

VAMHCS RESEARCH SERVICE
INVESTIGATOR GUIDELINE

SOP #HRP 07.06G

Approval Date: 11/8/07

THIS IS NOT A RESEARCH SERVICE SOP: it is NOT required that investigators and research staff follow the procedures below.
Instead, this is a **GUIDELINE** presented by the Research Service to aid investigators and research staff in conducting their research protocols.

STUDY-SPECIFIC STANDARD OPERATING PROCEDURES (SSSOPs)

OBJECTIVE:

- To ensure that study protocols are carried out by a staff that is well-trained in the *specifics* of *individual* protocols
- To minimize the possibility for mistakes in the implementation of a protocol

BACKGROUND:

Investigators and research staff must work within sets of standards from a number of sources including the VAMHCS, the Research Service, the VHA, the IRB, state and federal regulations, and Good Clinical Practices. The VAMHCS Research Service has a set of standard operating procedures (SOPs) which deal directly with general research issues and principles. In instances where there is no specific VAMHCS SOP on a research issue, investigators and research staff are to follow UMB IRB SOPs. In addition, research units or larger research programs may (are advised to) have their own unit/program-specific SOPs.

Campus SOPs are found on the Research Service website www.maryland.research.va.gov and the IRB website <https://medschool.umaryland.edu/hrpo/policies.asp>. All VAMHCS research staff are required to be extremely familiar with these SOPs and to implement them within their research programs.

However, in addition to these important general SOPs, every protocol has its own procedures which must be followed in order to conduct the study accurately and uniformly. These procedures should be formalized into “**Study-Specific SOPs**” (**SSSOPs**). *Only staff who are assigned to the specific study need to be familiar with these SSSOPs. Study staff MUST know their study’s SSSOPs well and follow them unless otherwise indicated.*

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It is advisable for the Investigator to have a plan in place for designation of a person (s) who is responsible for coordinating the SSSOPs of the unit or research program (writing them, distribution & training, documentation, collecting into a central location). This plan below may serve as a unit-specific SOP or could be adapted.

RESPONSIBILITIES:

- It is the responsibility of the Investigator, Unit/Program Supervisor, Study Coordinator, or designee to collect, write, and establish the standard operating procedures for his/her stud(ies) (SSSOPs).
- It is the responsibility of the Investigator, Unit/Program Supervisor, Study Coordinator, or designee to arrange for or coordinate inservices or other opportunities for study staff to learn the study's SSSOPs.
- It is the responsibility of the study staff to learn and follow the study's SSSOPs.
- It is the responsibility of the Investigator, Unit/Program Supervisor, Study Coordinator, or designee to document that study staff is proficient in the study's SSSOPs.

DEFINITIONS:

- **Study-Specific Standard Operating Procedures (SSSOPs):** The procedures which must be followed in order to conduct a particular study accurately and uniformly. The SSSOPs are in addition to the general SOPs of the VAMHCS-UMB campus or the research unit's specific SOPs. Only study staff needs to be familiar with SSSOPs. They must know their study's SSSOPs well and follow them unless otherwise indicated.
- **“Umbrella” SOP/SSSOP:** An SOP which pulls together several SOPs on a particular topic. For example: a study may require several different methods of processing laboratory specimens, ordering supplies, obtaining measurements in different situations, etc. In cases such as these, an umbrella SOP is necessary. It should (1) give the “big picture” of how the different procedures fit together, (2) describe or attach the specific procedures in question, and (3) fill in details which may clarify how the procedures will be carried out in the particular research setting (room numbers, specific staff, etc).

DOCUMENTS (ATTACHMENTS):

Coordinator's Checklist for SSSOPs

Appendix 1

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Assignment of Responsibilities (PI)	Appendix 2
Assignment of Responsibilities (Study Staff)	Appendix 3
Time-Event Sheet & Guideline	Appendix 4

SEE ALSO:

Research Service Guidance	Guidelines for Setting Up a Study Binder and Regulatory Documents Binder (HRP 07.02G)
Research Service Guidance	Guidance on Source Documents (HRP 07.03G)
Research Service Guidance	Writing Standard Operating Procedures (HRP 07.05G)

