

VAMHCS Research Service  
Guidelines for Source Documentation

**HRP 07.03G****GUIDELINE FOR SOURCE DOCUMENTATION**

**Introduction:** This is meant to be a *guideline*. It is an *informal* guide for good practice on source documentation, including frequently asked questions and issues. It is published by the Research Service as a service to investigators and research staff who seek guidance on this subject or who would like to use it as a written guide for themselves or as instructional material for staff. Investigators may even use it as their own SOP for source documentation practices if they so choose.

The practices described here are recommended but *not* binding upon investigators or staff as long as investigators/staff follow some sort of formal, acceptable documentation standards.

There are two acronyms used throughout this Guideline: **DCF** (Data Collection Form) and **CRF** (Case Report Form). For the purposes of this Guideline, “DCF” refers to the forms used by sites to collect data during study visits (and thereby become source documents) and “CRF” refers to the forms used by sponsors and coordinating centers to report data to their data management centers. DCFs are used to collect data; CRFs are used to report data. DCFs are source documents for completing CRFs. Study staff transcribes data from DCFs onto CRFs.

**Definition:** Source documents are the original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects’ diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial). ICH GCP 1.52

Source documents also include data collection forms that have been designed by the Investigator/staff *as well as informal notes or data jotted down in any way*. Also included: study progress notes, telephone contact notes, entries into CPRS, PROFILE, and other electronic medical records or data entry systems. Electronic entries are confirmed by hard copy printouts of notes, reports, etc. which are placed in the study’s/subject’s source document chart. *Even studies with remote data entry or electronic data entry infrasystems need hard printouts of data pages to act as source documents.*

**Topics covered in these guidelines:**

- **Designing your own source documents**
  - General considerations
  - Format tips

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- Master Documents
  - Signatures/sign-offs
- **Photocopying source documents**
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- **Time-Event Sheets**
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**Designing your own Source Document (“Data Collection Form”, DCF):**

- The goal of any DCF is to collect concise, complete, accurate, consistent data.
- The goal should be for the fewest and simplest DCFs.
- DCFs are most successful when they are “bedside/visit friendly” i.e. in a format that is logical and chronological for a study visit (in contrast to Sponsors’ “Case Report Forms” (CRFs) which are often designed for ease of data entry into the Sponsor’s databases rather than ease or logic of data collection).

For example: Sponsors often use CRFs that collect types of data: a page for vital signs, a page for concomitant meds, a page for weights, etc. In this case, for a single study visit, you might have to fill out small parts of several pages. Instead, consider using a single, “per visit” DCF that collects everything you need onto one page. In this way, a glance at the form will show missing data for that visit.

- Unless there is a good reason, source documentation should not be repetitive or burdensome.

For example: Use a copy of a lab report as the source document instead of copying lab values onto a DCF.

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- The more places a data point is asked to be recorded, the higher the risk of inconsistencies between entries. However, *some* redundancy *may be* permissible since it increases the likelihood that data points will be recorded in at least one place (and therefore, not missed altogether).
  - For example: If you must use a separate “Vital Signs Sheet”, you may not want to also ask for VS to be recorded on the “Time-Event Sheet”.
- Frequently there is reason for a DCF to contain more information or ask for more data than the CRF.
  - For example: A DCF might contain detailed instructions on a certain measurement or context for a certain decision point (‘if this, then do that...’).
  - ...OR...**
  - A CRF may merely ask the question: “Have all entry criteria been met?” Your DCF should contain boxes/spaces for particular, potentially exclusionary data points such as specific lab values, weight, age (ask for actual birth date), etc. (**Avoid checklists!!!** See below)
  - ...OR...**
  - The CRF may ask for a calculated value but not the raw numbers. For example: the CRF asks for oxygen content at several points during an intervention, but doesn’t ask for serial PaO<sub>2</sub>’s or SaO<sub>2</sub>’s or a pre-intervention Hgb in order to make the calculations. Your Time-Event sheet should specify a draw of a serum hemoglobin prior to intervention and there should be a DCF (or boxes on the T-E Sheet) for serial ABGs.
- **Avoid checklists!!!**, especially for important categories such as I/E criteria. Checklists are simple but they lead to mindless checking of boxes rather than true checking of whether you are actually in possession of a required document or whether a lab value truly fits criteria!!! By asking a coordinator to fill-in even obvious information, s/he may discover missing items or items which turn out to disqualify the subject or which may require follow-up.
- **Avoid checklists!!!** (see above!)
- Have we mentioned that you should **avoid checklists!!!**
- The DCF **should have visual cues** for data collection, triggering of study activities, etc.
  - For example: boxes , • bullets, tables, indentations, shading, borders, blank spaces, etc.
- The DCF **should NOT be visually disorganized** (=confusing).
  - For example:
    - data points scattered haphazardly throughout the page (instead, line them up along a single vertical tab);
    - misaligned text (instead, stick to margins and use tabs and indentation carefully);
    - boxes used one place, bullets or blanks used other places (instead, use a consistent method);
    - fonts, bold, italics, underlining used inconsistently;
    - study events not listed in a logical order (instead, be chronological, group them by staff member involvement [e.g. events to be performed by PI, by RN, by other therapist, etc.], group them by topic [e.g. what is done in the micro

