

MULTICENTER AIDS COHORT STUDY

NEW ENROLLMENT ELIGIBILITY FORM GUIDELINES

General Instructions:

1. The Eligibility Form is used to compile information on HIV/therapy status, demographic and risk factor information for monitoring the enrollment of new recruits: a) the proportion of HAART users and HAART-naïve men among the seropositives, and b) comparability between the HIV seropositive and the HIV seronegative cohorts.
2. This form is NOT administered to participants but should be filled out by sites after the screening interview and medical record abstraction (if indicated) has taken place. Each time the Eligibility Form is completed, one of the last steps is to assess the enrollment eligibility of the potential participant. *Question 9* should be used to document whether the man is eligible for the study and, if he is, whether he is willing to participate.
3. Upon enrollment, the participant should be given a MACSID. All new enrollees should have a “4” as the second digit of their MACSID. The first digit should be the center code. Sites are responsible for assigning MACSIDs to all newly enrolled participants. All other men, should not be assigned a MACSID.
4. The completed forms should be sent to CAMACS on the 15th and 30th of each month for everyone that is screened for the study, regardless of final eligibility and enrollment disposition. The data will be manually entered at CAMACS.

Question 1:

Question 1 from **Screening Form**.

Question 2:

Question 2 from **Screening Form**.

Question 3:

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

- 1) Seronegative
- 2) Seropositive, No HAART
- 3) Seropositive, HAART.

For status, sites should use the following guidelines: All men must have blood drawn at screening for ELISA/Western Blot tests. Results of these tests should be used to categorize the HIV status of these men.

Retrospective medical record abstraction (**MRA Form**) should be used to categorize the man’s HAART status. This information can be found on the **MRA Form** in *Question A.1*. The response to *Question A.1* should be used to categorize each man as “seropositive, no HAART” or “seropositive, HAART.” If the medical records showed

that the man received HAART for even a very short period of time or has discontinued use of HAART, he should be categorized as having used HAART.

Question 4:

Question 5 on Screening Form. Leave blank if refused.

Question 5:

Question 6 on Screening Form. Leave blank if refused.

Question 6:

Sites should code the race that the participant considers *himself* to be (**Question 7 on Screening Form**). *More than one race can be checked.*

Questions 7/8:

These questions serve as a way to monitor and track high risk behaviors (sexual activity and injecting drug use) that a participant may practice. This information can be obtained directly from the **Screening Form** (*Question D.1 and D.3*).

Question 9:

Fill out **Question 9** based on responses on the **Screening Form** and **MRA**. This section is designed to identify whether or not a participant is eligible or ineligible for enrollment into the MACS. If a participant has a response marked in any of the shaded areas, he is ineligible for enrollment.

- a. - Answer **Yes** if 18 years or older or **No** if younger than 18 years.
- b.i. - Obtain this information from *Section A, Q.5* of the **MRA Form**.
- b.ii.(1) - Answer **Yes** if any medical records exist. If you have looked for records but could not find any or if respondent reported not receiving medical care, answer **No**. Seropositive men who used HAART must have medical records.
- b.ii.(2) - If no medical records, leave blank. If medical records exist, answer **Yes** if they were reviewed, **No** otherwise.
- b.iii.(1) - Refer to *Section A, Q.2.A* of the **MRA Form**.
- b.iii.(2) - Refer to *Section A, Q.4.A & Q.4.B* of the **MRA Form**. Answer **Yes** if this information is known.
- c. - Answer **Yes** if prospective participant signed the consent form.

Question 10:

The purpose of this question is to try to determine if some recruitment procedures are more effective than others and to be able to document the recruitment procedures used in the study. The answers can be found on the **Screening Form, Question 8**.

Eligibility Determination

Overall:

1. Age \geq 18 years
2. Signed Consent Forms

Seronegative:

1. Negative HIV serology (ELISA/Western Blot) at screening

Seropositive, no HAART:

1. No AIDS diagnosis
2. Medical records reviewed, **if medical records exist**
3. Positive HIV serology (ELISA/Western Blot) at screening

Seropositive, HAART:

1. No clinical AIDS prior to or at HAART initiation
2. Medical records reviewed
3. Date of first HAART known
4. HIV RNA and CD4 cell counts within 4 months prior to HAART initiation known