|  |  |
| --- | --- |
| **Information about the Project:** | |
| Project title: |  |
| Sponsor number: |  |
| IRAS number: |  |
| REC number: |  |
| R&D number: |  |
| Public Benefit & Privacy Panel (PBPP) | Yes / No / Not applicable |
| Is your study registered on a Public Database? | Yes/No  If Yes, which database?........................................................................  ID Number:........................................................................................... |

|  |  |
| --- | --- |
| **Contact Details:** | |
| CI/PI name: |  |
| Contact information: |  |
| Trial Manager: |  |
| Contact information: |  |
| Research Nurse: |  |
| Contact information: |  |

|  |  |
| --- | --- |
| **Rationale for monitoring plan:** | |
| CTIMP  MHRA Categorisation: A / B / C (\*delete as appropriate) |  |
| High Risk (surgical, medical device trial, etc) |  |
| Low Risk |  |
| Hosted |  |
| Investigator request |  |
| Other (please specify): |  |

Will an Audit be required for monitoring processes? \*Yes / No

\*If Yes, an in depth audit will be arranged separately by the QA Manager.

Single Centre Study  \*Multi-Centre Study

\*Remote monitoring checklists will be carried out for additional sites other than Aberdeen. If applicable, copies of the monitoring plan for the multi-centre sites to be provided to the Research Monitors.

Paper System  \*Electronic System  Hybrid System

\*If electronic, access to the live system will be required for the Research Monitors at Initiation.

|  |  |
| --- | --- |
| **Location of documents while project is being conducted, including source data** | |
| Consent Forms | ie locked filing cabinet |
| CRFs |  |
| SAEs |  |
| Standard project documentation (ISF/TMF) |  |
| Results from labs | ie medical notes / SCI-Store |
| IMP accountability | ie Pharmacy Site File |
| Source data | ie Medical notes or part electronic/medical notes |

A percentage of consent forms/source data shall be reviewed depending on recruitment and shall be risk adapted.  This shall include reviewing of e-CRFs.

|  |  |  |  |
| --- | --- | --- | --- |
| **Departments to be visited** | **Yes** | **No** | **N/A** |
| Clinic area |  |  |  |
| \*Pharmacy |  |  |  |
| \*\*Laboratory |  |  |  |
| Centre for Healthcare Randomised Trials (CHaRT) |  |  |  |
| Other: Specify |  |  |  |

\*Pharmacy visits will include, but are not limited to, review of the Pharmacy File, accountability, destruction certificates, IMP returns, temperature monitoring/storage.

\*\* If Labs are involved, then an audit may be carried out by QA prior to recruitment.

**Sponsor Risk Assessment:** \*High / Medium / Low (\* delete as appropriate)

**Please specify the areas identified as High Risk:**

**Risk Adaptive Monitoring:** \*Increased / Regular / Reduced (\* delete as appropriate)

(As per SOP-QA-28)

**Project Specific information for monitoring:**

The close-out visit must be completed prior to any database lock; it is the responsibility of the PI to notify the Research Monitors when data collection is complete.

Planned number of visits: (Initiation, increased monitoring, close out visit)

Planned monitoring frequency: (3/6 monthly or annually)

Time of first monitoring visit in relation to first trial subject \*consented/after first treatment received (\*delete as appropriate):

One month after trial subject included

Planned level of source data verification:

Due to monitoring being risk adaptive, the frequency and level of monitoring can change anytime throughout the period of the study. The CI/PI will be notified if this does occur.

All approved CRFs are to be provided to the Research Monitors at Initiation or prior to the first monitoring visit.

**Approval signatures**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Designation** | **Signature** | **Date** |
|  | **Principal Investigator** |  |  |
|  | **QA Manager** |  |  |
|  | **Research Monitor** |  |  |