|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Site Initiation and Outstanding Actions Report** | | | | |
| **Title:** |  | | | |
| **Chief Investigator:** |  | | **IRAS Number:** |  |
| **Sponsor Reference Number** |  | | **EDGE Number:** |  |
| **Overview of the Protocol and background/purpose of the research:** | |  | | |
| **Overview of IMP(s)/Device(s) (if applicable):** | |  | | |

# Site and Visit Information

|  |  |  |  |
| --- | --- | --- | --- |
| **Site Number:** |  | **Site Name:** |  |
| **Principal Investigator:** |  | **Main Site Contact:** |  |
| **Date of Site Initiation Visit:** |  | **Initiation Visit Method:** | Onsite  Remote |
| **Conducted by** |  | **Date of Report:** |  |

*Attendees must sign the SIV Attendance Log. Those unable to attend must ensure they undergo appropriate training and be signed-off on the Delegation of Authority and Signature Log prior to conducting any research-related activities.*

# GCP and Regulatory Compliance

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| **Prinicipal Investigator obligations** |  |  |  |  |
| **Sponsor obligations** |  |  |  |  |
| **Standard Operating Procedures** |  |  |  |  |
| **Reporting requirements (REC/MHRA/Sponsor)** |  |  |  |  |
| **Amendments** |  |  |  |  |
| **Archiving arrangements for all site records** |  |  |  |  |

# Trial Master File/Investigator Site File

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| **Master/Site File status** |  |  |  | In progress  Complete  Requires review |
| **Named and Delegated individual(s) for Master/Site File maintenance** |  |  |  |  |
| **Storage location (including CRFS and ICFs)**  **(signposting and notes to file)** |  |  |  |  |

# Essential Records

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Version/ Comments** |
| **Regulatory Approvals (i.e., REC/HRA/MHRA)** |  |  |  |  |
| **R&D/I Approval (including relevant contract)** |  |  |  |  |
| **Indemnity/Insurance Certificate** |  |  |  |  |
| **PI Signed protocol (include version and date)** |  |  |  |  |
| **Localised approved documents (contact numbers/emails checked)**  **<listed latest versions of approved documents, add additional lines if necessary>** |  |  |  |  |
|  |  |  |  |
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# Investigator Site Personnel

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| **Key Site staff (i.e., Sub-Investigators, lead Nurse(s), Admin, etc.)** |  |  |  |  |
| **Completion of Delegation of Authority and Signature Log** |  |  |  |  |
| **Staff training requirements (i.e., signed and dated CV (HRA template)/GCP/Consent/SOP training and read logs/Trial-specific training)** |  |  |  |  |

# Recruitment and Informed Consent

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| **Planned Number of trial participants (total/site)** |  |  |  |  |
| **Methods for identifying trial participants** |  |  |  |  |
| **Completion of Screening and Enrolment logs** |  |  |  |  |
| **Informed consent procedures/documentation** |  |  |  |  |
| **Eligibility criteria** |  |  |  |  |
| **Randomisation procedures** |  |  |  |  |
| **Blinding and Unblinding procedures** |  |  |  |  |
| **Procedure for withdrawn/lost to follow-up participants** |  |  |  |  |

# Investigational Medicinal Products (Check box if N/A )

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| **Overview of IMP management** |  |  |  |  |
| **IMP preparation and administration (i.e., maintaining blind)** |  |  |  |  |
| **IMP compliance and returns** |  |  |  |  |
| **Local IMP storage requirements (i.e., if stored on ward)** |  |  |  |  |

# Medical Devices (Check box if N/A )

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| **Clinical Investigation Plan (CIP)** |  |  |  |  |
| **Device instructions** |  |  |  |  |
| **Receipt of device** |  |  |  |  |
| **Device labelling** |  |  |  |  |
| **Device storage requirements** |  |  |  |  |
| **Device calibration/maintenance** |  |  |  |  |
| **Return of device** |  |  |  |  |

# Safety Reporting

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| **AE/SAE reporting procedures** |  |  |  |  |
| **Approved Reference Safety Information (RSI): Investigator Brochure/SmPC (version/date of document)** |  |  |  |  |
| **Causality and Expectendess Assessments (Delegated individual(s))** |  |  |  |  |
| **SUSAR reporting procedures (via ICSR; CTIMPs only)** |  |  |  |  |
| **Quarterly Medical Device reporting procedures (Device trials only)** |  |  |  |  |
| **Urgent Safety Measures** |  |  |  |  |
| **Data Safety Monitoring Committee meeting and reporting requirements** |  |  |  |  |

# Data and Sample Collection

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| **Site Source Data Agreement** |  |  |  |  |
| **CRFs as source data** |  |  |  |  |
| **CRF completion/corrections** |  |  |  |  |
| **Sample collection and management (i.e., training/manual/SOPs)** |  |  |  |  |
| **Review of clinical results (i.e., blood results, images, scans etc.)** |  |  |  |  |
| **Database training/completion/queries** |  |  |  |  |
| **Protocol Deviation recording procedures (using file notes)** |  |  |  |  |
| **Serious Breach reporting procedures** |  |  |  |  |

# Equipment List (Check box if N/A )

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| **Equipment provided or required for the trial** |  |  |  |  |
| **Calibration of equipment** |  |  |  |  |
| **Maintenance/service record requirements** |  |  |  |  |
| **Return of provided equipment** |  |  |  |  |

# Laboratory (Check box if N/A )

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| **Laboratory** |  |  |  | Local;  Central; |
| **Laboratory accreditation** |  |  |  |  |
| **Laboratory normal values** |  |  |  |  |
| **Laboratory training/manual/SOPs** |  |  |  |  |
| **Laboratory equipment and calibration** |  |  |  |  |
| **Laboratory kits** |  |  |  |  |

# Sponsor Oversight

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| **Communication with the Sponsor** |  |  |  |  |
| **Monitoring Plan** |  |  |  |  |
| **Monitoring requirements** |  |  |  |  |
| **Granting access to systems for monitoring (e.g. electronic medical records/ study database)** |  |  |  |  |
| **Data Management Plan/Quality Control Plan** |  |  |  |  |

|  |
| --- |
| **Additional Comments/Visit Overview** |