

MULTICENTER AIDS COHORT STUDY

NEW ENROLLMENT SCREENING FORM GUIDELINES

General Instructions:

1. The form is designed to capture screening data to help determine eligibility for recruitment into the new cohort.
2. The form is designed to be administered by an interviewer.
2. All prospective participants 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 prospective participant.

SECTION A: General Information

- Q1: Record the date that the prospective participant was screened. If the screening procedure is separated into different time points, the first date that the prospective participant visits the clinic for MACS screening should be recorded in this field.
- Q2: The purpose of this step is to determine in which language, English or Spanish, the prospective participant prefers to be interviewed. The use of a Spanish Screening Form is a local option for prospective participants who prefer to be interviewed in Spanish.
- Introduction: When reading the introduction and consent that describes the study, the interviewer should answer all questions to assure that the prospective participant completely understands the nature of this study and what will be required of him.
- Q3: After explaining the study, ask the prospective participant if he is willing to continue the screening process. If his response is "YES", record today's date and have the prospective participant sign the consent, then skip to Q5. If the prospective participant declines to continue or does not sign all consent forms required by site protocol, mark "NO," and ask Q4.
- Q4: If the prospective participant declines to consent, ask if you may inquire about his age and race (Questions 5-7). If he responds "NO", thank him for his time and END the screening. Otherwise, administer Questions 5-7 and then thank him for his time and END the screening.

- Q5. Obtain date of birth.
- Q6. Ask if he is of Hispanic or Latino origin. Allow prospective participant to report his ethnicity based on his personal perception.
- Q7: Read the question and code the race that the prospective participant considers *himself* to be. For prospective participants who have more than one race/ethnicity background, **mark all that apply**. If he considers himself something other than one of the choices listed, mark “other” and record his response verbatim.
- If prospective participant refused consent but agreed to answer the age and race question, thank him and END screening.
- Q8: 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 prospective participant found out about the study.

SECTION B: HIV Status and Medical Conditions

ALL PROSPECTIVE PARTICIPANTS ARE REQUIRED TO HAVE BLOOD DRAWN FOR A HIV TEST AT SCREENING, REGARDLESS OF THEIR ANSWER TO Q1A. Complete a MACS Seroconversion Reporting Form upon verifying the prospective participant’s first positive HIV date from his laboratory records and last negative date from laboratory records, if available, or recall if not available. If the participant refuses to sign a medical records release form, then he is ineligible for the study.

- Q1a - Q1c: Ascertain if the prospective participant tested positive for HIV. If yes, ask for month and date of first positive test.
- Q1d -1e: Ask him to sign a medical records release for his first positive HIV test and other related lab work, including white blood cell counts, HIV viral load, and history of antiretroviral medications. Ask for the name and contact information of the medical provider who managed his medical care at the time of his first positive test. If he refuses to sign a medical records release, he is ineligible for the study.
- Q1f - Q1i: Ask the participant is he ever tested negative for HIV antibodies.
- If no: proceed to Section Q2.
- If yes:
- Obtain the date of the last negative HIV test prior to first positive HIV test.
 - Obtain a signed medical records release and contact information of medical provider who managed his care at the time of his last negative test.
 - If there are no laboratory records, ask the participant to recall to the best of his ability his last negative test prior to seroconversion.

Q2 - Q4: Read each AIDS condition. All AIDS-defining illnesses need to be followed up with a medical records review to verify the diagnosis and that it occurred after initiation of ART medications.. If the prospective participant reports an AIDS condition and refuses to sign a medical records release, he is ineligible for the study.

Q5: Diagnosis of AIDS prior to initiation of ART medications makes the person ineligible for participation. Ask him if he took any HIV medications before he got sick with AIDS.

If NO or never treated prior to developing AIDS, he is ineligible for the study. Thank him for his time and END screening.

If YES to treatment with antiretroviral drugs before developing AIDS or if he is unsure, obtain a medical release and then proceed to Section C to ask about specific medications.

SECTION C: Antiretroviral Medication History

Once it has been established that the participant initiated antiretroviral therapy (ART) or highly active antiretroviral therapy (HAART) before developing AIDS, obtain his antiretroviral medication history.

If the prospective 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

Q1: If he responds “YES” to taking HIV related medications or is not certain, proceed to **Questions C2 – C6**, else **SKIP to Section D**.

Q2 – Q6: Administer **Q2 – Q6** to determine if the prospective participant had initiated ART or HAART. If the prospective participant confidently reports taking NO specific drugs listed in **Q2 – Q6**, then assume that he has never been on ART or HAART.

IF NO ART or HAART medications: there are no restrictions on seroconversion.

IF ART medications or HAART are reported: refer to Section B to determine if the prospective participant has a known date of seroconversion in last 5 years and last negative HIV and first positive serology test dates are within 12 months. If not, he is ineligible for the study.

If seroconversion criteria is NOT met: Thank the prospective participant for his time and END screening.

If seroconversion criteria is met: ask for a signed medical records release to obtain medical records that span the initiation of his antiretroviral medication treatment to the present. Obtain contact information of former and current medical providers in charge of his treatment. If he refuses to sign a medical records release, he is ineligible for the study.

If the prospective participant does not know if he took any of these medications, ask him for the contact information of his primary care provider. Sites should feel free to develop creative ways to try to encourage the prospective participant to remember the approximate date of the medications he took, as well as the place he received treatment.

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.

SECTION D: Behavioral Information

Q1 – Q3: A few sexual behavior questions are asked in order to capture information about whether or not the prospective participant has ever been sexually active. The purpose of this section is to ascertain that the prospective participant most likely became infected from sexual activity and not injected drug use.

Q3: By recreational drugs we also mean street or club drugs. This includes drugs such as cocaine, speed, meth, ice heroin and speedball. Mark “Yes” if any of these drugs were injected.

If the prospective participant is HIV infected and injected recreational drugs within one year prior to becoming infected, he is ineligible for the study.

If the prospective participant is HIV seronegative and injected recreational drugs within one year prior to date of screening, he is ineligible for the study.

Otherwise, history of drug use is not an exclusion criteria.