|  |  |  |  |
| --- | --- | --- | --- |
| Form number | **53.006A** | Version | **3.0** |
| Title | **Research & Innovation Monitoring Handover Checklist** | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **Current Trial Monitor:** |  | **New Trial Monitor:** |  |
| **Face-to-face Meeting Date:** |  | **Handover Period** | From:  To: |

|  |  |  |  |
| --- | --- | --- | --- |
| **Trial Background** | | | |
| **Trial Title (short name)** |  | | |
| **Research Title:** |  | | |
| **R&I Reference:** |  | **Trial Status:** |  |
| **Sponsor:** | NHSGGC  NHSGGC & UoG  UoG  Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| **RGL Date (first site):** |  | **Proposed Trial End Date:** |  |
| **Chief Investigator:** | Informed  Date\_\_\_\_\_\_\_\_\_\_\_\_\_ | **Project Manager:** | Informed  Date\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **CT Pharmacist:** | Informed  Date\_\_\_\_\_\_\_\_\_\_\_\_\_ | **R&I Co-ordinator:** | Informed  Date\_\_\_\_\_\_\_\_\_\_\_\_\_ |

|  |  |  |
| --- | --- | --- |
| **Site Information** | **Number of sites open:** | **Number of Sites to Open:** |
| **Number of sites closed:** | **Number of sites to close:** |
| **Recruitment Information** | **Current recruitment:** | **Target recruitment:** |
| **Next visit as per Monitoring Plan (confirm if Scheduled or to be):** | **Visit type:** | **Site:** |
| **TMG information:** |  | |
| **Data reports type (please list) / Frequency:** |  | |

|  |  |  |
| --- | --- | --- |
| **Sponsor Contact Information** | | |
| **Chief Investigator** | **Print name:** | **Contact email/phone:** |
| **Project Manager** | **Print name:** | **Contact email/phone:** |
| **Pharmacist** | **Print name:** | **Contact email/phone:** |
| **R&I Coordinator** | **Print name:** | **Contact email/phone:** |
| **Data Centre** | **Print Name:** | **Contact email/phone:** |
| **Other key contact/print designation:** | **Print Name:** | **Contact email/phone:** |

|  |  |
| --- | --- |
| **Have working documents been fully updated/maintained/closed?** | |
| **Study Monitoring Folder** | Yes  No Tasks Required:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Trial Master File Status** | Is filing up to date?  Yes  No Tasks Required:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Protocol Deviation log** | Yes  No Tasks Required:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Site Contact List** | Yes  No Tasks Required:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Q-Pulse Actions Outstanding (transferred by QA)** | Yes  No Tasks Required:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Trial Issues/ Ongoing Problems** | | | | |
| **Site Name/Number** | **Status/Outstanding Issues** | | **Date Resolved/ Reason Issue was not resolved prior to Handover** | |
|  |  | |  | |
|  |  | |  | |
|  |  | |  | |
|  |  | |  | |
| **Essential Study Monitoring Documents** | | | | |
| **Document** | **Version** | **Location** | | **Handed Over?** |
| **Protocol** | **Version:**  **Is an update required:** |  | | Yes  No |
| **Informed Consent Form** | **Version:**  **Is an update required:** |  | | Yes  No |
| **Patient Information Sheet** | **Version:**  **Is an update required:** |  | | Yes  No |
| **Monitoring Plan** | **Version:**  **Is an update required:** |  | | Yes  No |
| **Monitoring Risk Assessment** | **Version:**  **Is an update required:** |  | | Yes  No |
| **Monitoring Checklist Template** | **Version:**  **Is an update required:** |  | | Yes  No |
| **Sponsor Risk Assessment** | **Version:**  **Is an update required:** |  | | Yes  No |
| **Protocol Deviation Log** | **Version:**  **Is an update required:** |  | | Yes  No |
| **Completed Deviations** | n/a |  | | Yes  No |
| **MV Follow-up Documentation** | n/a |  | | Yes  No |
| **ISF tracker** |  |  | | Yes  No |
| **Additional information helpful to monitoring the trial:** | | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **Signatures** | | | |
| **Outgoing Trial Monitor** | Print Name: | **Date:** | Signature: |
| **Incoming Trial Monitor** | Print Name: | **Date:** | Signature: |
| **Line Manager Sign Off** | Print Name: | **Date:** | Signature: |

**Form signatories**

|  |  |  |  |
| --- | --- | --- | --- |
| Prepared by | Sheila McGowan | | |
| Signature |  | Date |  |
| Approved by | Caroline Watson | | |
| Signature |  | Date |  |

**Document history**

|  |  |  |
| --- | --- | --- |
| **Version** | **Date** | **Description** |
| 1.0 | 11/12/2018 | First Release |
| 2.0 | 25/08/2022 | Minor clarification of terms, inclusion of site details |
| 3.0 | 08/09/2025 | Addition of new sections and clarifying details |

|  |
| --- |
| This Form is a controlled document. The current version can be viewed on the GCTU website.  Any copy reproduced from the website may not, at time of reading, be the current version. |