SITE MONITORING VISIT CHECKLIST

*Study Monitor: Please complete this monitoring report prior to the conclusion of your current monitoring visit to assist us with our overall quality assurance.*

|  |  |
| --- | --- |
| Sponsor: |  |
| Monitor Name: |  |
| Study Name: |  |
| Monitoring Date(s): |  |
|  | dd/mmm/yy |

**Site Staff Responsible for Study / Visit**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Title** |  | Name |  | **Initials\*** |
| Qualified Investigator: |  |  |  |  |
| Study Coordinator/Nurse: |  |  |  |  |
| Data Manager: |  |  |  |  |
| Other: |  |  |  |  |

\* required only if personnel met with monitor at this visit

1. **Study Activity** *(enter ‘N/A’ if not applicable at this visit)*

|  |  |  |  |
| --- | --- | --- | --- |
| Number of charts requested |  | Number of study visits |  |
| Number of charts reviewed |  | Number of treatment cycles |  |
|  |  | Number of follow-up visits |  |

1. **Study Conduct** *(select ‘N/A’ if not applicable at this visit)*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | N/A | Yes | Number |  | No | Number |
| Consent available |  |   |  |  |   |  |
| Patient eligible |  |  |  |  |  |  |
| Initial evaluation complete |  |  |  |  |  |  |
| Follow-up documentation complete |  |  |  |  |  |  |
| Adverse event documentation complete |  |  |  |  |  |  |
| Source documentation verified |  |  |  |  |  |  |

|  |
| --- |
| Comments: |
|  |

1. **Serious Adverse Events** *(select ‘N/A’ if not applicable at this visit)*

|  |  |  |
| --- | --- | --- |
| Number of SAEs reviewed at this visit |  |  N/A |

|  |  |  |  |
| --- | --- | --- | --- |
| Were the SAEs appropriately reported? | Yes | No | If “No”, provide patient I.D. and specify problem |
| SAE No. 1 |  |  |  |
| SAE No. 2 |  |  |  |
| SAE No. 3 |  |  |  |

1. **Protocol Compliance**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  No | If “Yes”, specify |
| Were any protocol deviations noted? |   |   |  |
| Were any protocol violations noted? |   |   |  |

1. **Regulatory Documents**

|  |  |  |  |
| --- | --- | --- | --- |
| Documents reviewed at this visit: | Yes |  No | If “Yes”, specify |
| CV |   |   |  |
| Signature Pages |   |   |  |
| Laboratory Certification |  |  |  |
| REB correspondence |  |  |  |
| Other |  |  |  |

1. **Pharmacy**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  No | If “Yes”, did you have any concerns? |
| Did you visit the pharmacy? |   |   |  |

1. **Additional Comments**

|  |
| --- |
|  |
|  |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Study Monitor’s Signature |  | Date (dd/mmm/yy) |

### Site Action Plan/Resolutions/Follow Up

|  |
| --- |
|  |
|  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Staff Name |  | Signature |  | Date (dd/mmm/yy) |