

MULTICENTER AIDS COHORT STUDY

NEW ENROLLMENT

MEDICAL RECORD ABSTRACTION GUIDELINES

(MRA GUIDELINES)

General Instructions:

1. The **Medical Record Abstraction (MRA) Form** MUST BE filled out for all HIV infected prospective participants who have initiated antiretroviral medications (ART), and if available, for men who have not initiated ART. Abstracted information includes: ART medications, HIV viral load, blood cell counts prior to ART, AIDS conditions, history of viral loads and T-cell results starting with seroconversion, and inventory of repositied specimens.
2. Enter the completed MRA into a database for prospective participants who have enrolled into the MACS. CAMACS will provide a codebook and input file for data entry purposes. **MRA Form data** for prospective participants who were screened but not eligible for enrollment should not be sent to CAMACS.
3. Remove the front page tear-off sheet after completing the MRA. The front page should not be data entered or stored in the patient file with the **MRA Form**. The function of the front page is to facilitate abstraction by providing patient information so abstractionists can more easily identify pertinent patient files.
4. Request medical records 6 months prior to the prospective participant's first date of ART and those 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. Use as many top sheets as necessary to track multiple medical providers.
5. There are 2 sections of this form; *Section A*, required for determining eligibility, *Section B*, a history of ART, lab markers, and inventory of available samples for the time period from seroconversion to enrollment.
6. Throughout this form, a regimen refers to a combination of medications taken simultaneously.
7. Follow the skip patterns as they appear on the form.
8. Fill in the screening ID.
9. Assign a MACSID only for prospective participants who are deemed eligible for enrollment into the MACS. This field will remain blank for all men who complete the screening process but are not eligible for enrollment.
10. In filling out dates, code the day as "15" if the day of the month is not known.

SECTION A: Abstraction to determine eligibility

As indicated in the general instructions, this entire section must be completed to determine eligibility for enrollment. If any of the required information is unavailable or cannot be located in the medical records, the prospective participant is NOT eligible. There are several exceptions to this:

- 1) In **Question A.2.B**, the stop date and prescribed dosage are not required for a participant to be eligible.
- 2) While **A.3.B** asks for CD4, CD8, and CD3 counts and percentages, only the CD4 numbers are required.
- 3) Only **Q.A.1** (ART yes or no) **and Q.A.4** (AIDS diagnoses) are required for seropositives not on HAART

Questions 1-2A: First antiretroviral therapy drugs (ART)

Check the prospective participant ever used ART. If not, **SKIP TO Q4**.

Enter the combination of the first prescribed ART drugs and date. The checklist is regimen specific in that it was created as a method for documenting a specific combination of drugs taken at the same time. Carefully check if drugs indicated on any given checklist were all taken by the patient at the same time.

Complete a separate checklist for each regimen found in the medical records (see page 6). **DO NOT** fill in all drugs in the patient's history in one checklist. Rather, document every separate regimen of drugs in a separate checklist, one for each regimen as defined through the patient's medical records.

Question 2.B:

List only the medications which comprised the first documented ART regimen here, as well as the corresponding drug code, the start date, stop date and the prescribed dosage. All medications for that particular regimen should be listed. Note - initiation dates of drugs within a regimen may vary. Drug codes can be found in **Appendix A: Drug List**. If a drug is reported that is not listed on the Drug List, sites should call the CAMACS Coordinator (Janet Schollenberger) at 410-502-2495. If additional spaces are needed (i.e. a participant has more than 5 medications comprising his first HAART regimen), xerox the chart in *A.2.B*, fill in additional medications, and attach to the **MRA Form**.

If no changes in medication following the initial prescription are found in the medical records, leave the stop date blank.

While prescribed dosage is not required information for a participant to be eligible, try to find and abstract this information from the medical records. Under prescribed dosage, record the target (full) dose in mg's (e.g. if starting dose of ritonavir is 300mg and increased to full dose of 600mg bid, over 14 days, record the full dose). Use the following notation to denote frequency of dosing:

qod	=	every 48 hours, or every other day
qd	=	every 24 hours, or every day
bid	=	every 12 hours, or 2 times/day
tid	=	every 8 hours, or 3 times/day
qid	=	every 6 hours, or 4 times/day.

Example: If a prescription is written: "Norvir 100mg; take 6 caps bid," convert and record this as 600mg bid. If the prescription read "100mg; take 4 caps bid," convert and record as 400mg bid.

Example: The oral solution for Norvir comes as 80mg/mL, so a full dose of 600mg = 7.5mL bid. While this will be seen infrequently in the medical records, the abstractor should note the 7.5mL bid but then convert to mg's, and the dose should be recorded as 600mg bid.

Pills containing multiple medications in one pill (such as Combivir and Trizivir), are coded by the name and 3-digit code of the combination pill. Therefore, if a participant reports Combivir, write in "Combivir" in the space for the drug's name, and the 3-digit code "227" for the drug code. The dosage amount (e.g. mg's) cannot be recorded. In this case, code the prescribed dosage as number of pills and frequency (e.g., "Trizivir one bid").

Question 3A.1:

Record the HIV viral load at the time of ART initiation (blood drawn same day that regimen was prescribed or if not indicated, the closest blood draw prior to ART initiation). Ideally, the blood draw must be within 4 months of the date that ART was first prescribed.

Question 3A.2:

If the results of the assay are below the limit of the assay's detection (may be called "undetectable"), mark "YES" to and list the assay kit's lower limit of detection.

Question B.1-2:

Record the CD4, CD8 and CD3 counts and percentages at the time of ART initiation (blood drawn same day that regimen was prescribed or if not indicated, the closest blood draw prior to ART initiation). Ideally, the blood draw must be within 4 months of the date that ART was first prescribed.

Question A4:

If an AIDS-defining illness is found in the medical records, mark "YES". Ascertain if the AIDS diagnosis was prior to ART initiation, if so, stop here and do not continue with the medical record abstraction. If the AIDS diagnosis was after ART initiation, record the diagnosis date, disease, disease code (Appendix C) and method of diagnosis (see codes, 4C.d).

SECTION B: Abstraction to document lab markers prior to enrollment

Question 1:

List other ART regimens initiated after the first ART recorded on page 1. Follow the same instructions specified for table in Q2.B

Questions 2a-b:

Record any additional HIV RNA and/or T-cell results prior to enrollment, starting with closest to Seroconversion and thereafter .

Question 3:

Fill out available repository specimens prior to enrollment.