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Site Initiation/Study Start-Up Visit Tip Sheet

A Site Initiation Visit (SIV) or Study Start-Up is an organized meeting to discuss the new protocol before the research project is ready to screen and enroll potential patients. It also serves as training for the protocol of interest. All members on the study (*everyone listed on the Delegation Log and IRB approved*) should attend the meeting. The study team members should have reviewed the protocol prior to this meeting. The study start up meeting should lay the ground work for the study and allow all team members to ask any questions they may have prior to accrual.

Objectives:

- Educate the study team on the protocol and Good Clinical Practices
- Ensure the study team understands their delegated roles and sign the Delegation Log
- Discuss any issues and concerns about the protocol

Tips:

- Use the Site Initiation Visit Checklist to confirm the SIV presents all items necessary for training.
- Book the SIV far in advance and send reminders to the study team when getting closer to the date.
- Prior to the meeting, provide an agenda for all study team members, in case some members need to leave they can plan to be present during the sections pertinent to them.
- Plan a mock study visit within the SIV to walk the team through each part of the study to ensure proper study conduct including reviewing the informed consent in detail to ensure those who execute the informed consent process are able to answer participant questions.
- Give plenty of time during the SIV for study personnel questions or concerns to be resolved. Something might be clear at a Pharmacy standpoint, but unclear at a Nursing standpoint.
- Have everyone that attended, sign the Delegation Log under their delegated roles. Attendees must also sign in on a sign in sheet to prove protocol training was provided to the attendee. Ensure the PI has signed off on the delegated roles as well.
- Confirm everyone has access to the correct databases at the SIV. Also assess if anyone else needs access to each database at the SIV.
- Work with the other departments, if applicable, to make a process during the meeting (i.e. if working with Investigational Pharmacy, talk about how the drug will be delivered or how to do an urgent order in EMR).
- Document the SIV in a Training Log and store the document in the training section of the Regulatory Binder.

References:

SOP SS-303 – Site Initiation Visit (PDF)
Site Initiation Frequently Asked Questions (SIV FAQs) (Word .doc)
Site Initiation Visit (SIV) Guide and Checklist (Word .doc)
Site Initiation Visit Agenda (PDF)
Site Initiation Visit Slide Presentation Template (PPTX)