



Clinical Research Monitoring Standard Operating Procedures

This procedure is intended to inform sponsor-investigators and their study teams on the process of clinical research monitoring carried out by an OVPRI monitor. This guidance document provides information on what to expect before, during and after a monitoring visit. For questions about this document or about monitoring obligations and processes, please see contact information provided in this document.

Types of studies monitored:

OVPRI helps institutional sponsor-investigators fulfill their obligations as stated under 21 CFR § 312.56; 21 CFR § 812.46 to monitor studies under their IND/IDEs. OVPRI monitors studies that fall under many indications and are categorized under: 1) drugs, 2) biologics, and 3) devices.

Monitoring Plans:

An OVPRI monitor creates monitoring plans specific to the sponsor-investigator's protocol at study initiation emphasizing a risk-based approach. The following items are updated to better fit the protocol being monitored:

- Study contact information
- Frequency of monitoring visits (usually between 8-12 weeks)
- Items that may be reviewed at the interim monitoring visit(s)
- Documenting and reporting protocol deviations
- Documenting and reporting SAEs

Monitoring plans are drafted at the beginning of the OVPRI team meeting with the study team, where the sponsor-investigator will review and discuss the plan. If the plan has been agreed upon, the sponsor-investigator will sign and the study team will file the monitoring plan in the investigator site file (ISF) (paper or electronic). OVPRI will retain a copy of the monitoring plan. Any updates to the monitoring plans will be done as needed.

Monitoring frequency may be adjusted throughout the duration of the study. Examples that may prompt change to monitoring frequency are, but not limited to, change in accrual rate or completing accrual.

Scheduling a monitoring visit:

Once a sponsor-investigator has established a clinical trial and begins to enroll patients, an OVPRI monitor will reach out to the sponsor-investigator and/or study team to schedule a monitoring visit. A monitoring visit may take a full day or may take several days depending on availability of the site, OVPRI monitor and volume of study documentation being reviewed. An email is sent to the study team with available dates to choose from.

Once a visit is scheduled, the OVPRI monitor will review current IRB approved study materials in preparation for the monitoring visit. The study team can expect a confirmation letter 1 week before the scheduled visit which will include the following:

- The date and time of the scheduled visit



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- Items expected to be available for review, including, but not limited to:
 - Regulatory binders
 - IP logs
 - Participant study binders
- How to contact the OVPRI monitor

It is important for the study team to provide access to all source documents in order to facilitate a thorough monitoring visit.

During a monitoring visit:

During a monitoring visit, the OVPRI monitor will review all available items related to the study. The OVPRI monitor will take notes based on findings and check in with available study team members to ask questions and receive clarifications.

At times, the OVPRI monitor may need to touch base with the sponsor-investigator to discuss monitoring findings and review responsibilities.

At the end of the monitoring visit, the OVPRI monitor will review any items that may need to be reported and/or overall findings with the study team. In the event that the OVPRI monitor finds something that meets reporting criteria to the IRB and/or the FDA, the OVPRI monitor will review with the study team why the event meets reporting criteria and provide them with instructions on how to report to the applicable parties. At the subsequent monitoring visit, the OVPRI monitor will verify that the study team reported the event to the applicable parties. The OVPRI monitor will help the study team resolve findings and research processes, by providing guidance and best practice.

After a monitoring visit:

The sponsor-investigator and study team can expect a drafted monitoring report of the visit approximately **14 days** from last study visit. This drafted report will contain recommendations for the study team and allow the study team to provide the OVPRI monitor feedback. Feedback may include:

- Clarifications related to study assessments, endpoints, etc.
- Resolved items
- Items in process of being resolved
- Changes in the research process due to findings and recommendations

The OVPRI monitor will also be available for a video conference (via zoom) to discuss the report in more detail and help with providing feedback on research processes.

The final signed report will be sent to the sponsor-investigator and study team for them to file in the ISF (paper or electronic) within **21 days** of the last study visit.

Additionally, the OVPRI monitor will provide available dates for the next monitoring visit (based on monitoring frequency) and schedule with the study team.



Contact

Please contact for questions regarding this document or about the monitoring process:

OVPRI Regulatory Affairs

indide@vcu.edu

Document History

Version	Version Date	Brief Description of Change
1.0	06/06/2024	Initial