**CO-MONITORING Tool**

This tool can be modified to suit the requirements of the study or the purpose of co-monitoring.

|  |
| --- |
| **Study Summary** |
| Study Title or Acronym: |  |
| R&D Number: |  |
| Sponsor: | The Newcastle upon Tyne Hospitals NHS Foundation Trust |
| Chief Investigator: |  |
| Study Status: | □ Open to recruitment | □ Closed to recruitment (in follow up) |
| □ Closed (follow up complete) | □ Completed (closed out) |
| □ Archived | □ Disseminated |
| Study Type: | □ CTIMP | □ ATIMP |
| □ Clinical Investigation of a non-CE marked Medical Device | □ Randomised surgical trial |
| □ International study | □ Other; please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Part 1: Visit Summary**

|  |
| --- |
| **Site Details** |
| Site visited: |  |
| Date(s) of visit: |  |
| Principal Investigator: |  |
| Site team personnel present: |  |
| Trial management team present: |  |
| Sponsor representative present: |  |

|  |
| --- |
| **Visit Narrative** |
| *Include details such as documents & records reviewed (including study IDs, records, ISF sections), significant findings, areas for concern etc. Also include comparison against findings by study monitors.*  |

**Part 2: Monitoring Overview**

|  |
| --- |
| **Monitoring Schedule & Monitoring Plan Compliance** |
| What is the approved version and date of the monitoring plan?\* | Version: □ N/ADate: |
| *\*Provide comments as necessary including adequacy of content & whether it has been signed off by all relevant parties.*  |
| Is the monitoring frequency appropriate to the type of study?\* | □ Yes □ No |
| *\*Provide details* |
| Has the monitoring schedule to date complied with the monitoring plan?\* | □ Yes □ No |
| *\*Provide details & specify reason for any non-compliance*  |
| Have previous monitoring reports been issued in a timely manner?\* | □ Yes □ No |
| *\*Provide details* |
| Is there evidence that previous monitoring reports have been accepted by the PI and that all actions have been completed and closed out?\* | □ Yes □ No |
| *\*Provide details* |
| Are there any trends within monitoring reports to date or outstanding actions that have been carried through?\* | □ Yes □ No |
| *\*Provide details and explain how these issues have been addressed / escalated?* |

**Part 3: Investigator Site File**

|  |
| --- |
| **Investigator Site File (ISF)** |
| ***General*** | **Yes, No or N/A** | **Comments:** |
| Is the ISF readily available for co-monitoring? |  |  |
| Is the ISF up to date? |  |  |
| Does the ISF include all required documentation? |  |  |
| Is all documentation stored in a secure location? |  |  |
| ***REC / HRA Approvals*** |  |  |
| Copy of final REC approval? |  | Date of approval: |
| Have all REC conditions been met? |  |  |
| Have REC been notified and approved all amendments? |  | Date of approvals: |
| Copy of final HRA approval? |  | Date of approval: |
| Have the HRA been notified and approved all amendments? |  | Date of approvals: |
| Copy of initial IRAS form signed? |  |  |
| ***MHRA Approvals*** |  |  |
| Copy of full MHRA CTA on file? |  | Date of approval: |
| Have all MHRA conditions been met? |  |  |
| Have MHRA been notified and approved all relevant amendments? |  | Date of approvals: |
| ***Other approvals*** |  |  |
| Copy of all other approvals on file? E.g. GTAC etc.  |  |  |
| ***Insurance*** |  |  |
| Is there a copy of the annual insurance certificate? |  |  |
| Are there previous certificates? |  |  |
| Are they consecutive? |  |  |
| ***Contract*** |  |  |
| Is there a signed and dated copy of the site agreement? |  | Date fully executed: |
| ***Confirmation of Capacity & Capability*** |  |  |
| Is there a copy of the CoCaC? |  | Date of CoCaC at site: |
| Is there a signed copy of the PI/CI responsibilities form? (at NuTH) |  |  |
| Green light present? |  | Date of green light: |
| ***Data Protection / Caldicott*** |  |  |
| Is there a copy of the caldicott approval? |  |  |
| Have there been any substantial amendments submitted that would impact on the caldicott approval? *If yes is there an updated approval?* |  |  |
| Are electronic files stored on a password protected computer? |  |  |
| Is patient data on network computers pseudo-anonymised? |  |  |
| Is the site file stored in a secure area with restricted access?  |  | State location of secure area: |
| ***Study Documentation*** |  |  |
| Approved final version of protocol on file? |  |  |
| Protocol signed by CI & PI? |  |  |
| Are all the latest versions of study documentation being used and filed in the site file?Docs to be listed below: |  |  |
| Are there copies of superseded documents and are these clearly identified or segregated from current documents? |  |  |
| Are superseded documents accessible if required? |  |  |
| ***Amendments*** |  |  |
| Copy of all relevant amendments present?  |  |  |
| Is the documentation for each amendment complete? |  |  |
| Have all relevant amendments been notified to R&D? Is this notification present in the site file? |  |  |
| Have all staff working on the study been made aware of any amendments which affect their department? |  |  |
| Is there a training log for any amendments where appropriate? |  |  |
| ***Delegation Log*** |  |  |
| Is the delegation log up to date with all current and past staff clearly indicated? |  |  |
| Are all entries on the delegation log signed off by the PI? |  |  |
| Have all duties been delegated by the PI appropriately?  |  |  |
| Is there a copy of the delegated tasks key? |  |  |
| ***Training*** |  |  |
| Is there a CV and GCP certificate (demonstrating training within 3 years), in place for each staff member listed on the delegation log? |  |  |
| Does this include those no longer involved? |  |  |
| Is any study specific training required? |  |  |
| If so, has this been documented for all appropriate staff? |  |  |
| Has site initiation training been provided to site? |  |  |
| Is the SIV attendance log present and complete? |  |  |
| ***Informed Consent*** |  |  |
| Do all staff who consent subjects to this study have this activity appropriately delegated on the delegation log and appropriate training? |  |  |
| Is a signed consent form for all study participants held in the site file? |  |  |
| Are all signatures and dates present?Are patient signature dates and staff signature dates the same date? |  |  |
| Was the correct version of the consent form used for each participant? |  |  |
| Are superseded versions of the form clearly identified and segregated from current versions? |  |  |
| Does the version number and date of the PIS match with what is stated in the ICF? |  |  |
| Has the participant initialed all the boxes rather than ticked them, where appropriate? |  |  |
| Is there a copy of the signed consent form in the patients’ notes? |  |  |
| Can you confirm that documentation of the consent process has been written into the patient notes? |  |  |
| Were participants given a copy of the signed ICF and was this documented in their notes? |  |  |
| Has the provision of study information to the participant been documented in their notes? |  |  |
| Has consent to inform the G.P. been obtained?Has this been recorded in the patient’s notes/ICF? |  |  |
| Was the correct version of the G.P. Letter template used for each participant? |  |  |
| Does the ICF include a statement granting permission for external authorities to review medical notes? |  |  |
| Is there evidence of re-consent where there have been amendments to the consent form, participant information sheet or protocol, which impact on study participants? |  |  |
| In all cases, was consent taken prior to any study intervention? Can you evidence this? |  |  |
| Are all the people responsible for taking informed consent appropriately trained to do so? Is this documented accordingly? |  |  |
| Is evidence of this training available for each person if the individual taking consent is not a clinician? |  |  |
| ***Summary***: (Comment on any gaps in the ISF which cannot be correct) |  |  |
|  |  |  |