PROCEDURES

1. As soon as a study is accepted, the appropriate person (see “Responsibilities” above) should begin collecting or writing study-specific SOPs (SSSOPs).
2. SSSOPs should be collected into a central binder or file which should be kept current for the duration of the study. Other options might be (for example) keeping SSSOPs in a portion of the Regulatory Binder, in additions to the study’s operations manual, or in additions to specific types of binders/files such as laboratory procedures, shipping procedures, sampling procedures, etc. The designated person should determine where and how SSSOPs will be kept, however all members of a study’s staff **MUST** know where to find SSSOPs
3. Possible topics of SSSOPs may be: procedures for collecting specimens, procedures for processing, storing and shipping specimens, sponsor’s rules for completing CRFs, how to order supplies, how to perform specialized measurements, etc.
4. Possible sources for SSSOPs are: the protocol, materials distributed at investigators meeting(s), operations manual(s), etc.
5. There are several items which **are strongly recommended** to be included as SSSOPs:
 - The study’s Time-Event Sheet (sample can be found in Appendix 4)
 - “Assignment of Responsibilities” for the Principal Investigator (Appendix 2)
 - “Assignment of Responsibilities” for Study Staff (Appendix 3)

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- A SSSOP on source documentation; see “Guidelines on Source Documentation” (HRP 07.03G).
 - A SSSOP on the study’s rules of signatures/initials: see “Guidelines on Source Documentation” (HRP 07.03G), Section 1.3.
6. The “Coordinator’s Checklist for SSSOPs”, found in Appendix 1, may act as an “SSSOP Flowsheet” while SSSOPs are in development. A final version may serve as a “Table of Contents” for the study’s SSSOPs.
7. The study coordinator does NOT need to write SOPs in a particular format or to rewrite procedures if they have already been written by the sponsor. In some instances, photocopies of portions of the protocol or operations manuals may be adequate. However, these photocopies must be clearly labeled in some way as SSSOPs using tools such as headers, titles, introductions, simply hand-writing ‘SSSOP’ across the top of a photocopy, etc. It may also be useful to simply color-highlight sections of applicable photocopies from the protocol, ops manual or other source.

In some instances a memo directing staff to an entire section or pages of the protocol or operations manual, etc. may be most logical. Place the memo in the appropriate place of the SSSOP file.

It may sometimes be necessary for the coordinator to write new SOPs or to clarify a sponsor’s SOPs. Most likely, a combination of all of these will be necessary for most studies.

8. In some cases an “**umbrella SOP**” may be necessary. This occurs when there are several ways to perform some processes. For example: there may be several ways to order supplies for a study (different requisition forms for different suppliers, etc.), or there may be several ways to process blood/urine samples or to store or ship them. Because multiple processes can become confusing, it is advisable and helpful to have a SSSOP which summarizes the procedures and clarifies when each one should be used. Then procedural details can be given within the instructions for individual procedures. See the definition of “Umbrella SOP” in the “Definitions” section above for more details.
9. There may be occasions where a sponsor’s or protocol’s procedures will conflict with a research unit’s or a VAMHCS/UMB SOP. The sponsor should be contacted to see if it will accept the unit’s/VAMHCS’/UMB’s SOP in lieu of its own.

However, if a specific sponsor or study requires that a particular task be performed in a way that differs from a unit’s SOP, the PI or the unit management may approve a deviation to the unit SOP. *There may be NO*

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deviation from a VAMHCS or UMB SOP unless it has been approved by the Research Compliance Office (VAMHCS) or the Human Research Protections Office (UMB).

The new SOP applies to that study only and is filed in the study's SSSOP binder and in the study regulatory binder along with a "memo to file". The "memo to file" states that the deviation applies only to the study in question, that the deviation is at the sponsor's request, and that it expires as soon as the study has ended.

10. The PI or the Unit/Program should have an SOP regarding whether or not SSSOPs must be signed and by whom.
11. All study staff must be inserviced in SSSOPs. This should be documented in some way even if this is simply to have the study staff initial the SSSOPs when they read them.

APPROVAL

This SOP entitled "Study-Specific Standard Operating Procedures (SSSOPs)" has been approved effective 11/8/07.

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**APPENDIX 1: Coordinator’s Checklist for
Study-Specific SOPs
(SSSOPs)**

GUIDELINE

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**COORDINATOR'S CHECKLIST FOR STUDY-SPECIFIC SOPS
(SSSOPs)**

Items in **BOLD** are required for *all* studies; others are suggested as appropriate. Specific studies may need other/additional SSSOPs. See also, notes at bottom.

This worksheet is proposed as an aid to coordinators. It may be revised as needed. Be aware of SOP requirements contained on this worksheet.

This checklist may act as an "SSSOP Flowsheet" while SSSOPs are in development. A final version may serve as a "Table of Contents" for the study's SSSOPs.

