How many different regimens have you been on?*

*What are some strategies are helpful in adhering to your meds?*

*Can you think others of that would be helpful in adhering to your meds?*

**Do you have a regular doctor you go to?**

*If no, what do you do when you're not feeling well?*

*We'll talk about some ideas or referrals we have to get you hooked up with a doctor.*

*If yes, how often do you go to the doctor?*

*What are some of the reasons you don't go very often?*

### ***Overview of super-HIV infection***

*HIV-infected people can be re-infected or co-infected with another strain of HIV. This can occur when they are exposed to a different strain of HIV than what they already have. Being infected with two strains of HIV can make it hard find the right medicines to treat the infection and can even speed the progress of HIV disease for some.*

### ***Prevention for Positives***

*We talk to everyone about safer sex for positive men and how they can keep themselves as healthy as possible. I understand that this might be an uncomfortable topic, but I want to talk a little bit more about safer sex so you can stay healthy living with HIV.*

Some people who live with HIV don't engage in safer sex, while others try to be as safe as they can. Can you tell me about your experiences with safer sex after you found out you were HIV-positive?

Has who you're having sex with changed?

Has the types of sex you're having changed?

Tell me about the last time you had sex...

- What was your partner like? Male? Female? Older? Younger?
- Who did you have sex with?
- Do you have a primary partner? Tell me about that relationship.
- How many guys/men did you have sex with in the last 6 months?
- Where do you meet casual partners you have sex with?
- How do you find out about the HIV status of your sex partner?
  - How does your partner's HIV status determine what you'll do sexually with him or her?

Thinking about the last time you had sex without a condom what types of sex did you have? ...

***Anal sex:***

- Are you typically a top, typically a bottom? Both?
- How do you determine who you'll do what with?
- Do you think it's less risky for HIV to be a bottom/top?
- Do you ejaculate/cum in guys?
  - *If no, encourage that's a good risk reduction strategy*
  - *If yes, How do you feel about that?*
- Do guys ejaculate/cum in you?
  - *If no, encourage that's a good risk reduction strategy*
  - *If yes, How do you feel about that?*

***Oral sex:***

- What do you do in terms of oral sex?
- Do guys ejaculate/cum in your mouth?
- How was this last sex encounter typical of your usual sexual behavior?  
What was different?

### *Safer Sex:*

What does safer sex mean for you?

- How often do you have anal sex with a condom?
- What are your thoughts about using condoms in general?
- What's happening differently in those times when you're using condoms compared to when you don't use condoms?
- Think about times when you have discussed HIV with a partner and times when you haven't. How does that affect how likely you are to use condoms?

### *Sex with women:*

- Do you have sex with women? Do they know you also have sex with men?
- If/when you have sex with women – are you more likely to use condoms than when you have sex with men?
- Tell me about any concerns you have when thinking about using condoms with women. Are there any that are the same as having sex with men? Different?

Probes:

Pregnancy

Birth Control – protects against pregnancy, not STIs

Who have you told about your HIV status?

Are there people you want to tell but haven't said anything yet?

What's made it difficult to tell them?

Since your diagnosis, what reasons have become important to you when thinking about safer sex?

How important is it to you that you have safer sex?

*-Probe: Provide reasons if they have difficulty thinking of them:  
protecting from STIs, other HIV strains, transmitting virus to other  
people*

*The counselor should acknowledge and summarize difficulties the participant is having with safer sex, and then reiterate reasons they identified as why safer sex is important.*

So after discussing this, are there ideas that you can think of so that you can stay safe when having sex?

*-Possible suggestions involve disclosure, less sex partners, always using a condom for anal intercourse, not engaging in penetrative sex*

### ***Substance Use***

How do drugs and alcohol affect your being able to have safer sex?

- How often do you drink or use drugs?
- How often do sex and taking drugs or drinking alcohol go together for you?
- Alcohol – drink at home, go out?
- Marijuana – how does smoking pot change your sexual behavior?
- Cocaine/Crack – what happens to your sexual behaviors when you combine cocaine/crack with sex?
- Inject drugs? (If yes, discuss how use changes behavior & assess for sharing of needles)

### ***Stress and Depression***

- What are some of the stressful things in your life?
- How do you deal with stress?
- Do you have friends you can talk to if you're feeling down?
  - If no, who do you talk to or what do you do when you're feeling down?
- Have you ever thought about talking to a therapist or counselor?
- *(If yes and they haven't seen one, ask them what has stopped them)*
- How do you feel today?
- How does feeling down or stressed affect the safety of your sexual behaviors?

*If feeling depressed or stressed out – Is sex one way to deal with it?*

- Tell me about the sexual encounters you have when you're stressed or down. How do you think they're different or the same as when you're not stressed or down?

- *Probe:* sex more likely to be without a condom?

### *STI co-infection with HIV*

STI testing is important for HIV-infected people because syphilis, gonorrhea and Chlamydia infections increase the burden to the immune system, increase the viral load and make men more infectious to others when having unprotected sex with HIV-negative partners. Getting treatment for STIs helps HIV infected people stay healthy and stay less likely to transmit their infection to others.

