

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)