|  |
| --- |
| **Trial Title:** |

|  |  |
| --- | --- |
| **Trigger for Monitoring Visit** | |
| **Visit trigger:** |  |
| **Date of previous visit:** |  |

|  |  |
| --- | --- |
| **Visit Information** | |
| **Date of visit:** |  |
| **Site name:** |  |
| **Site address:** |  |
| **PI:** |  |
| **Site personnel present:** | *<include role>* |
| **Monitor(s):** | *<include role>* |
| **Trial patients and CRFs reviewed:** | *<specify which patients were reviewed for Consent & Eligibility, SAEs, SDV, etc. If appropriate, also indicate the CRFs reviewed.>* |
| **Version of Monitoring Plan used at visit:** |  |

|  |  |
| --- | --- |
| **Report Information** | |
| **Date report sent:** |  |
| **Site personnel report sent to:** |  |
| **Deadline for response:** |  |

|  |
| --- |
| **Report Sections** |
| 1. General Comments/Major Findings 2. Summary of Monitoring Performed At Site 3. Attachments 4. Signatures   Appendices   * Appendix 1 – On-site Monitoring Visit Report Actions (CAPA) – Research Team |

***<List actions in Appendix 1 for research team>***

| 1. **General Comments/Major Findings** |
| --- |
| The monitor would like to thank staff for their help and hospitality during the visit.  *<add additional comments or major findings>* |

| 1. **Summary of Monitoring Performed At Site** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Check** | **Y** | **N** | **N/A** | **N/D** | **Comments**  *<include brief comments if applicable – actions must be stated in relevant appendix>* |
| Signed informed consent present and correct in ISF and patient files? |  |  |  |  |  |
| Eligibility criteria confirmed against source? |  |  |  |  |  |
| All SAEs resolved and final reports submitted to CTC? |  |  |  |  |  |
| All SAEs have been reported? |  |  |  |  |  |
| Safety reporting requirements and timelines stated in the protocol have been adhered to? |  |  |  |  |  |
| Full review of Investigator Site File performed? |  |  |  |  |  |

| 1. **Attachments** |
| --- |
| *<list all documents to be sent to site with this report – e.g. documents missing from ISF/PSF>* |

| 1. **PRISM admin team signatures** | | | |
| --- | --- | --- | --- |
| **Role** | **Name** | **Signature** | **Date** |
| **Monitor** |  |  |  |
| **Reviewed by** |  |  |  |

***1 copy for PRISM Trial Master File; 1 copy for Investigator Site File***

| **Consent and Eligibility Actions Check box if no actions:** | | | |
| --- | --- | --- | --- |
| **Trial No.** | **Comment/Observation/Finding** | **Actions for site** | **Site response (initial & date)** |
|  |  |  |  |

| **SAE Actions Check box if no actions:** | | | |
| --- | --- | --- | --- |
| **Trial No.** | **Comment/Observation/Finding** | **Actions for site** | **Site response (initial & date)** |
|  |  |  |  |

| **SDV Discrepancies** *<repeat for each patient>* **Check box if no actions:** | | | | |
| --- | --- | --- | --- | --- |
| **Trial Number:** | | | **Patient Initials:** | |
| **CRF Form** | **Field/Question** | **Summary of concern** | **Actions for site** | **Site response (initial & date)** |
|  |  |  |  |  |

| **Investigator Site File Actions Check box if no actions:** | | | |
| --- | --- | --- | --- |
| *<add/delete rows as applicable>* | **Comment/Observation/Finding** | **Actions for site** | **Site response (initial & date)** |
| Status of Investigator Site File |  |  |  |
| Subject Recruitment |  |  |  |
| Trial Specific Logs |  |  |  |
| Training Records and CVs |  |  |  |
| Other Essential Documents |  |  |  |

| **Trial Specific Requirements Actions Check box if no actions:** | | | |
| --- | --- | --- | --- |
| **Trial Specific Requirement** | **Comment/Observation/Finding** | **Actions for site** | **Site response (initial & date)** |
|  |  |  |  |

| **Site Comments** |
| --- |
| **Please use this section for any comments regarding the Monitoring Visit or Monitoring Report.**  *<expand section>* |

| **Signatures** | | | | |
| --- | --- | --- | --- | --- |
|  | **Role** | **Name** | **Signature** | **Date** |
| **Person completing responses** |  |  |  |  |
| **For CTC use upon receipt** |  |  |  |  |

***Please return 1 copy to PRISM Trial team admin@prismtrial.org for Trial Master File; file 1 copy in Investigator Site File***