LJMU Audit Report form (Clinical Research)

|  |  |
| --- | --- |
| Study title: | PI: |
| Sponsor: | Visit Date: |

|  |  |
| --- | --- |
| Site Address |  |
| Research team present & role |  |
| R&D personnel present & role |  |

1. **Patient Recruitment**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Total screened |  | Total screen failures |  | Number in screening |  | Number recruited |  |
| Number active on study |  | Number withdrawn |  | Number completed |  | | |

1. **Site Personnel Evaluation**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Yes | No | NA | Comments  (if applicable include a comment) |
| 2.1- Is the Delegation Log up-to-date? |  |  |  |  |
| 2.2- Has the PI authorised each research team member? |  |  |  |  |
| 2.3- Are roles & responsibilities of each member assigned appropriately? |  |  |  |  |
| 2.4- Are all the team members appropriately trained, qualified and experienced? |  |  |  |  |
| 2.5- Is there a signed CV & GCP certificate for each team member (where applicable)? |  |  |  |  |

1. **Informed Consent**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Yes | No | NA | Comments  (if applicable include a comment) |
| 3.1- Is there a copy of the ICF in the site file for ALL patients? |  |  |  |  |
| 3.2- For ALL patients, was the correct ICF version used? |  |  |  |  |
| 3.3- Are only appropriately delegated site personnel performing informed consent? |  |  |  |  |
| 3.4- Were all the ICFs signed and dated by both patient & investigator? |  |  |  |  |
| 3.5- Did the patient and investigator sign & date on the same day? |  |  |  |  |
| 3.6- Have patients initialed rather than ticked the appropriate boxes? |  |  |  |  |
| 3.7- Is the consent log up to date? |  |  |  |  |
| 3.8- Have there been any amendments to the consent form, information sheet or protocol that require patients to re-consent? |  |  |  |  |
| 3.9- If yes, have all patients been re-consented as required? |  |  |  |  |

1. **Site File / Study Documentation**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Yes | No | NA | Comments  (if applicable include a comment) |
| 4.1- Are there screening & enrolment logs in place? |  |  |  |  |
| 4.2- Are the Screening/Enrolment Logs accurate & up-to-date? |  |  |  |  |
| 4.3- Is full Ethical approval granted and up-to-date? |  |  |  |  |
| 4.4- Is R&D approval granted and up to date? |  |  |  |  |
| 4.5- Is regulatory approval (MHRA) granted and up to date (where applicable)? |  |  |  |  |
| 4.7- Are all SAEs (initial/follow-up) on file & have they been reported to the CI / EC? |  |  |  |  |
| 4.8- Are all SUSAR / Safety Reports on file? |  |  |  |  |
| 4.9- Is all relevant documentation present according to the filing index? |  |  |  |  |
| 4.10- Are the most up-to-date versions of study documents being used?  Eg Protocol, PIS, GP letter, Invite letter? |  |  |  |  |
| 4.11- Are patient related documents appropriately headed & contain local contact details? |  |  |  |  |
| 4.12- Is the site file in good condition with regards to filing? |  |  |  |  |

1. **Summary of Findings:**

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| --- | --- |
| Signature of Monitor/Date | Printed Name and Title |
|  | Monitor: |
| Signature of Reviewer/Date | Printed Name and Title |
|  | R&D Manager: |