TYPE/TITLE OF SOP	NEW	MEMO FOR LOCATION	COPY OF SPONSOR'S PAGES
"Assignment of Responsibilities" (PI)¹			
"Assignment of Responsibilities" (Study Staff)			
Time-Event Sheet²			
Source Documentation³			
Signatures/initials on TE Sheet and source docs⁴			
Ordering supplies			
Obtaining blood specimens			
Obtaining urine specimens			
Obtaining other specimens			
Processing specimens ⁵			
Storing specimens ⁵			
Shipping specimens ⁵			

¹. See HRO 07.07G: "Accepting a Protocol" [and unit/program SOP ____]

². See HRP 07.03G: "Source Documentation", **Section 4** [and unit/program SOP ____]

³. See HRP 07.03G: "Source Documentation" [and unit/program SOP ____]

⁴. See HRP 07.03G: "Source Documentation", Section 1.3 [and unit/program SOP ____]

⁵ See HRP 07.08G: "Processing Laboratory Specimens"; A copy must also be placed in the CRU Lab Binder [and unit/program SOP ____]

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Informed Consent (if different from Research Service SOPs)			
AE Reporting (if different from Research Service SOPs)			
Drop-out/death of participants			
Pharmacy / Drug Dispensing / Drug Accountability			
Specialized/Unusual Procedures or Measurements			

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**APPENDIX 2: Assignment of
Responsibilities (Principal
investigator)**

Investigators/research staff should change column headings and row titles as needed (for example: “Sponsor responsibilities”, “Study coordinator responsibilities”, etc.) and signatories at the bottom

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PRE-STUDY INVESTIGATOR-SPONSOR-STAFF MEETING(S)
AGREEMENT ON ISSUES, ASSIGNMENT OF RESPONSIBILITIES, POINTS FOR FOLLOW-UP

DATE: _____ MEETING ___ OF ___ STUDY: _____

PARTICIPANTS: _____

	UNIT Responsibility	Investigator Responsibility	_____ Responsibility
IRB submission		X	
IRB amendments			
IRB reports: annual			
IRB reports: SAE			
Notification of other party of IRB approvals & amendments			
Regulatory Docs file			
Time-Event Sheet	X	Accept? Y / N Wants input into revisions? Y / N	
Design of DCF's (source documents): Screening			
Enrolled			
Maintenance of DCF's (source documents): Screening			
Enrolled			
Recruitment activities (specify if responsibilities are split)			
Screening activities (specify if responsibilities are split)			
Enrolled activities (specify if responsibilities are split)			
Registration			

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	Unit Responsibility	Investigator Responsibility	_____ Responsibility
Admission			
Scheduling: sbjts			
Scheduling: staff			
Contact forms			
MD coverage			
Supervision of staff			
Coordinator			
Phlebotomy			
Shipping samples			
Storing samples			
Other activity:			
Other activity:			
Acquiring equipment			
Returning (shipping) loaned equipment			
Training on new equipment			
Clerical (significant amounts of FAXing, xeroxing, mailings, etc)			
QA			
Transcription to CRF's			
Monitor visits: CRF's			
Monitor visits: Reg Docs			
Notifying Sponsor of SAE's			
Other items:			

Other items:

Question	Answer
PI allows contact with Sponsor?	Contact person(s):

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PI allows direct budget with Sponsor for CRU portion?	Contact person(s):
How many destinations for shipped samples?	
How many shipments per sbjt/visit/etc?	
How much notice before an admission?	
Likelihood of cancellations/postponements	
Financial arrangement for cancellations:	
Financial arrangement for postponements:	
What equipment needs to be obtained?	
CRU space needed? (cross-out those not needed; specify amount, etc of those needed)	Offices, exam rooms, inpatient rooms, storage space, other: _____
CRU equipment needed? (cross-out those not needed; specify amount, etc of those needed)	Refrigerators, freezers, centrifuges, telephone lines, computers, special equipment: _____; other: _____
CRU personnel needed? (cross-out those not needed; specify amount, etc of those needed)	RN's, PCA's, phlebotomists, screeners, recruiters, data managers, chart reviewers, NP's, other _____
CRU rep to Investigator Meeting? (significant CRU role only)	
Acknowledgement of CRU in publications	
Sponsor must know that CRU is an entity independent of PI	
Other providers of services which the CRU will work with / coordinate, etc?	Names & #'s:
Other:	

We understand and agree with the items as outlined on the preceding pages. We accept the above responsibilities.

Investigator: _____ Date: _____

Unit Representative: _____ Date: _____ Role in Unit: _____

Coordinator(s): _____ Date: _____ (Investigator Coordinator)

APPENDIX 3: Assignment of Responsibilities (Research Staff)

This is the same basic table as in Appendix 2 but is presented here as a way to list a fairly comprehensive list of clinical trials tasks. Investigators/research staff should change column headings, row titles and signatories at the bottom in order to adapt this to their specific situation.

