Subject ID: _____
Study: _____
Date: _____

Study Visit Procedures

Utilize this worksheet for every patient at every visit. It is expected that the person completing the action will initial and date the action only when completed. *Despite delegation of these actions to other CRCs or assistant, lead CRC retains the final responsibility for ensuring the below actions are completed.* Once completed sign and upload this sheet into applicable CRIO visit. By signing below you are certifying that all actions have been completed.

Pre-Visit

Initial/Date	Action	Comments
	Gather all questionnaires necessary for visit (if applicable). If completed on tablet ensure it has been updated and charged	
	Gather study specific lab kits, ECG machine, urine cup, etc.	

During Visit

Initial/Date	Action	Comments
	Nothing study specific can happen without a signed ICF!! Have patient sign ICF (initial or reconsent) following SOP's	
	Schedule next visit or place reminder in Google/CRIO calendar	
	Activate payment card with address and release payment	

Post-visit: All post-visit activities must be completed within 72 hours of clinic visit (exception allowed for lab results).

Initial/Date	Action	Comments
	Ensure all physician signatures are obtained • ECGs • Questionnaires (if applicable) • Lab Results • AEs (if applicable)	
	Process Labs (if applicable) • Schedule Fedex or UPS pick-up	
	Complete Drug Accountability Logs • Subject Level **AND** Master Level	
	Progress Note- Master Progress Note Template is in Dropbox • Note significant finding or issues with study procedure • Document any AE discussion with PI • Document any visit specific conversations and issues • Include any procedure discrepancy or unusual circumstances	
	If study requires imaging/outside procedures: • Call to schedule patient and then fax order.	
	Upload all visit patient specific documents to CRIO and tag	
	Enter visit data into eCRF System	
	Update subject enrollment log (if applicable)	
	Update Patient Tracking Binder	

Lead CRC Signature:_____

Subject ID: _____
Study: _____
Date: _____

For Screenfails

Initials/Date	Action	Comments
	Update IRT/IVRS system	
	Contact patient to let them know	
	Notify PI	
	Update EDC	
	Update CRIO- close out all pending or open pages and progress note the reason for screenfail	
	Arrange for retrieval of all study supplies (eDiary, IP return if dispensed, etc.)	
	Complete IP Retrieval and Reconciliation	
	Update Subject Enrollment Log	

Once completed upload this sheet into applicable CRIO visit.

Lead CRC Signature:_____

By signing you are certifying that all above actions have been completed

Subject ID: _____
Study: _____
Date: _____

Uploading Visit Documents to CRIO

- Scan all visit related documents into CRIO by faxing to the proper CRIO account (IF vs Chubbuck)
- Under "Files" assign these documents to the proper study and person
    - Tag to Subject for Study related documents
    - Tag to Patient for general site-specific forms
    - Save first if there is PHI present on the form, otherwise click e-sign
- REDACT any protected health information (PHI) FIRST. This includes names, initials, signatures, medical records numbers, patient addresses, etc.
- eSign to finalize the document

Charge Sheet

- Create a charge sheet (found in templates) for any extra procedures performed outside the typical visit requirements. This includes:
    - Monitoring Visits
    - Phone calls with PI and Sponsor/CRO
    - Unscheduled Visits
    - Repeat lab draws
    - Mileage Reimbursement (if applicable)

Pending Visits

- Make sure that no prior visits are appearing on the CRIO homepage as Pending. If so, then these visits need to be completed.
- For Screen Fails, click Save and Continue for all procedures not conducted (due to screen fail) then click Mark Not Done. In the comment type SCREEN FAIL. THEN complete the visit, otherwise these will show as "incomplete" in the CRIO reporting.

HIPAA Authorization

- At each Screening visit we do ask subject to sign a HIPAA Authorization form for three reasons.
    - To obtain medical records IF the protocol requires historical records
    - To ensure we have a release in the event the subject has an AE or SAE during the study in which we need records for.
    - To obtain permission to send research records to the subjects PCP
- Of note, HIPAA regulation DO allow for records to be exchanged for "continuity of care" and this does cover the release of records from a hospital to clinical research in the event of an SAE or AE as well as for our clinical research clinic to release records in the event follow up by the PCP is advised. That said, obtaining the written release from the patient serves to also provide documentation of who and when records were requested or released and is advisable to obtain even in circumstances of "continuity of care"

Subject ID: _____
Study: _____
Date: _____

PCP Notification Letter

- In the event the ICF indicated that the PCP should be notified of a subjects involvement in a research study and the subject initials that they do want their PCP informed a PCP Notification Letter should be sent and this letter should be filed in the subject's chart.
- This letter is only sent if the ICF indicates this and/or the subject requests this letter be sent.