

# MULTICENTER AIDS COHORT STUDY

## NEW ENROLLMENT SCREENING FORM GUIDELINES

### General Instructions:

1. The form is designed to capture screening data to help determine eligibility into the new cohort. The form should be administered by an interviewer in either English or Spanish.
2. All men should be assigned a screening ID. Sites are responsible for assigning the screening IDs. The format of the screening ID is a local option.
3. Follow all specified instructions on the form. Statements in boxes are instructions and should not be read to the participant.

### **SECTION A: General Information**

Question A1: Record the date that the potential participant was screened. If the screening procedure is separated into different time points, the first date that the man visits the clinic for MACS screening should be recorded in this field.

Question A2: The purpose of this step is to determine in which language, English or Spanish, the participant prefers to be interviewed. The use of a Spanish Screening Form is a local option. If the participant does not speak Spanish, read the introduction in English and proceed with the English version. If the participant prefers to be interviewed in Spanish, obtain a Spanish version, read the introduction in Spanish, and proceed to conduct the screening procedures with a Spanish speaking interviewer.

When reading the introduction and consent that describes the study, the interviewer should answer all of the participant's questions. The participant should completely understand the nature of this study and what will be required of him.

Question A3: For protocol monitoring purposes, the **Screening Form** requires that all required consent be documented by recording the date that consent forms were signed. Read consent aloud and ask the participant if he is willing to continue. If his response is "YES", record today's date and have the participant sign the consent, then skip to Q5. If the participant declines to continue or does not sign all consent forms required by site protocol, mark "NO," and ask Q4.

Question A4: If the participant declines consent, ask if you may inquire about his age and race. If he responds "NO", thank him for his time and END the screening.

Question A7: Read the question and code the race that the participant considers *himself* to be. For respondents whose parents are not from the same race/ethnicity, **mark all that apply**. If he considers himself something other than one of the choices listed, mark “other” and record his response verbatim.

If participant refused consent but agreed to answer the age and race question, thank him and END screening.

Question A8: This question is used to track and assess the success/failure of various recruitment techniques. It also serves as a benign lead-in question before asking more personal questions. **PROBE** ("Any other way?") to obtain all of the ways the participant found out about the study.

If the participant does not know how he found out about the study, after probing, code **A8.f** as “YES” and skip to question **B1**.

## **SECTION B: HIV Status and Medical Conditions**

Question B1: All men are required to have blood drawn for a HIV test at screening regardless of their answer to QB1.

QB2 - B4: These sections ask questions to try to discern if the man has ever been diagnosed with an AIDS-defining illness. If any conditions are reported it is important to get a medical record release. All AIDS-defining illnesses which occurred after HAART will need to be followed up with medical records.

Question B5: History of conditions diagnostic of AIDS prior to HAART makes the person ineligible for participation. Thank participant and END screening.

## **SECTION C: Antiretroviral Medication History**

If the participant cannot remember the exact month he began taking the medication, probe for the season and assign month as follows:

Summer	=	July	=	07
Fall	=	October	=	10
Winter	=	January	=	01
Spring	=	April	=	04

Question C1: HAND THE PARTICIPANT THE ANTIVIRAL PHOTO MEDICATION CARDS BEFORE READING THIS QUESTION. Read the participant the question, and then walk through the photo med cards with the participant, saying each of the drug names aloud and asking whether he has ever taken this drug.

If C1 is “YES” proceed to **Questions C2 – C4**, otherwise **SKIP to Section D**.

QC2 – C5: The drugs listed in **Questions C2 – C4** are drugs that indicate that a person might have been on highly active antiretroviral therapy, or HAART. If a man does not report any of the specific drugs listed in **QC2 – C4**, sites can assume that this man is reporting that he has never been on HAART.

If any of the boxes are checked in **C2 – C4**, obtain medical records release and fill out the box on the front page of a **Medical Record Abstraction Form (MRA)** to indicate to the abstractionist that these records need to be found and abstracted.