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lab, what is done in the OR, etc.] or use another method that is practical for your study).

- When applicable, pages should be numbered as “Page \_\_ of \_\_” in order to minimize the chance of losing pages or confusing the chronology.
- Make sure there are headers for “Subject ID” and timepoint e.g. date, period #, visit #, etc.
- Footers should identify the version of the DCF (in order to assure that the most recent version is being used) and, if applicable, a space for signature of the person completing the form etc. (see below, the bullet on signatures/sign-offs).
- Early in the process of source documents design, the coordinator must determine the ground rules for signatures/sign-offs on source documents and ***document the rules in writing***. For example, does a signature or initial indicate the person completing the form?, the person doing the procedure?, the person interpreting a measurement or lab value?, the person witnessing that a study event has occurred?, the PI? Is one signature or initial at the bottom of a page sufficient or must several data points be signed-off?
- There should be a signature/initials log for everyone who makes entries on a DCF.
- Consider formalizing these rules in a “Standard Operating Procedure (SOP) for Source Documentation”. This SOP would stand for the current study and could also stand for all studies done by your group. *It is highly recommended to have a source documentation SOP established for all studies done by your group.*
- Include some way to trigger a thorough process of informed consent (such as an “Informed Consent Process Worksheet”, Attachment 1) and to document Inclusion/Exclusion criteria. Require narrative (progress) notes for each of these issues.
- It is highly recommended to maintain a central file of “Master Documents”. A single designated person (most likely the person responsible for designing the DCFs) makes sure that only the current versions of DCFs are in the file and that all old versions are removed. The Master DCFs in the file are then used to Xerox DCFs for subjects’ study binders. Alternatively, you can maintain and carefully monitor an *electronic* folder in your network so that staff can print out only current versions of DCFs.

**Use of photocopies as source documents:**

- Use of photocopies of Sponsor CRFs as source documents should be discouraged. If you determine that the format of the Sponsor CRF is preferable to designing a new DCF, then see the attached method for suggestions on turning a CRF into a DCF (“CRF-DCF Template”, Attachment 2). *The DCF created by using this method then becomes a “Master DCF” which is kept in the “Master Documents File” to be Xeroxed or printed out when needed.*
- If it is absolutely necessary to use an exact photocopy of a CRF as a DCF, *the DCF copy should be clearly identified as the source document.* If a form of this type (e.g. a photocopy of a questionnaire, diary, checklist, etc.) is later transcribed by the study staff to the actual Sponsor CRF, the original source must be identified as: “Source Document” *and a note placed on it indicating that it has been transcribed to the CRF and by whom.*

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- An exception to “the photocopy rule” is for data entered directly by subjects onto diaries, questionnaires, checklists or other similar forms. Staff must document on the “Time-Event Sheet” and/or the progress note that it was the subject who completed the forms. IMPORTANT: See section on making correction (p.8).

