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Ensure that updated documents are filed in reverse chronological order and older versions should have ‘SUPERCEDED’ written through them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

|  |  |
| --- | --- |
| **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 \* | □ |