

# ELECTRONIC MONITORING SYSTEM TRACKING - II

NIAID ADULT AIDS CLINICAL TRIALS GROUP

Patient Number         Date of Patient Visit          
 Protocol Number         Institution Code          
 Form Week    \*Seq No.  \*\*Step No.  Key Operator Code

\* Enter a "1" if this is the first of this form for this date. Designate subsequent forms on the same date with a 2, 3, etc.

\*\*Enter the subject's current study step number. Enter '1' if the study does not have multiple steps.

**INSTRUCTIONS:**

- Refer to "ACTG Guidelines for MEMS Cap Data" located at the DMC Web Site (<http://www.fstrf.org>).
- Complete a separate form for each drug/cap combination.
- Use 24 hour clock.
- The use of "-1" is not acceptable as an answer to any question.

**ACTU CLINIC**

1. Was an electronic monitoring cap used to monitor study drug for this subject? ..... (1-Yes, 2-No)   
 If No, STOP. Key question 1 only.  
 At Entry: Enter Yes if cap is being issued.

2. Enter the drug code of the study drug this electronic monitoring cap is used to monitor:  
 a. Drug Code:         Specify Drug [30]: \_\_\_\_\_  
 b. Indicate the dosing schedule of this drug: .....   
 1 - qd  
 2 - bid  
 3 - tid  
 9 - Other, specify  
 If Other, specify [30]: \_\_\_\_\_

3. Cap serial #: .....

4. Was use of this cap initiated at this visit or since the last visit? ..... (1-Yes, 2-No)   
 If No, go to question 5.  
 If Yes, complete 'a.'  
**Reason Issued**  
 1-Initial study cap  
 2-Previous cap needed to be replaced  
 Date Dispensed (mmm/dd/yyyy)  
 a.

5. Was there a period of time the subject wasn't using the cap and the cap was started again? ..... (1-Yes, 2-No)   
 If No, go to question 6.  
 If Yes, complete the following for each period of time not used:  
**Use the TAB KEY after the last entry.**

a. **1<sup>st</sup> Time Not Used Since last Visit:**  

Date Cap Last Used (mmm/dd/yyyy)	Approximate Time Last Used (hh:mm)
a1. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>
Date Re-Started (mmm/dd/yyyy)	Approximate Time Re-Started (hh:mm)
a2. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>
a3. Specify reason [30]: _____	
a4. Was the subject still taking this drug during the time the cap was not in use? ..... (1-Yes, 2-No) <input type="checkbox"/>	



Pt. No.      \* Seq. No.  \*\* Step No.  Date        
mmm dd yyyy

5. (Con't.) *Use the TAB KEY after the last entry.*

**b. 2nd Time Not Used Since last Visit:**

	<b>Date Cap Last Used (mmm/dd/yyyy)</b>	<b>Approximate Time Last Used (hh:mm)</b>
b1.	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>
	<b>Date Re-Started (mmm/dd/yyyy)</b>	<b>Approximate Time Re-Started (hh:mm)</b>
b2.	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>
b3.	Specify reason [30]: _____	
b4.	Was the subject still taking this drug during the time the cap was not in use? ..... (1-Yes, 2-No) <input type="checkbox"/>	

6. At this visit or since the last MEMS evaluation was there a non-dose event where the cap was removed but a dose was not taken? ..... (1-Yes, 2-No)   
 EXAMPLE: Cap was removed to refill a prescription or to perform a pill count.  
 If No, go to question 7.  
 If Yes, complete 'a' and 'b.'

	<b>Cap Opened? (1-Yes, 2-No)</b>	<b>Date Cap Removed (mmm/dd/yyyy)</b>	<b>Time Cap Removed (hh:mm)</b>	<b>Specify Event [30]</b>
a.	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	_____
b.	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	_____

7. Was the cap usage permanently stopped? ..... (1-Yes, 2-No)   
 If No, go to question 10.  
 If Yes, complete 'a' and 'b.'

	<b>Date Cap Last Used (mmm/dd/yyyy)</b>	<b>Approximate Time Last Used (hh:mm)</b>
a.	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>
b.	Specify reason stopped [30]: _____	

8. Was the cap sent for downloading? ..... (1-Yes, 2-No)   
**For Protocol A0000: Refer to Protocol Appendix \_\_\_\_\_ for shipping instructions.**  
 If Yes, complete 'a' and 'b.'  
 If No, complete 'c' and go to question 10.

a. Indicate time zone: ..... 1-Pacific   
2-Mountain  
3-Central  
4-Eastern

b. Was the cap sent locally (i.e. site pharmacist) to be downloaded or to an external central location? ..... 1-Local   
2-Central  
 If '1-Local', go to question 9.  
 If '2-Central', go to question 10.

c. If No, Specify reason [30]: \_\_\_\_\_