**You don’t *have* to design source documents for some data collection:**

- Use copies of lab reports, radiology reports, EKGs, films, etc. as source documents. Don’t recopy data unnecessarily (waste of time, potential transcription errors).
- Be sure to write interpretations or clinical significance on reports. All abnormal values MUST have notations of “NCS” (not clinically significant) or “CS” (clinically significant). All reports should be signed and dated by the PI or designated interpreter (whose signature and initials should be on the signature log mentioned above).
- Use the Sponsor’s actual CRFs for diaries, questionnaires, or other forms filled out by the subject him/herself.
- Use the “CRF-DCF Template” (see above; Attachment 2) when a Sponsor’s form contains what you need but contains lots of formatting that would be an inefficient use of your time to recreate.

**Time-Event Sheets:**

- The Research Service suggests using “Time-Event Sheets” (TE Sheets) or other similar form as the *master source document* for any study. The TE Sheet may be used as an actual data capture tool for some or all data points or it may serve mainly as a master flow sheet that ensures that all data are obtained at the correct time points. In either case, the TE Sheet is considered a source document.
- Small data sets may be incorporated into TE Sheets (such as vital signs, weights, scheduled sampling times, etc.). However, depending on the nature of the study, it may be more appropriate to have separate data collection forms for some studies, for example: vital signs sheets, blood draw sheets, lab processing sheets, etc.
- An important data point on TE Sheets is the time that informed consent is obtained (the time the consent form is signed) as well as a checklist format for the Informed Consent process (Attachment # 1). No screening activities should have occurred prior to the time the ICF is signed (except for measurements obtained for standard clinical care of the subject).
- The requirements for signing-off TE Sheets will vary depending on the nature of the study: whether initials/signatures indicate the person who did the task(s) or someone who merely observed/testifies that the task was completed; whether initials or complete signatures are required; whether individual tasks need to be signed-off or whether one signature for an entire page is acceptable; etc. Unless there is a SOP for your unit that covers this issue, a “memo to file” defining the parameters of the TE Sheet should be written for each study and filed in the Regulatory Documents File.
- See Attachment 3: “Guidelines for Time-Event Sheets”
- See Attachment 4 for an example of a Time-Event Sheet.

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**Narrative Notes as DCFs:**

- All study visits, endpoints, and adverse events must be documented in progress notes in the subject's permanent medical record and the study's source document chart. If medical progress notes are made via CPRS, use printouts of these notes for placement into the source document chart.
- There **MUST** be a progress note describing the informed consent process. This note is also used by the Research Service to tag signed informed consent forms when they are scanned into CPRS. The Time-Event Sheet should include the writing of this note in the flow list of study activities.
- There **MUST** be a progress note stating that I/E criteria have been met or that waivers have been obtained for any criteria that have not been met. The Time-Event Sheet should include the writing of this note in the flow list of study activities.
- *There must also be notes of missed visits and of study completion.*
- In some instances (decided by you or the Sponsor) additional forms of narrative notes may be required. These include: "Adverse Events Comments Sheets" which give specific details on adverse events, "Study Comments Sheets" which describe study-related events, etc.
- It is helpful to establish rules (Standard Operating Procedures, SOPs) for frequency of charting (qs, qd, q visit, etc.) This compels staff to write notes regularly... *even when there is no new info to record!!!*
  - For example: a note stating "no changes this shift, no AE's" can help to narrow down the onset of a subsequent AE and can document that someone was actively looking out for AEs.
- See Attachment 5: "Guidelines for Narrative Notes"
- When using narrative notes, late entries must be written *after the last entry* (not squeezed in between entries) and identified as a "Late Entry". They identify the time/date of the event being clarified but are signed and dated with the date the late entry is actually written.

