**Using the Protocol to Create Visit Checklists**

**What is a visit checklist?**

* A list of visit-specific tasks, activities, and procedures to be conducted before, during, and after the visit. The visit checklist is not a case-report form (CRF) or source document. It is a tool to be used by coordinators/study staff to ensure required procedures have been completed and visits are conducted in an orderly and logical manner and per the protocol.

**Why create visit checklists?**

* Can be used as a tool when planning how to operationalize a protocol.
* Creating them help you to focus on small but important details that sometimes get lost in lengthy protocols.
* They serve as quick-view reminders of what needs to be completed at each visit.
* Useful for back-up coordinators

**Should CRSP coordinators create visit checklists for their protocols?**

* Yes.

**When should visit checklists be created?**

* Before the study opens to screening/enrollment.

**What should a visit checklist look like?**

* Does not have to be fancy or complicated. A simple word document will do.
* Should include reminders of what needs to be completed before, during, and after a visit. Can also include post-visit follow-up activities.
* Tasks, activities, procedures should be listed in order of occurrence.
* The protocol SoA (schedule of activities) should not take the place of a visit checklist. The SoA and protocol should be used to create visit checklists.
* The same checklist can be used for visits with the same activities.

**Sample Visit Checklist**

**Protocol:** DX55 **Visit (circle):** 5 7 9 11 **Subject ID:** PEC999

***<<What can I do ahead of time to prepare for this visit? >>***

**Pre-visit:**

\_\_\_ Reminder phone call to participant (\*Instruct participant to return IP bottles & diary and not to take IP dose at home on study visit day)

\_\_\_ Schedule ECG

\_\_\_ Make sure tablet charged

\_\_\_ Complete COA registration forms

\_\_\_ Order dry ice

***<<What are the required procedures? In what order? Are there any specific details I need pay close attention to? >>***

**During visit:**

\_\_\_ Subject to complete PROs on tablet

\_\_\_ Con meds / AE

\_\_\_ Vital signs & Weight (\*supine BP required)

\_\_\_ Labs and UPT

\_\_\_ ECG

\_\_\_ Clinician Assessments (\*each assessment requires rater qualification)

\_\_\_ PE

\_\_\_ Drug Accountability / Collect empty bottles and unused IP

\_\_\_ Dispense IP and provide dosing instructions

\_\_\_ Administer dose in clinic

\_\_\_ Schedule next visit and add to shared calendar

\_\_\_ Participant payment in Greenphire

***<<What do I need to do immediately after the visit? What do I need to do in the coming days after the visit? Did anything occur at the visit that I need to follow-up on? >>***

**Post-visit:**

\_\_\_ Lab processing/shipping

\_\_\_ Oncore entry

\_\_\_ Enter Data in EDC

\_\_\_ Obtain lab results and submit to PI for signature