Investigator Site file (ISF) Template

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*Where local pharmacy and laboratories are used accreditation certificates and normal lab ranges may be held within these departments. Where external laboratories or pharmacies are used accreditation certificates and normal ranges should be obtained and retained in the site file.*

Study Information/Contact Page

**Study title:**

**UHBW reference number:**

**IRAS number:**

**EudraCT number:**

**Sponsor details**

**Name: Address:**

 **Telephone:**

**Principal Investigator (PI) details**

**Name: Address:**

 **Telephone:**

**Chief Investigator (CI) details (if different from above)**

**Name: Address:**

 **Telephone:**

**Point of Contact (PoC) details**

**Name: Address:**

 **Telephone:**

**Start date: Projected end date:**

File contents

Study Information/Contact Page

Section 1: Funding/costing

* Site Financial Arrangements

Section 2: Sponsorship

* Signed copy of the sponsorship letter
* Relevant ongoing sponsor correspondence

Section 3: Feasibility, Approvals and Permissions

* Records of feasibility activities (capability and capacity)
* Statement of Activities/Organisation Information Document (if applicable)
* R&D approval/NHS permission application (if applicable)
* R&D approval/NHS permission (if applicable)
* R&D correspondence
* HRA approval letter(s)
* REC membership list
* HRA correspondence
* CTA or other regulatory approvals (MHRA)
* MHRA correspondence

Section 4: Study documents

* Log of amendments to study documents (download from or refer to EDGE)
* Protocol and amendments
* Information sheets and amendments
* Consent forms and amendments
* GP letters and amendments
* Advertisements and amendments
* CRF and amendments

Section 5: Contracts

* Site agreement with sponsor OR
* Final Statement of Activities/Organisation Information Document
* Site sub-contracts with service providers

Section 6: IMP/Device information (as relevant)

* Investigator Brochure or Summary of product characteristics (and updates)
* Operating instructions (device)
* Instructions for handling the IMP/trial related materials/device
* Shipping records for receipt of IMP/trial related materials/device (may be held in pharmacy)
* Shipping records for return of IMP/trial related materials/device (may be held in pharmacy)
* Certificate of analysis of IMP
* IMP accountability records (may be held in pharmacy)

Section 7: Study staff (to be updated as staffing changes)

* Site staff CVs
* Site staff training records relevant to the research (GCP, professional, protocol)
* Contractual documents (Letters of Access, Honorary Contracts)
* List of staff working on the study/delegation log

Section 8: Site specific information

* Correspondence/information relating to the site not included elsewhere

Section 9: Trial Management (subdivide if necessary)

*Reference procedural information (as relevant):*

* Study specific standard operating procedures
* Normal/reference value(s)/range(s) for medical/laboratory technical procedure(s) and/or test(s) included in the protocol and any updates
* Medical/laboratory/technical procedures/tests. Including validation, accreditation, certification or quality control and updates
* Procedure for randomisation
* Unblinding procedures for blinded trials

*Patient-specific records*

* Subject screening log
* Subject enrolment log
* Signed informed consent forms
* Confidential subject ID code list (not to be shared with sponsor without consent)
* Record of retained body fluids/tissue samples (as relevant)
* Original CRFs and amendment documentation (may be stored in a separate file if necessary)
* Decoding documentation (to be kept confidentially)
* Treatment allocation

Section 10: Breaches and Pharmacovigilance (as relevant)

* Correspondence relating to breaches of GCP (as applicable)
* SAE reports, follow up reports and correspondence to sponsor
* Copies of SUSAR related correspondence between sponsor (or site as representative of sponsor) and MHRA/REC
* Relevant safety information received from sponsor

Section 11: Monitoring and Audit

* Correspondence relating to monitoring/audit visits
* Completed monitoring reports and responses
* Audit certificates (if applicable)

Section 12: Data management

* Data Management processes
* Documentation of deviation from Data Management processes
* Correspondence

Section 13: Reporting

* Reports to sponsor (as required)
* Reports to HRA (as required)
* Reports to MHRA (as required)
* Any other reports required (e.g. funder reports)

Section 14: End of study

* Copy of final report
* Planned archiving arrangement

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| **Study short title** |  |
| **UHBW ref no.** |  | **IRAS no.** |  | **Principal Investigator** |  |
| **Sponsor** |  | **Site** |  |
| **Site Staff Training Log** (for documenting protocol training, GCP training or SOP training – can be used for groups or individuals) |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Date of training | Type of Training Undertaken (e.g. trainer, meeting, read document) | Name of trainee or protocol/SOP**/**other**\***  (\*ensure the version number and date are documented please) | Name of trainer (if applicable) | Signature (trainee) | Signature of trainer (if applicable) |
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Name of SOP\* **or trainee**:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Use 1 sheet per person for multiple SOPs or one per SOP for multiple staff)

