**DIVISION OF RESEARCH AND INNOVATION**

**Monitoring/Audit Checklist**

|  |  |
| --- | --- |
| Date of monitoring visit/audit: |  |
| Study name: |  |
| R&D number: |  |
| Sponsor: |  |
| Study contact(s): |  |
| Name of monitor(s)/auditor(s): |  |
| Equipment booked: |  |

**Checklist**

|  |  |
| --- | --- |
| 🞎 | Monitor(s)/Auditor(s) ID confirmed. |

|  |  |
| --- | --- |
| 🞎 | All documents (originals and copies) requested have been returned (see document request list). |
| 🞎 | All equipment used by the monitor/auditor has been returned to the study team. |
| 🞎 | Electronic documents that have been saved onto equipment for the purpose of the monitoring visit/audit have been deleted from the equipment. |
| 🞎 | Monitor badge has been returned |

**Monitors/Auditors are not to remove anything from the Trust unless they have explicit permission from GOSH Pharmacy Clinical Trials Team or R&D; this includes equipment or documents (paper or electronic).**

Exceptions are: PI GCP/CV, monitoring visit log, CRFs, IMP accountability/shipping logs (with agreement from pharmacy)

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Name** | **Signature** | **Date** |
| **Study contact:** |  |  |  |
| **Monitor/Auditor:** |  |  |  |

**Document Request List (to be completed by study monitor/auditor)**

For participant files please list participant study ID

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Document** | **Original/Copy** | **Type** | **Provided** | **Returned** |
| Site file(s) | 🞎 Original  🞎 Copy/Scan | 🞎 Paper  🞎 Electronic | 🞎 Yes  🞎 No | 🞎 Yes  🞎 No |
|  | 🞎 Original  🞎 Copy/Scan | 🞎 Paper  🞎 Electronic | 🞎 Yes  🞎 No | 🞎 Yes  🞎 No |
|  | 🞎 Original  🞎 Copy/Scan | 🞎 Paper  🞎 Electronic | 🞎 Yes  🞎 No | 🞎 Yes  🞎 No |
|  | 🞎 Original  🞎 Copy/Scan | 🞎 Paper  🞎 Electronic | 🞎 Yes  🞎 No | 🞎 Yes  🞎 No |
|  | 🞎 Original  🞎 Copy/Scan | 🞎 Paper  🞎 Electronic | 🞎 Yes  🞎 No | 🞎 Yes  🞎 No |
|  | 🞎 Original  🞎 Copy/Scan | 🞎 Paper  🞎 Electronic | 🞎 Yes  🞎 No | 🞎 Yes  🞎 No |
|  | 🞎 Original  🞎 Copy/Scan | 🞎 Paper  🞎 Electronic | 🞎 Yes  🞎 No | 🞎 Yes  🞎 No |
|  | 🞎 Original  🞎 Copy/Scan | 🞎 Paper  🞎 Electronic | 🞎 Yes  🞎 No | 🞎 Yes  🞎 No |
|  | 🞎 Original  🞎 Copy/Scan | 🞎 Paper  🞎 Electronic | 🞎 Yes  🞎 No | 🞎 Yes  🞎 No |
|  | 🞎 Original  🞎 Copy/Scan | 🞎 Paper  🞎 Electronic | 🞎 Yes  🞎 No | 🞎 Yes  🞎 No |
|  | 🞎 Original  🞎 Copy/Scan | 🞎 Paper  🞎 Electronic | 🞎 Yes  🞎 No | 🞎 Yes  🞎 No |