**Part 4: Recruitment**

Site recruitment target: \_\_\_\_\_\_\_\_\_

Site recruitment to date: \_\_\_\_\_\_\_\_\_

|  |
| --- |
| **Recruitment** |
|  | Yes, No or N/A | Comments: |
| Planned recruitment start/end date: |  |  |
| Actual recruitment start/end date: |  |  |
| Copy of screening log present? |  |  |
| Is the screening log complete? Are all required fields, signatures & dates complete? |  | No. of patients screened: |
| Are the persons who screened the patients listed on the delegation log as appropriate to undertake this role? |  |  |
| Is the site meeting their recruitment target? |  |  |
| Copy of enrolment log present? |  |  |
| Is the enrolment log complete? Are all required fields, signatures & dates complete? |  |  |
| Has it been documented in the patient notes that participants meets the inclusion criteria? |  |  |
| Does the enrolment log demonstrate that eligibility was assessed by an appropriately delegated person? |  |  |
| Have all participant visits occurred within the protocol specified time frames? |  |  |
| If no, have any missed / delayed appointments been documented on the deviation log?  |  |  |
| Have these deviations been sent to Sponsor? |  |  |

**Part 5: Case Report Forms**

|  |
| --- |
| **Case Report Forms** |
|  | Yes, No or N/A | Comments: |
| Have all CRFs been completed accurately and legibly? |  | State whether CRFs are paper or electronic: |
| Are all relevant entries signed and dated? |  |  |
| Are all corrections made with a single line through, initialed & dated? |  |  |
| Are there copies of completed Data queries? |  |  |
| Has the answer to the data query been accepted and signed off/closed out? |  |  |
| Do patient notes include involvement in this research? |  |  |

**Part 6: Pharmacovigilance / Safety Reporting**

|  |
| --- |
| **Pharmacovigilance / Safety Reporting** |
|  | Yes, No or N/A | Comments: |
| Have all SAEs been identified within the patient notes? (Identify notes reviewed) |  |  |
| Have all Serious Adverse Events (SAEs) and Suspected Unexpected Serious Adverse Reactions (SUSARs) been reported to the study Sponsor and recorded in the patients’ notes and the site file? |  |  |
| Is there evidence of PI oversight in assessing causality? |  |  |
| Have all SUSAR notifications to sites been acknowledged by the PI? |  |  |

**Part 7: Deviations / Serious Breaches**

|  |
| --- |
| **Deviations / Serious Breaches** |
|  | Yes, No or N/A | Comments: |
| Have there been any protocol deviations or serious breaches identified and recorded? |  |  |
| Have potential breaches been reported to the study Sponsor and R&D within the agreed timeframe (within 24 hours)  |  |  |
| Have all deviations been notified to Sponsor? |  |  |
| Has all the associated documentation been completed, signed and dated? |  |  |
| Have actions been agreed to prevent reoccurrence? |  |  |
| Have all actions been completed and closed? |  |  |

**Part 8: CAPA**

|  |
| --- |
| **Corrective and Preventative Actions (CAPA)** |
|  | Finding | Suggested Corrective / Preventative Actions | Completed by initials & date completed | Additional comments |
| 1 |  |  |  |  |
| 2 |  |  |  |  |
| 3 |  |  |  |  |
| 4 |  |  |  |  |
| 5 |  |  |  |  |
| 6 |  |  |  |  |

|  |
| --- |
| **Authorisations** |
| Co-monitoring Tool completed by: |  |
| Position: |  |
| Signed: |  |
| Date: |  |
| Comments: |  |
| Co-monitoring Tool reviewed by: |  |
| Position: |  |
| Signed: |  |
| Date: |  |
| Comments: |  |