

Monitoring: Before the Visit Tip Sheet



Monitor: "I'm going to monitor your site. Here is the monitoring confirmation report."

You: "Now what do I do?"

1

Confirm logistics:

- Make sure a room is reserved
- Make sure all regulatory and subject materials are readily available
- PI availability is confirmed

2

Review Essential Documents, which can include:

- Protocol and ICFs (All versions)
- IRB approvals, submission and correspondences
- DOA log (signed and current with start/end dates)
- Lab Manuals and reference ranges

3

Review Source Documentation, which can include:

- Medical records: All relevant health information for a participant should be properly recorded, updated and finalized
- Notes signed and dated by appropriate staff

4

Review Participant Files, which can include:

- Eligibility confirmed and documented
- Signed ICF prior to study procedures with all fields completed appropriately.
- IP accountability up to date
- AEs/SAEs documented and reported per protocol/IRB of Record

Addition information on what documents should be filed prior to the monitoring visit is located in [Essential Records Guidance](#).

Additional questions? Contact us at indide@vcu.edu. We are here to help!