Guidelines for Completing Visit 38 Drug Form 1  
(MACS Questionnaire)

General Instructions:

1. A Drug Form 1 should be completed for each drug reported by participant in Section 4, Q.15.B(3) unless a drug combination is being taken as part of a blinded clinical trial (see part 2 below).

   Coding Example: (See S4 guidelines, Question 15, for other specific examples.)

   Participant is in a ddI, d4T, nelfinavir and efavirenz clinical trial. He knows he is taking ddI and d4T, but does not know whether he is taking nelfinavir, efavirenz or a placebo.

   ▶ Complete 4 drug forms, one for each drug.
   ▶ For ddI and d4T, bubble “NO” for placebo (Q1B).
   ▶ For nelfinavir and efavirenz, mark “YES” for placebo (Q1B) and ask participant Q1 only on Drug Form 1.

2. Drugs listed in combination for blinded research studies, (i.e. AZT/ddC) should be reported as one drug. This is the only time when you report two drugs on one drug form. A blinded study is one in which the participant may have taken a placebo or is unaware of the actual treatment.

   ▶ Fill out one Drug Form 1 for combinations of this kind. (Please note that these specific studies were common during the combination therapy era, but are unlikely to appear in the current era of HAART therapy.
   ▶ Fill out form through Q1 only.

3. If a participant is taking a medication as part of a research study but then continues that medication after the trial ends during the same visit period, complete two drug forms.

   ▶ One form will correspond to the portion of the visit when the participant was enrolled in the trial.
   ▶ The second drug form will correspond to the portion of the visit continuing the medication usage but not part of the trial.

4. If a participant is taking a medication as part of a research study but is not blinded to the treatment, complete the entire drug form 1. Do not stop after Q1.E.
5. The listings of medications on Drug Form 1 and 2 are not complete. However, each drug still retains a unique code. Refer to each form’s respective current drug list. Mark "Other" and use the specify box for reported antiviral medications not listed on Drug Form 1 and reported non-antiviral medication that are not listed on Drug Form 2. Be sure to cross-check the two Drug Lists for reported participant's responses and fill out the appropriate form. Notify CAMACS of any frequently used medications that do not have unique codes. (See, 15B of Section 4 for more detailed instructions.)

6. All questions refer to the period since the participant's last visit.

7. Note that all known protease inhibitors have now been given unique codes.

**Question 1:** This question asks participant if he is taking the drug as part of a research study.

- If “No”, skip B – E and GO TO Q2.
- If “Yes”, ask B - E

**Q1.D**

If the participant answers “yes” to this question, there are two options:

- If the participant is BLINDED to the treatment, he should STOP at this point (i.e. if Q1.B is “Yes”).
  
  Do not answer Q.2-Q.12 if the participant is taking this drug as part of a blinded research study and therefore does not know whether he is taking a placebo or the actual drug.

- If the participant is UNBLINDED to the treatment, SKIP TO Q4.

**Q1.E**

This question should only be answered if the participant took the medication as part of a research study since last visit but is not currently taking the medication as part of the research study. If the participant cannot remember the exact month, probe for the season.

<table>
<thead>
<tr>
<th>Season</th>
<th>Month</th>
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<tbody>
<tr>
<td>Summer</td>
<td>July</td>
</tr>
<tr>
<td>Fall</td>
<td>October</td>
</tr>
<tr>
<td>Winter</td>
<td>January</td>
</tr>
<tr>
<td>Spring</td>
<td>April</td>
</tr>
</tbody>
</table>

**Question 2:** This question asks participants whether they are not taking the drug as part of a research study.
**Question 3:** If the participant cannot remember the exact month, probe for the season as follows:

- Summer = July
- Fall = October
- Winter = January
- Spring = April

**Question 4:** There are a few drugs that are administered by injection. Ask participant if he is taking the drug reported orally (in a pill or tablet) or by injection?

- If by pill, ask Q5 and Q6 and go to Q8.
- If by injection, skip Q5 and Q6 and go to Q7

**Question 5:** This is the number of times per day prescribed by the physician.

**Question 6:** This is the number of pills per dose prescribed by the physician.

**Question 7:** Ask the participant how many time he injects this drug and record accordingly and ask if the number of times reported is per day, week or month. Fill in the provided time frame.

**Question 8:** This question refers to whether or not the participant started the medication since his last visit.

**Question 9:** This question should only be answered if the participant started the medication since his last visit (Q6 = yes). If the participant cannot remember the exact month, probe for the season as follows:

- Summer = July
- Fall = October
- Winter = January
- Spring = April
Question 10: Mark only one response. Note:

- "One to two months" means one month and longer up to less than 3 months.
- "Three to four months" means three months or longer up to less than 5 months.

Question 11: Mark all the side effects that the participant has experienced on this medication. If the participant says that he does not know exactly which medication causes which side effects (or if he suspects the side effects are a result of medication interaction) mark the side effect for each of the drugs, which the participant believes could be contributing to this particular side effect. “None of the above” should only be answered “yes” if all the possible responses above it are “no” (blank).

Question 12: Stopping medication does not include alternating drug regimens. If that is the reason the participant stopped taking the drug, Q12 should be answered “No”.

Question 13: This question should only be answered if the participant is not alternating drugs and has stopped his medication usage since the last visit.

Each item should be read to the participant. If an item above the line is marked as a reason for stopping the drug, but was not marked in Q11 as a side effect, please confirm the participant’s answer and modify Q11 appropriately. Make sure to the extent possible that the items reported in Q13 as reasons for stopping the medication are reported as a side effect in Q11. If participant responds with reasons not listed on the form, mark "Other" and record in participant's words the reason(s) in the specify box.

Question 14: This question is designed to assess adherence to a prescribed medication schedule.