### *Action Plan- Next Steps*

- After talking about all of this, are there some ideas you can come up with for changes you might like to make in terms of your sexual safety?
  - Probes:
    - What do you think are the most important things you can do to lower your sex risk behaviors?
    - What are some things you would be willing to do to reduce the sexual risk to yourself and your partners?
    - What are some ideas to make using condoms a bit more realistic?

## HIV/STI Pre-Test Counseling

***For Participants Who Know They Are HIV Positive at the Start of 12-Month Visit***

### ***STI Testing (if agrees to STI testing)***

What do you know about STIs, that is, Sexually Transmitted Infections, also known as STDs?

*Mini overview of Chlamydia/gonorrhea/syphilis? Symptoms, treatment, etc*

Have you ever been tested for STIs? [skip question if participant tested for STIs at prior visits]

When was the last time you tested for STIs?

How do you feel about getting tested for Chlamydia, gonorrhea & syphilis today?

(If applicable) I want to let you know that in (State) named reporting is required for HIV/Syphilis, etc. If you should test positive for (reportable STIs) we will report your name to the local department of health. Outline local procedures that participant may experience should this occur.

Partner notification is one component of named reporting. The department of health will notify partners identified by you that someone they have been with sexually has recently tested positive for either HIV or STIs, and recommend that they get tested. The department of health does not tell partners your name, it is kept anonymous. This is an important process in order to make sure your partners are tested and treated as quickly as possible.

### ***Explanation of how/what specimens will be collected:***

I will draw some blood from you today that we will be using to test you for a few things, including confirming your HIV status. This blood test will be used to test your CD4 T-cell count and viral load measures. You will also be tested for syphilis, and we'll get those results back in about XX (*local lab time*). We're also going to collect urine from you for Chlamydia and gonorrhea testing. Chlamydia and gonorrhea will also be tested for by collecting a swab from your rectum/butt – the reason for the rectal swab test is that these STIs can cause infection in both your penis and your butt.

***If treatment being offered on-site:***

Once we get your results if you are positive for any of the STIs tested for, we will be able to offer some treatment at our office or make a referral to an agency for care.

*Each site to develop own language/plan of how treatment to be handled.*

***If no treatment available on-site; referring out:***

If you test positive for gonorrhea, Chlamydia or syphilis we will refer you to a doctor/facility for treatment. It's really important that you follow-up on the referral so that you can be treated. These STIs are all curable, and when cured, can help you stay healthy. We will check-in with you to see how it went or any problems experienced.

## STI post-test counseling

*All  
Participants*

### *If negative for all STIs:*

Let's take a look at your test results for Chlamydia and gonorrhea and syphilis; the test results are all negative, which means that you are not infected with any of these STIs. *[If participant will be having follow-up visits]* We will be testing you again for Chlamydia, gonorrhea and syphilis at your 6- and 12-month follow-up visits. If you think you may have been exposed to any of those STIs between your study visits we'll want you to come back to our office to get tested.

### *If positive for one/multi-STIs:*

Let's take a look at your test results for Chlamydia and gonorrhea and syphilis. The test results show that you are positive for (one, two or any of them). What this means is that you have had sex with someone who had [Chlamydia, gonorrhea and/or syphilis] and you were exposed, and infected. Exposure may have happened from oral sex or anal sex.

*What sorts of feelings are you having as I tell you about your positive test result? [If person is distressed or upset, take time to talk with him and let him have his reactions. Normalize feelings of upset or embarrassment.]*

*This/These STI(s) is/are easily treated, and we will be treating you (or referring you for treatment) today.*

*(If applicable) As I mentioned earlier in (State) I am required to report your name to the department of health when infection of (STI) is identified. Can we take a minute and collect some information about recent sexual partners who may have been exposed? I have to submit this paperwork to the department of health, and will not be the one notifying your partners. Your name will not be given as how they may have been exposed, only that they should be immediately tested.*

*Let's take a few minutes and talk about the behavior that you think got you exposed to this/these infections. Talk again of risky behavior and also changes discussed that could be made.*

***For Participants Who Are HIV Negative or Unknown Status at Start of 12-Month Visit***

## **HIV Post-Test Counseling**

*(Please refer to the Network Lab Western Blot algorithm, can be found in SSP section 11.4.2 for further explanation of HIV testing procedures. HIV+ participants do not undergo HIV post-test counseling so they should proceed directly to the next section)*

### **For negative/non-reactive test results**

Thanks for hanging out while waiting for your test - let's take a look at your HIV test result. The test result shows that you are HIV-negative. This means that any behavior you engaged in until about [a month/three months] ago has not infected you with HIV.

What do you think about this test result?

How can you stay HIV-negative?

### **For Preliminary HIV Positive Test Results**

Thanks for hanging out while waiting for your test – let's take a look at your HIV test result. This initial test result is showing as preliminary positive. What this means is that you are probably infected with HIV, and we will send out your blood to the lab before we determine for sure whether you are infected with HIV or not. Given what we've discussed about your potential exposures to HIV, today's result may/may not accurately reflect whether you are infected with HIV.

Take your time to think about what's going on right now. We have plenty of time to talk about how you're feeling and what we do from here.

