**Site Initiation Visit (SIV)**

*Scheduling an SIV:*

* Make sure you ask the monitor:
  + How long do you anticipate the visit lasting?
  + How long do you need to meet with the PI?
  + Do you need to see any of our facilities?
  + Do you need to see the pharmacy/meet with the pharmacist?
* Check the research calendar for availability
* Notify Meredith and Dorothy that the monitor wants to conduct an SIV
* Notify Dorothy when date and time is finalized
* Arrange all other appointments for visit (PI, pharmacy, lab, etc)

*Questions to ask at the SIV:*

***Site:***

What is our site number?

How do you obtain patient screening/randomization numbers?

Can a nurse practitioner conduct the physical exams and sign off on AEs?

What problems have other sites had with enrollment?

***Supplies:***

Do we have all of our supplies? (For lab kits: are they providing urine cups, pregnancy test kits? Are they providing supplies for drug administration?)

Has everyone completed all the necessary training?

Will the sponsor provide source documents?

Will the sponsor provide mini protocols?

How are lab kits re-supplied?

***Drug:***

How is drug ordered for the patient? (IVRS, web-based, site assigned?)

How is drug re-supplied? Is it automatically resupplied or do we need to order the drug?

How are drug dose reductions handled (per protocol, package insert, physician discretion?)

\*\*Make sure you know when drug is dispensed and how it is administered

***Protocol:***

Know the screening process steps

What is the visit window for each visit?

Are there prohibited medications?

***Enrollment:***

What is our enrollment goal?

Have other sites opened for enrollment?

What is the current status of enrollment for the entire study?

Is there an enrollment/screening log that needs to be completed? How often does it need to be submitted?