**Some examples of DCFs (not exhaustive):**

- Telephone contact logs: record significant telephone conversations with Sponsor, PI, subjects, study personnel; document the conversants, their roles, the date of conversation, a short summary of the conversation; filed in the Correspondence section of the Regulatory Documents Binder or with study source documents (whichever is appropriate).
- Electronic messages and facsimiles: printed and filed in Correspondence section of Regulatory Documents Binder.
- Screening and recruitment logs: must include reason(s) that subject failed screening / did not enroll; filed in study documents.
- Signature logs of study personnel
- Laboratory processing, storage, and shipping logs.
- Copies or printouts of lab or other reports. Be sure to comment on any result that is outside normal limits ("CS". "NCS", see \_\_\_\_\_)
- DCFs designed by the study staff or the Sponsor, see guidelines above.
- Medication administration records

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- Study drug inventory, dispensing/administration records

**Filling out a DCF/source document:**

- All entries must be made with black ballpoint pen.
- Errors must be crossed out with a single line and corrections initialed and dated with the date of correction.
- **There should be no blank pages.** *If a DCF page does not apply (“NA”) or if the required info is unknown (“UNK”) or was not obtained (“ND”), this is written across the entire page with explanations as necessary. Subject and timepoint identifiers must still be completed.*
- **There should be no blanks on any DCF.** *If a data point is unknown (“UNK”), not obtained (“ND”) or does not apply (“NA”), this is written on the DCF with explanations as necessary.*  
For example: “Blood draw ND because no venous access.”
- If you have received a **waiver** from the Sponsor, PI, etc. to suspend an I/E criterion or a particular study activity, be sure to specify this to explain a “ND”, “NA”, etc.  
For example: “Past medical hx. not able to be obtained due to sbjt’s decreased LOC. Waiver obtained from Sponsor.”  
The Sponsor’s written documentation of the waiver **must** also be placed in the study’s regulatory binder.
- Record all data, even if the results are unexpected or undesirable.
- Record the absence of expected events, complications, or other events specifically asked for in the CRFs.
- Be sure to fill out all headers and footers (Subject ID, time point, etc.). Imagine what would happen if study files spilled out all over the floor...
- The form or entry should be signed and dated according to the rules (SOPs) you’ve established for your study.
- ***Used DCFs do not have to look beautiful or neat!!! (Although they MUST be readable!!!)*** Use margins or other space for jotting down details, questions, explanatory notes, reminders to follow-up, etc. These notes are sometimes ***extremely helpful*** to jog memories later, to communicate valuable information to staff, to complete other portions of data collection, etc.  
For example: when asking about medications, a subject may tell you something that might need follow-up re Medical Hx with possible implications for Inclusion/Exclusion Criteria. Jot this down somewhere on the DCF in order to document the info and to remind yourself to do some follow-up.
- Be sure to jot notes about why a scheduled activity did not occur, why it was outside a time window, why/how an error occurred, etc. This will help to document protocol deviations. It will also help in completion of CRFs and answering monitors’ questions.
- Think about the form from this point of view: “If I don’t get a chance to do the CRFs until next week, should I jot down a few more details here while they’re still fresh in my mind?” OR “When my study coordinator uses this DCF to complete the CRF, should s/he have a few more details to help her understand what happened?” OR “When my monitor comes, will s/he be able to understand why I gave a particular answer on the CRF?”...

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- When using narrative notes, late entries must be written at the end of the text (not squeezed in between entries) and identified as a “Late Entry”. They identify the time/date of the event being clarified but are signed and dated with the date the late entry is actually written.
- There must be progress notes written in the medical record (with copies/printouts in the study binder) describing the informed consent process and confirming that all I/E criteria have been met (or that waivers have been obtained for criteria that have not been met). There should also be progress notes for all visits and endpoints and for study completion. Include reminders of these in the Time-Event Sheet.
- When using copies of lab or other reports as source documents, be sure to write interpretations or clinical significance on the report. *All abnormal values MUST have notations of “NCS” (not clinically significant) or “CS” (clinically significant).* All reports should be signed and dated by the PI or designated interpreter.