How are you feeling about this initial result?

How will you be for the next few days between now and when we get the confirmatory results?

Do you have any ideas of how to take care of yourself between now and then?

Do you have a friend or someone you would like to call right now to come and meet you, or just talk with?

***Some thoughts of where to go from here:***

*Offer participant opportunity to talk with site clinician about what HIV infection means; participant may not want to discuss anything until confirmatory tests are back.*

**For Confirmed HIV-negative test result following preliminary positive**

Thank you for coming back to the office for your confirmatory result, how have you been over the last few days? We have gotten the result from our lab, and the result of the HIV Western Blot test is negative. This means you are not infected with HIV at this time.

This was one of those times, which are rare, when the rapid test result shows HIV positive and the more sensitive and accurate HIV-Western Blot test shows HIV negative. In these cases, it's good to review the commitment to staying HIV-negative and developing a plan to help stay that way.

How are you doing – with this test result?

Although your participation is ended on this trial, I highly recommend that you follow-up this test in about XX (dependent on window behavior of last potential exposure). Let me give you a list of places you can go for a follow-up HIV test.

**Positive HIV WB Test Result:**

*[Note: it would be a good idea to ensure that a clinician and PHN is scheduled to be available in person whenever a confirmatory result is being given out to a person who's newly diagnosed as positive]*

Thank you for coming back to the office for your confirmatory result, how have you been since the last time I saw you?

We have gotten the result back from our lab, and these results are also HIV positive. The primary test we did was what is called an HIV Western blot test. This was followed up with an HIV viral load test which measures the amount of virus in your blood, and a CD4 test which measures your body's response to the HIV. For your safety and to make absolutely certain we know you are HIV positive, we are going to draw another tube of blood today for another HIV Western Blot test. Once we receive these results, we should have a definitive

HIV result, but it is extremely unlikely that those results would be any different from the ones we have now. You will come back to our office in one week for these results.

*(site plan of how to discuss results with participants – clinician to take charge/counselor able to discuss)*

How are you doing?

*Appropriate post-test counseling stuff including referrals/PHN.*

*(If applicable) As I mentioned earlier in (State) I am required to report your name to the department of health when HIV infection is identified. Can we take a minute and collect some information about recent sexual partners who may have been exposed. I have to submit this paperwork to the department of health, and will not be notifying and will not be the one notifying your partners. Your name will not be given as how they may have been exposed, only that they should be immediately tested.*

## End of visit check-in

All  
Participants

*The counselor will complete the check-in below, and the PHN will also do a check-in if the participant has a PHN*

### **Between counselor and participant**

We're nearly done with the visit today. Before we finish up, I wanted to talk with you about a couple of things. First, as we have talked, you've mentioned some issues about \_\_\_\_\_ [substance use, depression, desire for primary health care, housing assistance, etc.]. If you would like, I can help you [get an appointment, find a program, etc.].

Would you like me to make a referral or appointment for you?

[Whether participant agrees to referral or not] I also have this list that has resources you could use if at a later time you decide that you would like to get help with something. Can I give you a copy to hold on to?

The other thing I wanted to do is check in with you before you leave. Between the computer questionnaire and our conversation, we've covered a lot of topics that people can find painful or difficult. Some experience emotional reactions that can be unexpected and strong – now or even after you leave here. After all involved in this visit, are you having ANY feelings that you might harm yourself or someone else? To make sure, I'd like to hear from you how intense your feelings have been to today's visit on a scale of 1 to 10, with "1" being "no reaction" and "10" being "most intense feelings ever."

*Depending on response, may go something like this.*

- (1-2) Okay, so it sounds like this wasn't too intense an experience for you. Even so, we're here for you and are available to you to talk with about any difficult or painful feelings that may come up. Would you like to talk with me or a professional therapist about your feelings? *Depending on response, can talk more, provide a referral, or call on-site clinician.*
- (3-5) Okay, so it sounds like this visit brought up some stuff for you. Would you like to talk with me or a professional therapist about your experience? *Depending on response, can talk more, provide a referral, or call on-site clinician.*
- (>5) Today's visit was pretty intense for you. It might be a good idea for us to talk some more about how you're feeling or if you would like, you could talk with a professional therapist. *Depending on response, can talk more, provide a referral, or call on-site clinician.*

*[Be sure to document any explicit decline of option for speaking to therapist in progress notes.]*

*[If the participant has any inclination toward killing himself or hurting someone else, activate the emergency protocol.]*

## **Emergency Plan for participants**

**All  
Participants**

*Participants may present with behavior during the visit that causes concern with study staff. Each site must determine an emergency plan for how site staff will respond to such situations. For example, the plan may be to alert the site coordinator and/or investigator of record immediately for a consult on how to proceed when such a situation presents itself. If the counselor/PHN and supervisor feel the participant may have depression, substance use or mental health issues, their next response may be to contact the on-site/on-call mental health professional for a real-time consultation. If the participant appears violent, dangerous or speaks of potential harm to himself or others, the plan may be to call 911. This plan must be worked out in advance among site staff and practiced in trainings so that it will be executed correctly in an emergency.*