# Accompanied Visit Checklist

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| Study and Personnel Details | | | | | | | |
| **Study Reference:** | | | **Study Site:** | | | | |
| **Monitor’s Name:** | | | **Position:** | | | | |
| **Reviewer’s Name:** | | | **Position:** | | | | |
| **Visit Date:** | | | | | | | |
| **Study Site Personnel Present:** | | | | | | | |
| **Type of Study Site Visit: (tick as appropriate)**  Pre-Study  Initiation  Monitoring  Closure  Other (Specify): | | | | | | | |
| **Purpose of Study Site Visit: (tick as appropriate)**  Quality  Training  Monitor sign off  Other (Specify): | | | | | | | |
| Objectives of Visit *(to be completed in advance of visit with input from Line Manager)* | | | | | | | |
| **Monitor’s Objectives for Visit** | | | | | | | |
| **Monitoring tasks to be done:** | | | | | | | |
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| **Topics for discussion with Principal Investigator:** | | | | | | | |
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| **Topics for discussion with Study Site personnel:** | | | | | | | |
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| **Other:** | | | | | | | |
| **Reviewer’s Objectives for Visit** | | | | | | | |
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| **Topics for discussion with Principal Investigator:** | | | | | | | |
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| **QC Review tasks to be completed:** | | | | | | | |
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| **Areas for Support / Development of Monitor:** | | | | | | | |
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| **Other:** | | | | | | | |
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| Observations | | | | | | | |
| **Quality Issues**  *Record quality issues requiring urgent attention / that need to be brought to the attention of Line Management / CPrM / etc.* | | | | | | | |
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| **Monitor’s preparation to achieve objectives for the study site visit.**  *Include awareness of study site issues, therapy area/protocol knowledge, all materials and info to hand etc.* | | | | | | | |
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| **Monitor’s performance of monitoring tasks.** *Include adherence to SOPs, use of tracking systems, organising and prioritising work, management of documentation, accuracy, cross-referencing between CRF modules, methodology for SDV, checking consents etc. Include suggestions for best practice, development/training needs, compliance issues etc.* | | | | | | | |
| Consent Issues | | Protocol Deviations | | | Monitoring Plan Compliance | | |
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| **Monitor’s discussions with Investigator and Study Site personnel.** *Include interpersonal & communication skills, discussions on study targets and action plans, use of study site management plans / contingency, problem solving, negotiation skills, non-study issues, product discussions. Include suggestions for sharing as best practice, development/training needs etc.* | | | | | | | |
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| **Assessment of achievement of Monitor’s objectives for visit.** | | | | | | | |
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| **QC Review observations.** | | | | | | | |
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| **Observations relating to areas for support/development of Monitor noted in objectives.** | | | | | | | |
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| **Assessment of achievement of Reviewer’s objectives for visit.** | | | | | | | |
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| Monitor’s Comments | | | | | | | |
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| **Follow up of actions** *(where applicable, to be discussed with Line Manager and reviewer, and completed by Monitor)* | | | | | | | |
| **Actions /training needs** | **Comment** | | | | | **Date completed/to be completed** | |
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| **Signatures** | | | | | | | |
| **Monitor:** |  | | | **Date:** | | |  |
| **Reviewer:** |  | | | **Date:** | | |  |
| **Report copied to:**  **(Governance Manager)** |  | | | | | | |