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PRE-STUDY INVESTIGATOR-RESEARCH STAFF MEETING(S):
AGREEMENT ON ISSUES, ASSIGNMENT OF RESPONSIBILITIES, POINTS FOR FOLLOW-UP

DATE: _____ MEETING ___ OF ___ STUDY: _____

PARTICIPANTS: _____

	Coordinator Responsibility	Investigator Responsibility	Staff Responsibility
IRB submission		X	
IRB amendments			
IRB reports: annual			
IRB reports: SAE			
Notification of other party of IRB approvals & amendments			
Regulatory Docs file			
Time-Event Sheet	X	Accept? Y / N Wants input into revisions? Y / N	
Design of DCF's (source documents): Screening			
Enrolled			
Maintenance of DCF's (source documents): Screening			
Enrolled			
Recruitment activities (specify if responsibilities are split)			
Screening activities (specify if responsibilities are split)			
Enrolled activities (specify if responsibilities are split)			
Registration			
Admission			
Scheduling: sbjts			

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	CRU Responsibility	Investigator Responsibility	_____ Responsibility
Scheduling: staff			
Contact forms			
MD coverage			
Supervision of staff			
Coordinator			
Phlebotomy			
Shipping samples			
Storing samples			
Other activity:			
Other activity:			
Acquiring equipment			
Returning (shipping) loaned equipment			
Training on new equipment			
Clerical (significant amounts of FAXing, xeroxing, mailings, etc)			
QA			
Transcription to CRF's			
Monitor visits: CRF's			
Monitor visits: Reg Docs			
Notifying Sponsor of SAE's			
Other items:			

Other items:

Question	Answer
PI allows contact with Sponsor?	Contact person(s):
PI allows direct budget with Sponsor for CRU portion?	Contact person(s):

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How many destinations for shipped samples?	
How many shipments per sbjt/visit/etc?	
How much notice before an admission?	
Likelihood of cancellations/postponements	
Financial arrangement for cancellations:	
Financial arrangement for postponements:	
What equipment needs to be obtained?	
CRU space needed? (cross-out those not needed; specify amount, etc of those needed)	Offices, exam rooms, inpatient rooms, storage space, other: _____
CRU equipment needed? (cross-out those not needed; specify amount, etc of those needed)	Refrigerators, freezers, centrifuges, telephone lines, computers, special equipment: _____; other: _____
CRU personnel needed? (cross-out those not needed; specify amount, etc of those needed)	RN's, PCA's, phlebotomists, screeners, recruiters, data managers, chart reviewers, NP's, other _____
CRU rep to Investigator Meeting? (significant CRU role only)	
Acknowledgement of CRU in publications	
Sponsor must know that CRU is an entity independent of PI	
Other providers of services which the CRU will work with / coordinate, etc?	Names & #'s: _____
Other:	

We understand and agree with the items as outlined on the preceding pages. We accept the above responsibilities.

Investigator: _____ Date: _____

Coordinator(s): _____ Date: _____

_____ Date: _____

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APPENDIX 4: Sample Time-Event Sheet and Guideline

GUIDELINE

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A: Pages 1 and 2 of an outpatient study. 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 ___"

Subject ID: _____

Emergency /Contact #'s

DATE: _____

EVENTS; done by CRU staff unless otherwise indicated		COMMENTS	INITIALS
Date:	DAY 0: BASELINE		
Check for copy of SIGNED informed consent form			
Make sure that subject has been activated in DHCP system			
Review I / E criteria	Dr. XXXXX		
Sbjt has had no antidepressants for at least 2 months		Y / N	
Review concomitant meds		CRF p.76	
Psych testing	Dr. XXXXX		
Vital Signs	Wt (w/o shoes)	CRF p.	
Sitting BP	HR	RR	T
Notify J.Haywood of subject enrollment			
Obtain WEEK 1 bottles from J.Haywood			

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#caps am bottle

#caps pm bottle

Study Medication Record

CRF p.75

Instruct subj:

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
next appointment
bring med bottle to next appointment
remember the time s/he took 1st dose

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.

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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.

Sitting BP	HR	RR	T

Obtain WEEK 1 bottles from sbjt

CRF p.

