

Monitoring: Before the Visit Tip Sheet



Monitor: "I'm here to monitor your site."

You: "Now what do I do?"

1

Beginning of review:

- Guide monitor to reserved location
- Make sure all regulatory and subject materials are readily available
- Confirm with monitor how often study team should check in

2

During review, check in with monitor to:

- Provide any missing items noted
- Review and fix findings that can be addressed in real time
- Answer questions and provide clarifications on items being reviewed

3

End of Review:

- Be prepared to answer additional questions or clarifications
- Monitor to provide study staff and PI/Sponsor-Investigator with a summary of findings and any time-sensitive reportable information

4

Key Take-Aways:

- Discuss expectations for the visit and study team availability at the beginning
- Monitor will provide a summary of the visit and review key responsibilities of site staff
- Study team can resolve findings during the visit
- Visits can help in re-education and re-training, as applicable

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