**RDT040 Post Monitoring Visit Checklist**

This form must be completed using indelible ink, pencil is not acceptable. Forms completed electronically must be printed and signed by the person completing the form.

|  |  |
| --- | --- |
| Study Title: |  |
| RRK: |  |
| Sponsor: |  |
| CRO: |  |
| Monitoring Visit Date: |  |
| Monitor Name: |  |
| Date Monitor trained on EPR: |  |
|  | |
| Name of Person completing checklist: |  |
| Role: |  |
| Signature: |  |
| Date: |  |

By signing above you are confirming that the following checks have been completed for this monitoring visit.

|  |  |  |  |
| --- | --- | --- | --- |
| **Checks** | **Yes/No/N/A** | **Confirmed by** | **Date** |
| 1. Were paper medical records reviewed? |  |  |  |
| 1. Were electronic medical records reviewed? |  |  |  |
| 1. Monitor trained on the electronic patient record (Clinical Portal)? |  |  |  |
| 1. Has an audit trail been performed on Clinical Portal for electronic records?   If `Yes’ indicate the date below:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  *<If `No’ provide reasons in the comments section below>* |  |  |  |
| 1. Were any breaches identified for either the paper or electronic record review?   *<If yes indicate in the comments section>* |  |  |  |
| 1. If answering yes above has a Datix report been completed?   If `Yes’ list the Datix report ID below: *<usually starts with a `W’>*  *\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*  *\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* |  |  |  |
| 1. Has the breach been reported to the sponsor? |  |  |  |
| ***Additional Comments:***  ***<Include any additional comments below – delete this text on completion>*** | | | |

**Send a copy of the completed checklist to the R&D Governance (R&D@uhb.nhs.uk) and retain a copy within the site file as evidence of checks completed following the monitoring visit.**