#caps remaining am bottle	#caps remaining pm bottle	Doses missed?
---------------------------	---------------------------	---------------

Obtain WEEK 2 bottles from J.Haywood

#caps am bottle	#caps pm bottle
-----------------	-----------------

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

next appointment

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- 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 **Encounter Form** 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 ___"

SUBJECTS:

INITIALS:

01	
02	

_____ MD Beeper 410-

SCHED. TIME	ACTUAL TIME	EVENTS	COMMENTS	SIGN OFF (INITIALS)
7am		Admission		
		Sign-in on Master List	Time of Admit: _____	Master List
		Check-in ("Check-in List")		Check-In List
		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	List on
		Any new script/OTC drugs since screening?	Y* / N (Med,Dose,Freq,Rte,Start,Stop,Continuing,Indication)	List on
		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		

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T=-1 hr
approx

Aim for dosing to start at 9am: Pre-Dose tests MUST be 1 hr before dose

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 ≥ 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:

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 ≥ 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:

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Enter Password: Choose Menu Option 1 Enter Patient info above Randomization # <input style="width: 40px; height: 20px;" type="text"/> Med Kit # <input style="width: 40px; height: 20px;" type="text"/> Reenter Med Kit# to confirm randomization If error in entering DOB/gender, enter "***"; see	Enter Password: Choose Menu Option 1 Enter Patient info above Randomization # <input style="width: 40px; height: 20px;" type="text"/> Med Kit # <input style="width: 40px; height: 20px;" type="text"/> Reenter Med Kit# to confirm randomization If error in entering ee manual				
Notify J.Haywood of randomization Obtain study drug from pharmacy					
Breakfast 15 mins apart					
T=-30 mins aprx 0830 Sbjt 01 Sbjt 02	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 70%;">Scheduled:</td> <td style="width: 30%;">Actual</td> </tr> <tr> <td>Scheduled:</td> <td>Actual</td> </tr> </table>	Scheduled:	Actual	Scheduled:	Actual
Scheduled:	Actual				
Scheduled:	Actual				

Day 1 continued on next page

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GUIDELINES FOR USE OF TIME-EVENT SHEET (for example*)

1. This form is meant to help study staff accomplish all the tasks required for a patient's completion of a study. It assumes that the study coordinator and other study personnel will use it as a checklist on study days. For the sake of space and time I use key words and phrases in order to remind staff what needs to be done. Remember that the study protocol and other materials contain MUCH more detailed information should questions arise.
2. The TE Sheet includes events that are study requirements but also some that are clinical requirements for our unit / PI. The "non-study events" include daily vital signs (even when not required by the protocol), I/O's (which happen to go from 6am to 6am in our unit), q8hr PICC line/heparin lock flushes, discussion of our unit's "Rules and Regulations" with the subject, etc.
3. Whenever there is an empty box with "AM", "PM", "ml", "kg", etc., some piece of data should be inserted. The time-event sheet is meant to be redundant with some Data Collection Forms (DCF's) in order to increase chances that essential information will be obtained. The data are meant to be transcribed to the appropriate form when time allows. For example: weights to the "Weight Summary Sheet", urine volumes to the I/O or "Urine Processing Sheet".
4. Empty boxes for insertion of times are ESPECIALLY important. At times when a scheduled time can be predicted or approximated, that time has already been entered. However, when scheduled times are timed from an unpredictable event (such as patient voids, actual time of dosing, etc.) the event becomes "t₀" ("time zero") and all subsequent blood draws, urine collections, etc. are timed from this. As soon as the event occurs, someone (preferably the coordinator) must be able to take a few minutes to accurately fill in the blanks for scheduled times for the remainder of the study day. If this is not done, mistakes in timing are sure to occur.
5. Once scheduled times are filled in, as the day proceeds and study events occur, put a simple checkmark in the grey spaces of the "Actual Time" column if the event occurred on time. If the actual time was different from the scheduled time then enter the actual clock time in the grey space. It is important that SOMETHING be entered into each space so that it is easy to see at a glance where you are/what is your next step (this can be crucial on the hectic dosing mornings and is ideally done by a coordinator whose only task is to coordinate the dosing by/with others and not to do it her/himself).
6. The "Comments" column is for quick jots of reminder notes to be documented later in more detail on appropriate DCF's. For example: "HA" to document the start of the patient's complaint of a headache. This would later be documented on an Adverse Event Form but would at least remind you of what and when something happened.
7. "Events Observed" column is for an observer to document that an event occurred. In our unit, the person actually performing an action signs it off on the appropriate DCF (vital signs, blood draw, etc.) that s/he did it. Therefore the coordinator or other observer can sign off on the TE Sheet that s/he knows it was done.

(*adapted from a BVAMC research unit's use of T-E Sheets)