If the man does not know if he took any of these medications, interviewers should try to **PROBE** for more information. One suggestion is to **PROBE** “Do you have pill bottles with you today of any pills that you are currently taking?” If the participant has his current pills on him, interviewers can look at the label to identify dates of the medications and the doctor who prescribed the medications. Interviewers can also **PROBE** to ask the man where he gets his care – this information can be noted in the margins to help abstractors try to locate the medical records of this person. Sites should feel free to develop creative ways to try to get the participant to remember the approximate date of the meds he took, as well as the place he received care.

Question C2: Ask the participant the question, and read through each of the specific PIs listed on the form. If the participant reports use of any PIs listed in this section, check the box next to the drug(s). **PROBE** to see if the man has taken any other PI(s) not listed. If so, record the name of the drug(s) in the space provided. If, overall, only 1 PI is reported, list that PI in **C2.b** as the first PI the man took. If more than 1 PI is reported, ask the man which PI(s) he took first. It is possible that the man started taking multiple PIs at the same time. If this is the case, list all PIs that the person reports as taking first in the spaces provided, and record the date he first began using these PI(s) in **C2.c**.

Question C3: Follow above instructions for **C2**, asking about all the non-nucleoside reverse transcriptase inhibitors (NNRTIs) that the participant has ever taken.

Question C4: For the nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs), we are only interested in if the participant has ever taken Ziagen or Trizivir. For this reason, there is no place in this question to list any other NRTIs the participant may report taking. If he reports any other NRTIs, this information should not be recorded in **C4**. However, the interviewer might want to make a note of the medication and pass this information along to the abstractionist so that they can try to abstract this information for the supplemental medical record abstraction section of the **MRA Form**.

## EXAMPLES:

Example 1: In reading through the antiviral photo med cards, a participant reports that he has taken only AZT, 3TC and nelfinavir. No other drugs are identified through probing. In **C2**, check the box next to Viracept (nelfinavir) and list Viracept in **C2.b**. In **C2.c**, record the date the participant first began taking Viracept. No boxes should be checked in **C3** or **C4**.

Example 2: Participant reports that he has taken AZT, 3TC, ddI, ddC, Crixivan, saquinavir and efavirenz. In **C2**, the boxes next to Crixivan and Invirase/Fortovase (saquinavir) should be checked. Upon asking, the man took saquinavir first. Saquinavir should be recorded in **C2.b** with **C2.c** recording the date the man first took saquinavir. In **C3**, the box next to Sustiva (efavirenz) should be checked, Sustiva should be recorded in **C3.b**, and the date that he first took Sustiva in **C3.c**. No boxes should be checked in **C4**, and nothing filled out in **C4.b** or **C4.c**.

Example 3: Participant reports that he has taken AZT, 3TC and abacavir. Nothing should be recorded under **C2** or **C3**. Only the box next to Ziagen (abacavir) should be checked in **C4**, with abacavir listed in **C4.b** and the date the participant reported first taking abacavir in **C4.c**.

Example 4: Participant reports that he has taken AZT, ddI, ddC, 3TC, ritonavir, saquinavir, and tipranavir. In **C2**, the boxes next to Norvir (ritonavir), Invirase/Fortovase (saquinavir), and Other should be checked. In the specify field for Other, “Tipranavir” should be written in. When asked about the first PI he took, the participant reports that he began taking saquinavir and ritonavir at the same time. Both drugs should be listed in **C2.b**, and the date he reported for these two drugs should be recorded in **C2.c**. Nothing should be recorded in **C3** or **C4**.

## **SECTION D: Behavioral Information**

Q D1 – D2: These few sexual behavior questions are asked in order to capture information about whether or not the participant has ever been sexually active.

Question D3: By recreational drugs we also mean street or club drugs. This includes drugs such as cocaine, speed, meth, ice heroin and speedball. Only mark “Yes” if any of these drugs were injected.