**Source Document Completion Guidelines**

The following information will assist you in the creation of source documents to be used at the CRU.

1. **Header**
	1. Include CTSI Protocol # and a short protocol title.
	2. List the date the source document was originally created. Also include revised dates when revisions are made.
	3. Include the following subject information fields:
		1. Subject name
		2. Subject number
2. **Study Staff Contact Information**
	1. Include contact information (phone #, pager #, cell #) for the PI, Study Coordinator and any other MDs that may be working on the protocol or backing up the PI (e.g. Sub Investigators, Medical Safety Contact, etc).
3. **Visit Name**
	1. Create source documents for each individual study visit. Complete visit information at top of page. Include date of visit in the following format: DD/MMM/YYYY.
4. **Protocol Directed Time Point Column**
	1. Please indicate when procedure should be performed per protocol (pre-dose, 0-hour for dosing, and post dose). If pre-dose procedures need to be performed within a certain time of the dose, please indicate in this column (15 minutes pre dose, 5 minutes pre dose, etc). If there are no protocol directed time points, this box/column should be shaded.
5. **Actual Time and Staff Initials Column**
	1. CRU staff will document the actual time the procedure was performed, if required. If time is not required, shade out column. CRU staff will also initial the procedure they completed.
6. **Instructions/Procedures Column**
	1. Include all procedures that will occur in the CRU.
	2. Include fasting information, any resting restrictions for ECG’s, vital signs, etc.
	3. If weight needs to be obtained, please indicate whether pounds or kilograms should be documented.
	4. If height needs to be obtained, please indicate whether inches or centimeters should be documented.
	5. For temperature, indicate whether Fahrenheit or Celsius should be documented.
	6. Include any special instructions while obtaining vital signs (take pulse for 30 seconds, use manual blood pressure cuff, etc).
	7. When listing blood tubes, spell out the types of tubes that will be used (red top tube, purple top tube, gold top tube, etc). Please no abbreviations. For any tiger top tubes, please spell out the colors (red/black, green/gray, etc…).
	8. List all blood tubes to be drawn in the following order unless protocol specifies otherwise:
		1. Yellow top tube
		2. Light blue top tube
		3. Red, red/black tiger, or gold top tube
		4. Green, light green or green/gray tiger top tube
		5. Lavender or purple top tube
		6. Pink, white, or royal blue top tube
		7. Gray top tube
		8. Dark blue top tube
	9. For study drug administration, the following minimum information must be included:
		1. Study drug name
		2. Study drug dose
		3. Route of administration (PO, SQ, IM, IV, etc)

Also include calculations or any special instructions for medication administration.

1. **Send completed source document to CRU for review prior to first subject visit.**
	1. If you have difficulties with formatting the form, send the form as is and the CRU will assist.
	2. Once reviewed the documents will be sent back to Study Coordinator. Forms can then be used for subject visits.
2. **Revising source documents**
	1. It is up to the Study Coordinator to notify the CRU manager of any IRB approved protocol amendments and make revisions to the source document(s). In the event a revision is required, make revision(s) and email to the CRU for review.
	2. **REMINDER –** *Study Coordinators will also need to update lab-processing instructions in the event of a protocol amendment.*