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| **Study short title** |  |
| **UHBW ref no.** |  | **IRAS no.** |  | **Principal Investigator** |  |
| **Sponsor** |  | **Site** |  |
| **Site Staff List, Signature log and Delegation of Site Tasks** |

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|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Name | Role in Study | Start date | End date | Tasks delegated(Use codes below) | Staff Signature | Initials | Authorisation Signature of PI | Date of authorisation |
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**\*** **Please list study tasks (amend/delete as necessary)**. ***NB All eligibility decisions, prescribing of IMP and assessment of causality for Safety Reporting for CTIMPs must be taken by a medically qualified doctor (MQD), unless agreed in advance in writing with the sponsor and the MHRA. They cannot be delegated.***

|  |  |  |
| --- | --- | --- |
| **1. Screening of participants** | **7. CRF completion/corrections** | **13. Sample collection/Sample preparation** |
| **2. Confirming Eligibility** \* | **8. TMF/ISF Maintenance Responsibility** | **14. Statistical analysis** |
| **3. Obtaining Informed Consent** | **9. Data Management** | **15. Data QC and query resolution** |
| **4. Randomisation of participants** | **10. Safety Reporting- Identification and reporting of SAEs** | **16. Archiving** |
| **5. Prescribing of IMP**\* | **11. Assessment of Causality for Safety Reporting (MQD if CTIMP\*)** | **17. Other (Specify)** **1** |
| **6. Administration of IMP to patients** | **12. Reporting protocol breaches** | **18. Other (Specify)** |

**1** It may be appropriate for some studies, to have a separate pharmacy delegation log which breaks down pharmacy-specific activities (e.g. Maintenance of Pharmacy File, IMP dispensing, IMP accountability records, IMP receipt/storage and IMP return/destruction etc.

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| **Study short title** |  |
| **UHBW ref no.** |  | **IRAS no.** |  | **Principal Investigator** |  |
| **Sponsor** |  | **Site** |  |
| **Subject Screening and Recruitment Record** |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Initials | Gender | Screening date(dd/mm/yyyy) | Patient hospital number | Outcome -Please tick | 1. Study / randomisation number if applicable, or
2. Reason for screen failure
 | Withdrawal date(dd/mm/yy) | Completed study Y/N |
| Male | Female |
|  | [ ]  | [ ]  |  |  | Recruited |  | 1. |  |  | [ ] Y [ ] N |
|  Screening failure |  | 2. |  |
|  | [ ]  | [ ]  |  |  | Recruited |  | 1. |  |  | [ ] Y [ ] N |
|  Screening failure |  | 2. |  |
|  | [ ]  | [ ]  |  |  | Recruited |  | 1. |  |  | [ ] Y [ ] N |
|  Screening failure |  | 2. |  |
|  | [ ]  | [ ]  |  |  | Recruited |  | 1. |  |  | [ ] Y [ ] N |
|  Screening failure |  | 2. |  |
|  | [ ]  | [ ]  |  |  | Recruited |  | 1. |  |  | [ ] Y [ ] N |
|  Screening failure |  | 2. |  |
|  | [ ]  | [ ]  |  |  | Recruited |  | 1. |  |  | [ ] Y [ ] N |
|  Screening failure |  | 2. |  |
|  | [ ]  | [ ]  |  |  | Recruited |  | 1. |  |  | [ ] Y [ ] N |
|  Screening failure |  | 2. |  |
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|  Screening failure |  | 2. |  |

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| **Study short title** |  |
| **UHBW ref no.** |  | **IRAS no.** |  | **Principal Investigator** |  |
| **Sponsor** |  | **Site** |  |
| **Study Specific Document Log** |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study number/ Randomisation number | Date consent given(dd/mm/yyyy) | Patient Information Sheet | Signed Informed Consent Form | GP letter  |
| Date copy given to patient  | \* Copy to medical records | \* Original to site file | \* Copy to patient | \* Copy to medical records | Date sent to GP | \* Copy to medical records |
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*\* Please tick and date when complete*

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| **Study short title** |  |
| **UHBW ref no.** |  | **IRAS no.** |  | **Principal Investigator** |  |
| **Sponsor** |  | **Site** |  |
| **Record of retained body fluids/tissue samples** |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| PatientStudyNumber /Randomis-ation number | Patient consent for sample collection provided?Y / N | Date sample collected(dd/mm/yy) | Sample Type | Storage location\* | Storage period |
| From | To(date sample destroyed) |
|  | [ ] Y [ ] N |  |  |  |  |  |
|  | [ ] Y [ ] N |  |  |  |  |  |
|  | [ ] Y [ ] N |  |  |  |  |  |
|  | [ ] Y [ ] N |  |  |  |  |  |
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|  | [ ] Y [ ] N |  |  |  |  |  |

\*Please specify, Building, department, location and type of storage facility

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