PKASPER & ASSOCIATES
CLINICAL RESEARCH TRAINING AND OPERATIONS

Quality Monitoring Checklist

Instructions:

For each task below, the Quality Monitor indicates in the appropriate column if the Monitor accomplished the task by using the following codes

Yes = Monitor accomplished task (includes tasks where site failed to follow-up]
No = Monitor did not attempt / accomplish the task successfully
N/A = Task is not applicable for this project

Any "No" designations should be explained in the Comments section at the end of this checklist and should be assigned to the following criteria:

VISIT PREPARATION			
Did the CRA:	**Yes**	**No**	**N/A**
1. Schedule the visit and sent written confirmation in advance to the site?	☐	☐	☐
2. Inform site personnel that the Monitor would be attending the visit with a Quality Monitor?	☐	☐	☐
3. Conduct this visit (Frequency / Interval / Length) as per contractual requirements?	☐	☐	☐
4. Schedule realistic arrival and departure times and adequate time during office hours to accomplish required tasks?	☐	☐	☐
5. Reserve adequate time to meet with the principal investigator / designee and the study coordinator?	☐	☐	☐
6. Review study / site specific information (e.g. tracking reports, last MVR) to determine tasks and create an action plan to complete the visit and resolve outstanding issues?	☐	☐	☐
7. Bring appropriate monitoring tools and supplies (including tracking reports)?	☐	☐	☐

SITE MANAGEMENT	Yes	No	N/A
1. Interact with site personnel in a professional manner and addressed any issues in a constructive manner?	☐	☐	☐
2. Set expectations for the visit with the site staff (work to be performed, length of visit, site staff availability, office hours)?	☐	☐	☐
3. Address all follow-up issues and actions from the previous visit?	☐	☐	☐
4. Access e-malls / voicemail periodically throughout the visit?	☐	☐	☐
5. Notify the CTM / designee immediately of any significant issues?	☐	☐	☐
6. Discuss the overall study status, new safety and / or other relevant study issue, with the investigator and other key site personnel?	☐	☐	☐
7. Communicate protocol and / or regulatory deficiencies with investigator and other appropriate site personnel and assisted with plan for corrective action?	☐	☐	☐
8. Schedule the next monitoring visit prior to leaving the site, if applicable?	☐	☐	☐
SITE FACILITIES / PERSONNEL	**Yes**	**No**	**N/A**
1. Verify that the facility / equipment / personnel continue to be adequate?	☐	☐	☐
2. Identify any changes to facility / equipment / personnel and obtained appropriate documentation (e.g., lab certification, 1572,CV, license)?	☐	☐	☐
3. Confirm that the Investigator Personnel Team List and delegation of duties is current?	☐	☐	☐
4. Assess whether biological samples were obtained, handled, and stored per protocol and in accordance with local requirements?	☐	☐	☐

SUBJECT ENROLLMENT	Yes	No	N/A
1. Assess if enrollment was satisfactory based on expectations/predictions and verify the site's ability to meet contractual obligations?	☐	☐	☐
2. Ensure that subject source documentation was current and accurate?	☐	☐	☐
3. Verify tracking report information with screening logs, source documentation and eCRF dates and updated / corrected as necessary?	☐	☐	☐
4. Confirm the site is still recruiting for sub studies and did CRA have the conversation regarding recruitment activities?	☐	☐	☐
5. Confirm and verify that the site has IRB approval to conduct any and all sub studies?	☐	☐	☐
6. Confirm that the site does not have issues that would result in a CAP or screening hold?	☐	☐	☐

The checklist below refers only to subjects / eCRFs reviewed			
ADVERSE EVENTS			
Did the Quality Monitor:	**Yes**	**No**	**N/A**
1. Verify if any serious and / or unexpected AEs occurred since the last visit?	☐	☐	☐
2. Verify that AEs noted in the source documents are recorded on the eCRF?	☐	☐	☐
3. Verify that SAEs noted in the source documents are recorded on SAE form and reported to Safety within 24 hours?	☐	☐	☐
4. Verify that all SAEs were reported to IRB within the correct timeframe?	☐	☐	☐
5. Verify whether outstanding issues regarding SAEs have been resolved (refer to SAE listing and query trackers)?	☐	☐	☐

