



VAMHCS Office of Research Compliance  
Sample Time-Event Sheets

- Begin AE monitoring
- Begin NO PSYCHOTROPIC MEDS except: temazepam, lorazepam,  
zolpidem or oxazepam for sleep
- Continue concomitant med monitoring
- Write progress note
- Notify XXXXXXXX of next appointment
- Submit **Encounter Form** for this visit

**DAY 7: VISIT 1**

- Review AE's CRF p.
- Review concomitant meds / changes CRF p.76
- Sbjt tolerating study med? Y / N
- No psych testing this visit

Vital Signs Wt (w/o shoes) CRF p.

<b>Sitting BP</b>	HR	RR	T
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Obtain WEEK 1 bottles from sbjt CRF p.

#caps remaining am bottle	#caps remaining pm bottle	Doses missed?
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Obtain WEEK 2 bottles from J.Haywood

#caps am bottle	#caps pm bottle
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Study Medication Record CRF p.75

**If sbjt withdrawn from study, complete Day 56 visit**

Reinforce with sbjt:

1 cap in am from "am" bottle, 1 cap in pm from "pm" bottle  
same time every day if poss (ex: 8-9am, 5-6pm)

do not take any OTC or other med without checking w study staff  
phone numbers for questions/emergencies

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	next appointment	
	bring med bottle to next appointment	
	Continue AE monitoring	
	Continue NO PSYCHOTROPIC MEDS except: temazepam, lorazepam, zolpidem or oxazepam for sleep	
	Continue concomitant med monitoring	
	Write progress note	
	Notify XXXXXXXX of next appointment	
	Submit <b>Encounter Form</b> for this visit	

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**B: Page 1 of a study with timed events. These T-E sheets were created in Excel; in actual use, they are sized to fit onto one page per visit if possible. Headers contain the name of the protocol; footers contain “P. \_\_ of \_\_”**

\_\_\_\_\_MD

Beeper 410-

**SUBJECTS:**

**INITIALS:**

01

02

SCHED. TIME	ACTUAL TIME	EVENTS	COMMENTS	SIGN OFF (INITIALS)
7am		<b>Admission</b>		
		Sign-in on Master List	Time of Admit:	<b>Master List</b>
		Check-in ("Check-in List")		<b>Check-In List</b>
		Check for presence of signed Inf. consent		
		Inspect belongings for prohibited items; lock away for return to pt at discharge		
		Any changes in pt's condition since last screening visit?	Y* / N	<b>List on</b>
		Any new script/OTC drugs since screening?	Y* / N	<b>List on</b>
		<b>(Med,Dose,Freq,Rte,Start,Stop,Continuing,Indication)</b>		
		All screening tests within 14 days of this admission?	Y / N*	
		Pt continues to meet I/E criteria or has waiver?	Y* / N	
		<i>*Review with Dr. XXXXXXXX or XXXX XXXX before proceeding</i>		
		Confirm that Admitting Orders are activated in CPRS		
		Read Rules & Regulations of CRU		
		<b>Aim for dosing to start at 9am: Pre-Dose tests MUST be 1 hr before dose</b>		

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**T=-1 hr**  
approx

**Pre-dose**

EKG

VS - 5 mins supine x 2

VS - 1 min standing x 2

Baseline AE assessment

Nausea Visual Analog Scale

Blood Draw

Plan to stagger breakfasts and dosing 15 mins apart

**VS Sheet**

**VS Sheet**  
**AE**

**NVAS**

**Blood Draw Sheet**

**Menu Sheet**

**Randomization:**

**CRF p**

**Sbjt 01**

DOB:

M / F

Meets I/E's:

Must meet criteria:

- Hx previous L-dopa Rx? (N or 2wk washout)
- Hx other dopaminergic Rx? (N or 2wk washout)
- Epworth Sleep Score  $\geq 9$ ? (N)
- Meets other I / E criteria? (Y)
- Pt has signed ICF? (Y)
- All screening labs reviewed & meet criteria? (Y)

Call:

1-877-XXX-XXXX

Enter User ID:

Enter Password:

**Sbjt 02**

DOB:

M / F  
Mus

Meets I/E's:

- Hx previous L-dopa Rx? (N or 2wk washout)
- Hx other dopaminergic Rx? (N or 2wk washout)
- Epworth Sleep Score  $\geq 9$ ? (N)
- Meets other I / E criteria? (Y)
- Pt has signed ICF? (Y)
- All screening labs reviewed & meet criteria? (Y)

Call:

1-877-XXX-XXXX

Enter User ID:

Enter Password:

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Choose Menu Option 1

Enter Patient info above

Randomization #

Med Kit #

Reenter Med Kit# to confirm randomization  
If error in entering DOB/gender, enter "\*"; see


Choose Menu Option 1

Enter Patient info above

Randomization #

Med Kit #

Reenter Med Kit# to confirm randomization  
If error in entering DOB/gender,


Notify J.Haywood of randomization

Obtain study drug from pharmacy

T=-30 mins

aprx 0830

Sbjt 01

Sbjt 02

Breakfast 15 mins apart

Scheduled:	Actual
Scheduled:	Actual

*Day 1 continued on next page*