**Making Corrections on source documents:**

- Errors must be crossed out with a single line and corrections initialed and dated with the date of correction
- When in doubt, explain the why/how/details of an error.
- **For forms which have been completed by subjects themselves:** If corrections/clarifications are necessary, subjects themselves should make the corrections and initial and date them. If the subject is not available, staff may correct the form but ONLY if there is strong documentation substantiating the correction and ONLY if the original entry remains visible. *The new information must be signed and dated by the coordinator and MUST have a written explanation for the clarification AS WELL AS the source of the new information.*
- Source documents *may* be clarified by the study coordinator. If this is necessary, the original entry must remain readable. *The new information must be signed and dated by the coordinator and MUST have an explanation for the clarification AS WELL AS the source of the new information.*  
For example: *a narrative note describes an adverse event but an AE checklist suggests that no AE occurred; the AE checklist may be crossed out, initialed and dated and a note written which refers to the narrative note.*
- In general, source documents may not be recopied even for the sake of neatness or readability. It is OK if a DCF looks messy as long as it is readable! If an entry is illegible, the person who made the entry *may* write a clarifying note (initialed and dated) in the margin, but the original entry *MUST* remain visible and unchanged. If a DCF/source document is badly disfigured (spills, tears, excessive cross-outs that hinder readability, etc.), it *MIGHT* be acceptable to recopy the document(s) (check with the Sponsor, your unit’s SOPs, etc.). In this case, the original *MUST* be kept, preferably attached to the copy but if necessary, with a note as to where the original may be found. The copy *must be clearly identified as a copy* and the person making the copy must sign and date the copy.
- **SOURCE DOCUMENTS MUST NEVER BE DISCARDED.**

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### Checking yourself

- **“Worse Case Scenario” Rules as a way to foolproof your DCFs and documentation process:**

Imagine that, hypothetically:

1. The person collecting your data will be the busiest, messiest, most disorganized, most unprepared, least bright, most rushed, most clumsy (most likely to drop binder and scatter pages all over the floor) person in your institution AND...
2. The PI, Study Coordinator, and every other person who knows the study are snowed in at a conference in Alaska in which a monumental blizzard has taken down phone and power lines (no way to charge cell phones)...

...would your “Time-Event Sheet” (or other similar form) be able to guide the person in #1 through a study visit? Would your study binder be organized enough for an outsider to make sense of it? Would the DCFs be self-explanatory and easily completed? Would #1 know who and how to reach contact persons at the Sponsor for questions? Would your monitor who comes for a scheduled visit be able to find everything in order and have no need to leave yellow stickies on your pages? ...

- **Dr. Farley’s Anagram: ALCOA**

**A**tributable: is it obvious who wrote it?

**L**egible: can it be read?

**C**ontemporaneous: is the information current and in the correct time frame?

**O**riginal: is it a copy? Has it been altered?

**A**ccurate: are conflicting data recorded elsewhere?

- The IRB has several “Self- Assessment Tools” for source documentation, regulatory documents and other topics. Visit their website.

### Remember NOT to commit these violations found in audits:

- Source documents not changed in response to protocol amendments
- Missing subject and time point identifiers
- Use of expired/invalid Informed Consent Forms
- No documentation to support I/E criteria and subject enrollment
- Documentation of enrollment criteria came from subject’s files from previous studies up to 5 years prior to current study
- No progress note to document the informed consent process, mini-mental exam, etc.
- Protocol violations: data collected outside windows, missed evaluations without explanation,
- No note or explanation of protocol violations
- Incomplete source documents: missing pages, pages not completely filled out
- Incomplete/messy/disorganized study binder
- Abnormal lab values without notes on clinical significance and PI signature

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**Suggested SOPs for your research unit or program:**

- Source documentation and DCFs
- Frequency of and requirements for narrative notes
- Signatures/sign-offs on DCFs
- Time-Event Sheets
- Documentation of Informed Consent Process
- Documentation/substantiation of enrollment criteria
- “Study-specific” SOPs

Consider using the Research Service or IRB guidelines, policies or SOPs as your own SOPs (write memos-to-file stating that ‘ “\_\_\_” is your SOP for \_\_\_’) or use them as templates to adapt to your setting. This can save important time that can be used for implementing good research practices.

