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| **GENERAL INSTRUCTIONS** – delete this box from the completed form. Red text represents instructions to you – to be deleted from the final version.**NOTE: This form is designed to be a starting point on creating a Visit Checklist. Update it as necessary for your specific study.** * This template tool includes procedure and visit information as an example only. Study teams should delete all non-relevant information.
* Study teams should review this carefully and make all adjustments as necessary for their study requirements. The format and inclusion of rows or columns is only meant to provide study teams with examples of how to lay a table out.
* It is often helpful to build a complete Schedule of Events and use that to inform the information that is needed for each Visit Checklist.
* If using Visit Checklists in a study, all visits should have a checklist. This is regardless of how many or how few procedures any specific visit may have.
* A visit is not meant to imply that this is only for study timepoints that have an actual visit with a participant. There may be timepoints where the only procedure is data abstraction from the medical record. These types of visits should also have a checklist to ensure all steps are completed and to document who completed them.
* Visit Checklists should include all things associated with one specific visit including procedures completing directly with a participant as well as all preparatory steps as well as any items that take place after the visit is over.
* The name of the visit inserted into the Header should be consistent with what the visit is called in all other study documents including but not limited to INSPIR application, protocol, consent, and Schedule of Events.
* A Visit Checklist is not meant to operate as source documentation or data completion, merely to confirm that all tasks and procedures have been completed.
* Visit Checklists must be updated if a protocol amendment changes the timing of an event or anything else on the document.
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| **Assessment or Procedure** | **Completed** | **Staff Initials – Completed Procedure** | **Comments (N/A if no comments)** | **Associated CRF or Data Form** |
| --- | --- | --- | --- | --- |
| Eligibility Criteria Assessed and Confirmed | [ ]  Yes [ ]  No |  |  |  |
| Informed Consent | [ ]  Yes [ ]  No |  |  |  |
| Vital Signs | ☐ Yes ☐ No |  |  |  |
| Symptom Checklist*completed by participant* | ☐ Yes ☐ No |  |  | Symptom Form - Participant |
| Symptom Interview and Assessment*completed by medical clinician* | ☐ Yes ☐ No |  |  | Symptom Form - Clinician |
| Biospecimen Sample Collection |  |  |  |  |
| Order placed in medical record for research-specific for blood draw | [ ]  Yes [ ]  No |  |  |  |
| Order signed by study clinician or other appropriate individual | [ ]  Yes [ ]  No |  |  |  |
| Study specific kit with tubes provided to phlebotomy lab | [ ]  Yes [ ]  No |  |  |  |
| Sample Collected per protocol |  |  |  |  |
| Sample picked up from phlebotomy lab, processed per protocol, and shipped to sponsor |  |  |  |  |
| Sample picked up from phlebotomy lab, processed per protocol, and stored in study freezer |  |  |  |  |
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| Data Entry for Visit |  |  |  |  |
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| ***IS RECONSENT NEEDED AT THIS VISIT?*** |
| [ ] YesIRB-Stamped Approval Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Reconsent completed: [ ]  Yes [ ]  NoIf completed, copy of signed consent provided to participant: [ ]  Yes [ ]  No | [ ]  NoNew Consent but Reconsent not required per IRB | [ ]  NoNo new consent since last visit |

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| **Research Staff Completing Form** | Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |