**Checklist of actions required for on-site monitoring visits:**

|  |  |
| --- | --- |
| Discuss appropriate visit dates/times with PI/Research Nurse  | [ ]  |
| Write and send monitoring visit letter to site | [ ]  |
| Prepare trial-specific monitoring visit checklists:* ISF checklist
* Consent & eligibility checklist
* SDV checklist
 | [ ] [ ] [ ]  |
| Print out relevant number of each monitoring visit checklist | [ ]  |
| Review previous monitoring visit reports to confirm if there are any outstanding actions that should be followed up at this visit | [ ]  |
| Review patient records – check for missing CRFs/queries raised but not yet resolved | [ ]  |
| Take following information/documentation on visit:* Copy of protocol
* All relevant checklists (see above)
* Document version histories
* List of comments/queries from review of previous reports
* Pens, post-it notes, etc.
 | [ ] [ ] [ ] [ ] [ ]  |
| Carry out monitoring visit – ensure you complete:* Clinic
	+ ISF review
	+ Patient consent review
	+ Patient eligibility review
	+ Adverse event & SAE reporting review
	+ CRF completion up to and including 30 day follow-up
	+ CRF completion 1 year follow-up (if close-out visit)
* Close-out meeting
	+ Discuss main findings with PI
	+ Discuss specific ISF/patient data findings with Research Nurse/Data Manager
	+ Complete site visit log
 | [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]  |
| Write monitoring visit report | [ ]  |
| Send monitoring visit report to site listing all findings and actions required | [ ]  |