



Clinical Research Monitoring Standard Operating Procedures

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1. Purpose

This procedure is intended to inform 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.

2. Types of studies monitored

OVPRI's regulatory affairs monitoring program performs 3 types of monitoring:

- Routine/continuous monitoring: Routine monitoring is performed on all sponsor-investigator held IND/IDE clinical trials at VCU on an ongoing basis through the lifespan of the study
- Random monitoring: FDA regulated studies are randomly selected monthly to perform one-off monitoring visits
- For-cause monitoring: One-off monitoring visits that are triggered by an entity (ex: IRB of record, research compliance, School of Medicine's clinical research office or Massey's clinical trials office) due to a concern.

3. Routine Monitoring

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.

3.1. 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.



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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.

3.2. 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
- 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.

3.3. 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.

3.4. 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



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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.

4. Random Monitoring

Random monitoring at VCU is performed with the goal of maintaining a high quality of research at VCU and to provide education to study teams to strengthen their knowledge and experience.

4.1. Selecting studies

Studies are randomly selected monthly to be reviewed by an OVPRI monitor through a generated report of open studies. The studies selected will be reviewed prior to contacting the study teams to ensure that an OVPRI monitor hasn't recently reviewed a study of the same PI or department in order to avoid unnecessary and unwarranted strain on the study team.

4.2. Scheduling a monitoring visit

An OVPRI monitor will reach out to the study team on the selected study to schedule a monitoring visit within the next few weeks. A monitoring visit may take a full day or may take several days depending on availability of the study team, OVPRI monitor and volume of study documentation being reviewed. OVPRI follows [FDA's risk-based approach to monitoring](#) when determining the type and number of documents to be reviewed. Random monitoring will review a subset of the study documents rather than 100% of all study documents. This visit can be either an in person visit or be done fully remote if the study team utilizes Veeva SiteVault for the study in its entirety. 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. Examples such as, 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.

4.3. 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 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 and the investigator. 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.

4.4. After a monitoring visit

The principal investigator and study team can expect a drafted monitoring report of the visit approximately **7 days** from the 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 OVPRI monitor will follow up with the study team to verify that anything meeting reporting criteria to the IRB of record was reported by the study team.

The final signed report will be sent to the investigator and study team for them to file in the ISF (paper or electronic) within **14 days** of the last study visit.

5. For-cause Monitoring

For-cause monitoring is performed at VCU when there is a concern about potential ethics or compliance violations within a study. It is triggered by perceived or confirmed issues. A for-



cause monitoring visit may also be performed to verify the effectiveness of an implemented corrective and preventive action plan.

5.1. Requesting a for-cause monitoring visit

Entities such as, but not limited to, the PI, IRB of record, the department or school/center's clinical trial office can request a for-cause monitoring visit to be performed if they perceive or know of a confirmed issue on a study.

The requesting entity may refer the study for a for-cause monitoring visit by reaching out to regaffairs@vcu.edu with a formal request for a monitoring visit, what the perceived/confirmed issue is, the scope of what they would like reviewed and timeline for how soon they would like the visit to occur. If the referring entity is unsure of what the scope of the visit should be, they may ask for assistance in determining scope. Scope of for-cause monitoring visits should be limited to study documentation that pertains to the issue.

5.2. Scheduling a monitoring visit

An OVPRI monitor will reach out to the study team on the selected study to schedule a monitoring visit within the desired timeline. Every effort will be made to accommodate the timeline requested. A monitoring visit may take a full day or may take several days depending on availability of the study team, OVPRI monitor and scope of visit. This visit can be either an in person visit or be done fully remote if the study team utilizes Veeva SiteVault for the study in its entirety. 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
- Items expected to be available for review. Examples such as, but not limited to:
 - Delegation of authority log
 - Consent forms
 - Documentation pertaining to participant eligibility
- How to contact the OVPRI monitor

5.3. 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 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 and the investigator. In the event that the OVPRI monitor finds something that meets reporting criteria to the IRB and/or the FDA,



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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.

5.4. After a monitoring visit

The principal investigator and study team can expect a drafted monitoring report of the visit approximately **5 days** from the 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 OVPRI monitor will follow up with the study team to verify that anything meeting reporting criteria to the IRB of record was reported by the study team.

The final signed report will be sent to the investigator and study team for them to file in the ISF (paper or electronic) within **14 days** of the last study visit.

A copy of the report and a recommendation on whether the issue was valid, whether the issue expanded beyond what was identified/perceived and if any further action is needed will go back to the referring entity.

6. Study Initiation Visit

Conducting a successful study starts with setting it up correctly to ensure that the study team is equipped to follow good clinical practice (GCP) and good documentation practices. Good documentation practices aid in demonstrating that the study was conducting following GCP. Study initiation visits help the study team set up their investigator site file (ISF) correctly to start the study on the right path. These are educational visits that help the study team how to learn how to set up their ISF and what documentation they need to maintain during the study. This can be helpful for new principal investigators, new study coordinators or anyone in need of a refresher.

6.1. Requesting a study initiation visit

Entities such as, but not limited to, the PI, IRB of record, the department or school/center's clinical trial office can request a study initiation visit to be performed if they would like to learn how to better set up their study for success.

The requesting entity may refer the study for a study initiation visit by reaching out to regaffairs@vcu.edu with a formal request for a monitoring visit.



6.2. Scheduling a site initiation visit

An OVPRI monitor will reach out to the study team on the selected study to schedule a monitoring visit. A monitoring visit may take a half day, full day or may take several days depending on availability of the study team, OVPRI monitor and scope of visit. This visit can be either an in person visit or be done fully remote if the study team utilizes Veeva SiteVault for the study in its entirety. 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
- Items expected to be available for review. Examples such as, but not limited to:
 - Delegation of authority log
 - Consent forms
- How to contact the OVPRI monitor

6.3. During a site initiation visit

During a monitoring visit, the OVPRI monitor will educate the study team on how to set up the study and what documentation will be required. The OVPRI monitor will take notes based on observations and check in with available study team members to ask questions and receive clarifications.

At the end of the monitoring visit, the OVPRI monitor will review any items that may need to be completed with the study team and the investigator.

6.4. After a site initiation visit

The principal investigator and study team can expect a drafted monitoring report of the visit approximately **5 days** from the 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 investigator and study team for them to file in the ISF (paper or electronic) within **14 days** of the last study visit.



7. Contact

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

OVPRI Regulatory Affairs

indide@vcu.edu or regaffairs@vcu.edu

8. Document History

Version	Version Date	Brief Description of Change
1.0	06/06/2024	Initial
2.0	09/18/2025	Revised to add in random and for cause monitoring, and site initiation visits