6. Verify that SAE reports were reconciled to all source documents and eCRF?	☐	☐	☐
7. Verify if site personnel observed any trends in AEs?	☐	☐	☐
INFORMED CONSENT REVIEW	**Yes**	**No**	**N/A**
1. Verify that the latest version of an IRB (all pages present) prior to beginning any study related procedures or implementation of amendment changes?	☐	☐	☐
2. Verify that documentation of proper consenting process is noted in the source documents (e.g. confirming subject has read, all questions answered, signed ICF before study procedures & received a copy of the signed ICF?	☐	☐	☐
3. Verify that all versions of ICFs have been signed (screening, main consent, caregiver, sub study(ies) consents) and applicable national / local addenda are signed / attached to each signed ICF (HIPPA)?	☐	☐	☐
4. Verify that the subject signed appropriate and current (or multiple updated versions) of sub study ICFs prior to any study related procedures?	☐	☐	☐
eCRF / SOURCE DOCUMENT REVIEW (for subjects / eCRFs reviewed)	**Yes**	**No**	**N/A**
1. Verify that all available source documentation are reviewed and found to meet minimum requirements and are accurate, complete, current and maintained?	☐	☐	☐
2. Verify that source documentation supports the existence of the subjects enrolled and confirms a possible / probably history of indication under study?	☐	☐	☐
3. Verify that source documentation appears free of evidence of fabrication or falsification of data?	☐	☐	☐
4. Verify that inclusion / exclusion criteria were met by all enrolled subjects and for those not meeting criteria, documented client notification and Medical Monitor approval?	☐	☐	☐
5. Verify that early terminations were thoroughly documented in source documents and eCRF?	☐	☐	☐
6. Verify that laboratory reports and other safety assessment procedures were promptly obtained, reviewed, signed and any issues followed up by the PI (lab test repeated) and documented in source documents and e-CRF, if appropriate?	☐	☐	☐
7. Verify that study procedures were performed as per protocol and within window?	☐	☐	☐
8. Verify that documentation of any protocol violation, deviation, exemption, or noncompliance with GCP and regulatory requirements?	☐	☐	☐

9. Verify that all infusions and / or dosing modifications were documented?	☐	☐	☐
10. Verify that eCRF data were consistent across sections / visits and with source data / documentation (cross reference IVRS confirmation report, weight, date, etc.) and that endpoint data (Rating Assessments) are clearly documented?	☐	☐	☐
11. Verify that previously monitored eCRFs were done so as required by project?	☐	☐	☐
12. Verify if CRA conducted remote monitoring of queries since last IMV?	☐	☐	☐
13. Verify that outstanding data queries were resolved and supported by source documentation?	☐	☐	☐
CONCOMITANT MEDICATION (CM)	**Yes**	**No**	**N/A**
1. Verify that all baseline and ongoing concomitant medications are documented appropriately?	☐	☐	☐
2. Verify that there are no discrepancies between indications for concomitant medications noted in the Medical History and data on the eCREF pages?	☐	☐	☐
3. Verify that all AEs / SAEs, concomitant medication are noted in source and the eCRF?	☐	☐	☐
4. Verify that no disallowed medications or changes in dose for indication-related medications are being used without prior approval from Medical Monitor?	☐	☐	☐
REGULATORY / IRB / ESSENTIAL DOCUMENTS	**Yes**	**No**	**N/A**
1. Review the Regulatory Binder as specified in the monitoring plan and documented all findings with follow-up resolutions within 2 Interim Monitoring Visits?	☐	☐	☐
2. Verify follow-up letters and confirmation letters for all visits conducted are present?	☐	☐	☐
3. Identify documents to be retrieved for the Trial Master File?	☐	☐	☐
4. Sign Site Visit Log (each day at the site) – ensured all visits to date are documented (do not prompt CRA to do this during the visit)?	☐	☐	☐
5. Verify IRB approval granted prior to investigational product shipment, SIV date → IRB date → Activation → 1st subject screened IP → shipped?	☐	☐	☐

6. Verify IRB approval is current for all documents (e.g., protocol, informed consent, amendments, advertisements / recruitment / retention materials and granted prior to implementation?	☐	☐	☐
7. Verify IRB notification (as appropriate) of IND safety reports, progress reports, renewal updates, SAEs or noncompliance with protocol or GCPs?	☐	☐	☐
INVESTIGATIONAL PRODUCT (IP) ACCOUNTABILITY / STUDY SUPPLIES	**Yes**	**No**	**N/A**
1. Verify that randomization was performed correctly and Investigational Product was dispenses only to eligible subjects at doses specified in the protocol, by authorized personnel?	☐	☐	☐
2. Verify unblinding procedures were followed and documented appropriately (where applicable)?	☐	☐	☐
3. Verify if CRA understands how to recognize if blind has been compromised?	☐	☐	☐
4. Verify if the CRA understands the process if CRA discovers blind has been compromised?	☐	☐	☐
5. Verify all study procedures are being followed?	☐	☐	☐
GENERAL OBSERVATIONS	**Yes**	**No**	**N/A**
1. Determine if Corrective Action Plan / Quality Audit were conducted to a satisfactory outcome?	☐	☐	☐
2. Verify subject history of diagnosis?	☐	☐	☐
3. Confirm that all subjects that were terminated due to exclusionary findings were early terminated or screen failed from study?	☐	☐	☐
4. Verify that there was communication with Medical Monitor & it was clearly documented in source chart and or regulatory binder?	☐	☐	☐
5. Confirm study site activity supports the integrity of the blind?	☐	☐	☐