

MULTICENTER AIDS COHORT STUDY

NEW ENROLLMENT ELIGIBILITY FORM GUIDELINES

General Instructions:

1. The Eligibility Form is used for abstracting information collected from the screening and medical abstract forms as a final record of each prospective participant's HIV infection and therapy status, demographics, eligibility status and enrollment.
2. Sites are responsible for assigning MACSIDs to all newly enrolled participants. If enrolled, the participant should be given a MACSID. All new enrollees should have a "5" as the second digit of their MACSID
3. Send completed forms to CAMACS on the 15th and 30th of each month for everyone who is screened for the study, regardless of final eligibility and enrollment disposition. The data will be manually entered at CAMACS.

Question 1: **Date of Screening**

Source: Screening Form - Q1.

Question 2: **Language preference**

Source: Screening Form - Q2

Questions 3: **HIV status at screening before enrollment into the study.**

(All participants must have blood drawn at screening for ELISA/Western Blot tests to confirm HIV status prior to enrollment.)

Sites should categorize all men into one of the three following categories:

1) Seronegative

2) Seropositive...

- ▶ Known date of seroconversion ———▶ Complete seroconversion reporting form
- **Date of Last HIV seronegative test** is required for men who have initiated ART / HAART. For ART / HAART naive men, obtain if available.

Source: Screening Form (Section B), verified by laboratory records, or if no laboratory records, you may rely on participant's recall.

- **Date of First HIV seropositive test** is required for men who have initiated ART / HAART. For ART / HAART naive men, obtain if available.

Source: Screening Form (Section B), verified by laboratory records

- ▶ ART / HAART initiated ———> Complete Medical Records Abstraction and fill out MRA Form

- **Date of first prescribed ART** is required for men who have initiated ART / HAART.

Source: MRA form (Section A, Q2). Record the antiretroviral therapy status of seropositives according to information abstracted from the medical records and documented in the MRA form, Section A. If the medical records showed that the man received ART for even a very short period of time or has discontinued use of ART, he should be categorized as having used ART. If the participant reported never having used any antiretroviral drugs he is considered ART / HAART naive.

Question 4: Date of birth

Source: Screening Form, Section A, Q5.

Question 5: Hispanic or Latin origin

Source: Screening Form, Section A, Q6.

Question 6: Race (Check all that apply)

Source: Screening Form, Section A, Q7. (Mark all reported races.)

Question 7: Sexually active

Source: Screening Form, Section D, Q1.

Question 8: Injected drug use

Source: Screening Form, Section D, Q3.

Question 9: Eligibility for the MACS

Source: Screening Form, MRA form

If the answer is marked in any of the shaded areas of the form for any item, the prospective participant is NOT eligible for enrollment. The prospective participant is deemed NOT eligible if either injected drugs during indicated time period or clinical AIDS before ART initiation is marked “YES” or any other item is marked “NO”.

- Age \geq 18 years old.
- Injection drug use in year before infection (if HIV infected) or past year of enrollment if HIV seronegative excludes eligibility. History of injection drug use outside these time frames does not qualify as an exclusion criteria.
- For seropositives:

- i. Clinical AIDS dx before starting ART
- ii. If ART / HAART initiation..
 - a) Medical Records reviewed
 - b) Known date of seroconversion (last negative date within ~12 months prior to first positive date.
 - c) Date of HIV seroconversion was in past 5 years.
 - d) Date of first ART is known.
 - e) HIV RNA and CD4 cell count are known within 4 months before ART was prescribed.
- d. Consent is obtained.

Question 10: Method of recruitment.

Source: Screening Form (Section A, Q8).

Document the different ways that the prospective participant was drawn to the study.