**LJMU STUDY MASTER FILE AUDIT**

Please mark each item as ✓, 🗶, or n/a in the ‘Present’ column.

Ensure that updated documents are filed in reverse chronological order and older versions should have ‘SUPERCEDED’ written through them

|  |  |  |
| --- | --- | --- |
| **Item** | **Present?** | **Comment** |
| Title of Research Project |  |  |
| IRAS Ref |  |  |
| NHS Trust R&D Ref |  |  |
| Chief Investigator |  |  |
| Lead Centre |  |  |
| Other Members of the Research Team |  |  |
| ISRCTN Ref (if appropriate) |  |  |
| ClinicalTrials.gov ID (if appropriate) |  |  |
| EudraCT Ref (if appropriate) |  |  |
| Other Ref(s) |  |  |
| Start Date |  |  |
| Proposed End Date |  |  |

**PLEASE NOTE:** Those documents marked with an asterisk (\*) may not be required for all projects.

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| **1. Protocol**  |
| Final, signed research protocol and amended protocols, with version numbers  | □  |
| Confirmation of peer review  | □  |
| Example of Informed Consent Form and any amendments  | □  |
| Examples of any other written information provided to subjects and any updates \*  | □  |
| Copy of advertisement for subject recruitment and any amendments \*  | □  |
| Copy of any letter/information for a patient’s GP or Consultant \*  | □  |
| Investigator’s Brochure and updates \*  | □  |
| **2. Ethics**  |
| Final Ethics application and any amendments  | □  |
| Ethics approval letter(s)  | □  |
| Any Ethics Correspondence  | □  |
| Ethics Reports  | □  |
| **3. Research and Development**  |
| Trust R&D application form and approval letter  | □  |
| Copy of financial information relating to the study (funding application/award letter/costings)  | □  |
| Insurance Statement (copy of any certificate/letter/agreement)  | □  |
| Copy of Sponsor agreement and allocation of responsibilities  | □  |
| Copy of any signed agreement(s) between involved parties  | □  |
| **4. Regulatory**  |
| Regulatory Application Form(s) (if applicable) \*  | □  |
| Regulatory Approval(s) (if applicable) \*  | □  |

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| **5. Correspondence (except Trust and Ethics)**  |
| Relevant written correspondence  | □  |
| **6. Research Team – Staff and Training**  |
| Location of Signed/dated CVs evidencing the qualifications of CI/research team (or other relevant documents)  | □  |
| Delegation of duty log  | □  |
| Staff training records  | □  |
| Signature log  | □  |
| Location of Honorary Contracts or Licence To Attend or Letter of Access  | □  |
| **7. Participant Information**  |
| Location of informed consent forms signed by each project participant  | □  |
| Master randomisation list  | □  |
| Subject screening log  | □  |
| Subject ID code list  | □  |
| Subject enrolment log  | □  |
| **8. Data Collection**  |
| Sample Case Report Form and completion guidance  | □  |
| Record of retained body fluids/tissue samples (if any) \*  | □  |
| Normal laboratory reference ranges for any tests used or medical/technical procedures included in protocol (includes central labs) \*  | □  |
| Lab/technical procedures/tests certification or accreditation \*  | □  |
| Copies of calibration records for technical equipment \*  | □  |
| **9. Serious Adverse Events \***  |
| Sample SAE form and copy of reporting procedures \*  | □  |
| Completed SAE forms (if not included in the Case Report Forms) \*  | □  |
| Copies of correspondence from CI to Sponsor/Regulatory Authority(ies) reporting SAEs \*  | □  |
| Safety reports \*  | □  |
| **10. Pharmacy/Product-Related \***  |
| Decoding procedures for blinded trials \*  | □  |
| **11. Monitoring and Audit**  |
| Record(s) of all monitoring reports  | □  |
| Final close-out monitoring report  | □  |
| Audit certificate (if available) \*  | □  |
| Clinical trial report \*  | □  |