| **Monitoring – Medical Records Checklist** | | | |
| --- | --- | --- | --- |
| **Study Title:** |  | | |
| **REC reference:** |  | **EudraCT Number:**  (if applicable) |  |
| **Sponsor:** |  | **IRAS number:** |  |

*Add/remove items as required*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Check ID** | **Task** | **Yes** | **No** | **N/A** | **Comments** | **Action** |
| **1** | Research alert sticker on the inside cover of the medical notes? |  |  |  |  |  |
| **2** | Records flagged on local Patient Administration System (PAS)? |  |  |  |  |  |
| **3** | Signed copy of approved screening form filed (for presumed consent)? |  |  |  |  |  |
| 3.1 | Person confirming eligibility is authorised to do so? |  |  |  |  |  |
| 3.2 | Participant met all trial eligibility criteria? |  |  |  |  |  |
| **4** | Signed copy of approved patient/family/legal representative consent form filed? |  |  |  |  |  |
| 4.1 | Is the consent form the correct version? |  |  |  |  |  |
| **5** | Copy of approved patient/family/legal representative information sheet filed? |  |  |  |  |  |
| 5.1 | Is the information sheet the correct version? |  |  |  |  |  |
| **6** | Copy of GP letter signed by PI filed? |  |  |  |  |  |
| 6.1 | Is the GP letter the correct version? |  |  |  |  |  |
| **7** | Details about discussions with the patient/family/legal representative documented in the notes? |  |  |  |  |  |
| 7.1 | Details of discussions are signed and dated? |  |  |  |  |  |
| 7.2 | Is the person approaching the patient/family authorised on the delegation log? |  |  |  |  |  |
| **8** | Are reported serious adverse events verifiable against patient records? |  |  |  |  |  |
| **9** | Are there any serious adverse events recorded in the patient’s notes or other source data that have not been documented and reported in accordance with the protocol? |  |  |  |  |  |

*Please record any additional comments overleaf.*

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| **Comments** |
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|  |  |
| --- | --- |
| **Research monitor signature** |  |
| **Date** |  |
| **Name (PRINT)** |  |

|  |  |
| --- | --- |
| **Sponsor representative signature** |  |
| **Date** |  |
| **Name (PRINT)** |  |