

Appendix A: Meetings with Principal Investigator

This Appendix provides a general format of visits between the Principal Investigator (PI) and the Research Compliance Monitor (RCM). Please note, that depending on the complexity of the project, questions that arise, and other factors, additional meetings may be required to complete the monitoring process.

- First Meeting
 - a. The PI and RCM meet for approximately 30 minutes.
 - b. The Post-Approval Monitoring (PAM) program is discussed, allowing the PI an opportunity to learn more about the process and to ask any questions they may have.
 - c. PI is given an outline of expectations and timelines related to the process so that they feel comfortable and prepared.
 - d. The PI is given an *Investigator Self-Assessment Form* either during the meeting or immediately following via mail.
 - e. The PI completes the Investigator Self-Assessment Form and returns it to the RCM in approximately two weeks' time.
- Second Meeting
 - a. The PI and compliance monitor meet for approximately one hour. This meeting occurs typically within four weeks of the initial meeting and within two weeks of the Investigator Self-Assessment Form being completed.
 - b. During this meeting, the Research Compliance Monitor will interview the investigator to gain a better understanding of the research protocol and to identify areas that may need additional clarity, areas of concern, questions, etc.
 - c. Depending on the complexity the research project, the number of subjects enrolled, and other factors, investigators are informed that there may need to be a third meeting to complete the PAM process.
 - d. Investigators are also informed that a participant records review process may be done on a random basis and if they are randomly selected, they will be notified via email.
- Third Meeting
 - a. If necessary, or if randomly selected, the Research Compliance Monitor will meet with the Investigator, either in person or via virtual conferencing, to conduct a records review.
 - b. During this process, it is an opportunity for both parties to examine how records have been stored and maintained for the protocol and to identify areas for improvement.