**Attachments:**

“Informed Consent Process Worksheet”	Attachment 1
“CRF-DCF Template”	Attachment 2
“Guidelines for Time-Event Sheets”	Attachment 3
Example of a Time-Event Sheet	Attachment 4
“Guidelines for Narrative Notes”	Attachment 5

**See Also:**

Research Service Guideline:	“Guidelines for Study and Regulatory Binders”
Research Service SOP:	“Auditing Regulatory Documents Files”
Research Service SOP:	“Auditing Source Documents Charts”
Research Service SOP:	“Establishing Patients in CPRS”
Research Service SOP:	“Writing Standard Operating Procedures”
IRB Self-Assessment Tool:	“Investigator Records Checklist”
IRB Self-Assessment Tool:	“Subject Records Checklist”
IRB Self-Assessment Tool:	“IRB Records Checklist”

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**Attachment 1:****INFORMED CONSENT PROCESS WORKSHEET**

Study: \_\_\_\_\_

Subject ID: \_\_\_\_\_ Date: \_\_\_\_\_

Staff initials	Element explained /discussed	Subject / rep is able to restate	
	Background & Purpose of study	Y	N
	Procedures	Y	N
	Risks /Discomforts	Y	N
	Benefits	Y	N
	Alternatives	Y	N
	Costs / Compensation	Y	N
	Confidentiality	Y	N
	Right to Withdraw	Y	N
	Whom subject my contact for questions/emergencies	Y	N
	Storage of samples/genetic materials	Y	N
Person explaining the informed consent form:			
Length of time spent with subject/representative:			
Time CF signed:			
Representative's relationship to the subject:			
Copy of signed CF given to subject/rep?		Y	N
Comments:			

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**Attachment 2: CRF-DCF Template**

[TITLE OF DATA COLLECTION FORM]

[PERIOD / VISIT / COHORT]

[DATE\_\_\_\_\_]

[SUBJECT # / INITIALS]

CUT AWAY HEADER, FOOTER AND  
OTHER PORTIONS OF SPONSOR'S CRF.

PHYSICALLY PASTE THE DESIRED DATA COLLECTION  
PORTION(S) OF CRF HERE.

THIS PAGE THEN BECOMES THE MASTER DOCUMENT  
USED FOR PHOTOCOPYING ACTUAL DCF'S.

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**Attachment 3:****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 "t<sub>0</sub>" ("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)

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**Attachment 4: Example of Time-Event Sheets**

**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:	<b>DAY 0: BASELINE</b>		
	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.
	<b>Sitting BP</b>	HR	RR
			T
	Notify J.Haywood of subject enrollment		
	Obtain WEEK 1 bottles from J.Haywood		
	#caps am bottle	#caps pm bottle	
	Study Medication Record		CRF p.75
	Instruct 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		
	bring med bottle to next appointment		
	<b>remember the time s/he took 1st dose</b>		

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- 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
-----------------	-----------------

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

SUBJECTS:

INITIALS:

01

02

SCHED. TIME	ACTUAL TIME	EVENTS	COMMENTS
7am		<b>Admission</b>	
		Sign-in on Master List	Time of Admit: _____
		Check-in ("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
		Any new script/OTC drugs since screening?	Y
		(Med,Dose,Freq,Rte,Start,Stop,Continuing,Indication)	
		All screening tests within 14 days of this admission?	Y
		Pt continues to meet I/E criteria or has waiver?	Y
		<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>	
T=-1 hr		<b>Pre-dose</b>	
approx 0800		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	
		<b>Randomization:</b>	
		<b>Sbjt 01</b>	<b>Sbjt 02</b>

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	DOB: <input type="text"/>	M / F	DOB: <input type="text"/>	
	Meets I/E's:	Must meet criteria:	Meets I/E's:	
	- Hx previous L-dopa Rx? (N or 2wk washout)		- Hx previous L-dopa Rx? (N or 2wk washout)	
	- Hx other dopaminergic Rx? (N or 2wk washout)		- Hx other dopaminergic Rx? (N or 2wk washout)	
	- Epworth Sleep Score $\geq 9$ ? (N)		- Epworth Sleep Score $\geq 9$ ? (N)	
	- Meets other I / E criteria? (Y)		- Meets other I / E criteria? (Y)	
	- Pt has signed ICF? (Y)		- Pt has signed ICF? (Y)	
	- All screening labs reviewed & meet criteria? (Y)		- All screening labs reviewed & meet criteria? (Y)	
	Call: <input type="text"/>	1-877-XXX-XXXX	Call: <input type="text"/>	
	Enter User ID: <input type="text"/>		Enter User ID: <input type="text"/>	
	Enter Password: <input type="text"/>		Enter Password: <input type="text"/>	
	Choose Menu Option 1 <input type="text"/>		Choose Menu Option 1 <input type="text"/>	
	Enter Patient info above		Enter Patient info above	
	Randomization # <input type="text"/>		Randomization # <input type="text"/>	
	Med Kit # <input type="text"/>		Med Kit # <input type="text"/>	
	Reenter Med Kit# to confirm randomization		Reenter Med Kit# to confirm randomization	
	If error in entering DOB/gender, enter "*"; see manual		If error in entering DOB/gender, enter "*"; see manual	
	Notify J.Haywood of randomization			
	Obtain study drug from pharmacy			

