Checklist of Tasks for Monitoring Visit

YES	NO	Subjects Screening/Enrollment and Visit Data
□	□	All ICFs are signed and dated for all subjects and the process is fully documented in the source documents.
□	□	All subjects have received a copy of the signed and dated ICF.
□	□	Ensure that all ongoing patients have signed and dated the latest approved version of ICF.
□	□	Site personnel involved in the informed consent process have been delegated this responsibility by the PI on the Delegation and Signature Log.
□	□	The "Screening" and "Enrollment" logs are completed.

YES	NO	Source Document Verification/CRF Entries
□	□	Source documents (SD) and other trial records (e.g., CRFs) for all enrolled subjects are available, accurate, complete, and current.
□	□	Subject's participation in the trial is clearly indicated in the source data.
□	□	Subject is eligible.
□	□	All entries in the CRF are checked against the original source data.
□	□	Data required by the protocol are reported accurately in the CRF/queries and are consistent with the source documents.
□	□	The source documents reflect all CRF data as well.
□	□	Verify at each visit any change in therapy or dosage.
□	□	Protocol deviations have been documented on site and reported to the IRB/IEC as required by the protocol/local regulations.
□	□	Any corrections to the CRF/queries are dated and initialed, and do not obscure the original entry. All corrections to the CRF must be made on the original CRF page. (In case an eCRF is used, this is not applicable as it is automatically audit-trailed.)
□	□	For electronically-stored source documents, print-outs of the electronic data can be used as source documents as long as they are certified by the investigator through date and signature.
□	□	All data queries have been resolved and source data verified when applicable.

☐	☐	In case of early withdrawal of a patient, carefully check that the reason for withdrawal indicated in the source documents matches with the entries in the CRF (example: withdrawal for Adverse Event X is reported in the source document → the same adverse event should be found back in the CRF).
☐	☐	Document all the subject's visits you have reviewed and/or CRF pages collected/approved.

YES	NO	Safety Review
☐	☐	Adverse events are being reported in accordance with the protocol/safety guidelines.
☐	☐	Review all concomitant medications, potential procedures, ongoing or newly diagnosed events, lab reports, radiology reports, symptoms, and missed visits for potential adverse events or serious adverse events (SAE).
☐	☐	The availability of any start and stop dates and the outcome of the events appear in the source documents and CRF. Ensure the intensity of the event and the relationship to the study drug is available in the source documents and CRF.
☐	☐	Pay close attention to prohibited medications during the course of the trial. In case prohibited medication has been taken by a subject, immediately contact the Sponsor/Study Physician as defined in the Monitoring Guidelines.
☐	☐	Check if adverse events reported as "serious" have been reported as SAEs in a timely manner. In case an SAE is detected that the PI did not previously identify, the monitor should notify the PI immediately and initiate the appropriate reporting procedures.

YES	NO	Investigational Product (IP)/ Study Supplies
☐	☐	Only authorized personnel have access to the IP and can distribute it to the subject. This should be documented on the signature and delegation list.
☐	☐	Check the tracking of IP at the site and recording of the IP on the accountability logs.
☐	☐	Perform IP accountability/inventory at site and subject level. Document any discrepancies identified. Double check that the information is consistent with the entries in the CRF and what is written in the source documents.
☐	☐	Check the temperature log to ensure that the storage conditions of the IP are within the ranges defined for the product. In case of temperature excursion, contact the Sponsor and

		follow any procedures identified on temperature excursions.
☐	☐	Ensure that the expiration date of the IP present on site is still within acceptable range. If not, ensure new IP is sent to the site. Ensure that there are always sufficient supplies on site.
☐	☐	Ensure records of receipt, use, and return of IP are complete and accurate at the site. When applicable, ensure that unused IP is destroyed according to regulatory and client-specific requirements. IP destruction can only be done upon written approval of the sponsor.
☐	☐	If IP is destroyed, ensure a certification of IP destruction is available at the site.
☐	☐	If using an Interactive Voice/Web Response System, compare the electronic listing to the CRF, source documents, and IP Accountability Log.
☐	☐	Check for any potential code break (only applicable if blinded study).
☐	☐	At each monitoring visit, make copies of all of the above documents to keep your filing up-to-date.

YES	NO	Review/Collection of Essential Documents
☐	☐	Ensure that the Investigator's site file contains all current essential documents. Replace expired documents with new documents as needed.
☐	☐	Ensure that the Delegation and Responsibilities Signature Log is always up to date.
☐	☐	In case of new team member, ensure that all the documents are collected (CV, Financial Disclosure Form, GCP certification, updated FDA 1572, etc.).
☐	☐	Check that new documents that require submissions to the IRB have been appropriately submitted and approved (where applicable).
☐	☐	Sign the Site Visit Log each day of a site visit.

YES	NO	Study Personnel/Site Facilities
☐	☐	Ensure that the PI and staff are performing specified functions in accordance with the protocol and the client's requirements, and that the PI is providing adequate oversight.
☐	☐	In case tasks are delegated by the PI, ensure that delegates are appropriately qualified

		and trained.
□	□	Ensure that materials for the study are always used in the appropriate fashion and maintained on a regular basis.
□	□	Ensure that the site always keeps the study files in an appropriate and confidential way.
□	□	Ensure that the site is still acceptable.
□	□	Visit on a regular basis all departments involved into the trial and document this into your visit report.

YES	NO	Meeting with PI and Site Staff
□	□	Ensure that all your findings detected during the visit are shared and discussed with the PI and site staff during the visit. If the PI is not available that day, ensure that the Follow-up letter clearly identifies all the issues and action to be taken. When appropriate, do not hesitate to personally contact the PI after your visit in case you did not had the chance to meet him/her.
□	□	Address all the deviations you noted and ensure appropriate retraining of the site where needed.
□	□	Ensure the site understands all the actions they need to follow-up on after the visit.
□	□	Keep the site informed on every aspect of the trial, and not only on the site-specific situation. It may be of interest and encouragement for sites to know the general status of the trial.