T=-30 mins

apprx 0830

Sbjt 01

Sbjt 02

**Day 1 continued on next page**

Breakfast 15 mins apart

Scheduled:

Scheduled:

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**Attachment 5: Guidelines for Narrative Notes\***

*\*(These Guidelines were written in 1998 for a BVAMC Inpatient Unit. They are somewhat dated but may still be helpful as ideas for study-specific SOPs.)*

There are three places where narrative notes are recorded: VA (CPRS) progress note, Unit Comments Sheet, AE Comments Sheet.

1. VA Progress Notes: admission note, progress notes at least q shift and prn, note discharge. Focus on physical condition of subject as opposed to study events. Should include physical assessment, description of and follow-up of adverse events (AE's), short mention of study events and how well the subject tolerated the study events.

This is the main place where there is a detailed description of the subject's condition.

2. Unit Comments Sheet: study events, problems, protocol deviations, record of verbal communications from Principle Investigator (P.I.), P.I.'s staff, VA staff, CRU staff, etc., issues with subject's conduct/visitors' conduct, etc.

This is an internal document within the CRU that is mainly focused on the conduct of the study protocol (as opposed to the subject's clinical status which is mainly addressed in the VA Progress Note). Its main purpose is to keep staff informed of study events (especially unexpected ones) and to serve as a record of why things were done the way they were especially if there were protocol deviations.

Remember that questions frequently arise weeks or months after a subject has completed a study, long after staff can possibly recall details of an event. In this case, Comments Sheets are *incredibly* valuable and their presence or absence may often be the deciding factor in whether or not to believe or retrieve certain data.

Comments Sheets must be charted at least q shift. The note may be as simple as:

“Subject now in Washout Day 1. No c/o. No problems in study events. See Progress Notes for details”

**OR**

“Subject c/o headache. See AE Comment Sheet”.

Don't double-chart. If you've already described an event or condition in the AE Comment Sheet or in the VA Progress Note, just write “see \_\_\_\_ for further details” in the Unit Comments Sheet instead of rewriting the whole thing. (There's nothing terribly wrong with rewriting notes in different places except that it's extra time and unnecessary effort.) You must at least make reference as to where details are charted.

3. AE Comment Sheet: the second page of the “Adverse Event/Intercurrent Illness Form“. Focuses on the specifics of an adverse event (AE) as opposed to the subject's general physical condition (which is charted in the VA Progress Notes) or study events (which are charted in the Unit Comments Sheet). Must be charted q shift and prn, *even if no AE has occurred*.

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If no AE has occurred on your shift, you must at least write:

“No AE’s or c/o” on the AE Comment Sheet with date, time and signature.

If an AE or illness occurs-even minor ones-it must be described on the AE Comment Sheet (specific data must be entered on the AE form. See “Adverse Event Form“ section of manual for details). Describe the S/S, the context, onset, resolution (if it resolves on your shift), patient comments, your actions, therapeutic measures, who was notified (if necessary), other pertinent info. If the AE has not resolved, you must state that it continues as of the end of your shift.

If an AE continues from a previous shift, you must continue to chart on its follow-up. It might be as simple as: “headache continues” but needs to be detailed if there are changes in intensity, character, etc. or if there are any therapeutic interventions.

If an AE resolves all details MUST be recorded, including time and date of resolution.