**Pharmacy Site Checklist**

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| --- | --- |
| **Study Title:** |  |
| **Chief Investigator:** |  |
| **IRAS number:** |  |
| **Date Created:** |  |

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| --- | --- | --- | --- |
|  | **Document** | **Y/N** | **Comments** |
|  | **Administrative** |
|  | Contact list  |  | *To include contact details for out of hours study provisions* |
|  | Version control log |  | *Please list the current version of the protocol, PIS, ICF, GP Letter. Any other patient facing document.**Please reference the amendment which included the updated versions.* |
|  | File note log |  | *Deviations should not be logged on file notes. Use the deviation log accordingly* |
|  | **Study Protocol**  |
|  | Current version  |  |  |
|  | Superseded protocol(s) |  | To be marked as superseded |
|  | **Sponsor** |
|  | Sponsorship with conditions email |  |  |
|  | Confirmation of sponsorship email |  |  |
|  | Conditions of sponsorship  |  | *This is the sponsor-CI agreement*  |
|  | Study commencement notification to sponsor |  |  |
|  | Notification of first participant consented to sponsor |  |  |
|  | Correspondence  |  | *Pertinent/decision making correspondence only* |
|  | Departmental authorisation  |  | *Acknowledgment of study from Head of Department*  |
|  | Confirmation of Capacity and Capability email |  |  |
|  | Organisation identification document (OID) (or contract, or other agreement with site) |  |  |
|  | **Medicines and Healthcare products Regulatory Agency (MHRA)** |
|  | Original Competent Authority application  |  |  |
|  | **Ethics**  |
|  | Original ethics application  |  |  |
|  | **Health Research Authority (HRA)** |
|  | HRA approval |  |  |
|  | **Other Regulatory Approval (include Full submission, approval and correspondence in each case)** |
|  | Administration of Radioactive Substances Advisory Committee (ARSAC)  |  | *If applicable* |
|  | National Offender Management Service (NOMS), Her Majesty's Prison and Probation Service (HMPPS)  |  | *If applicable* |
|  | Confidentiality Advisory Group (CAG)  |  | *If applicable* |
|  | Gene Therapy Advisory Committee (GTAC)  |  | *If applicable* |
|  | Other approvals as applicable |  | *If applicable* |
|  | **Amendments** |
|  | Amendment log |  | *All versions, previous versions to be marked as superseded* |
|  | Non-substantial/amendments |  | *All full amendment packages including evidence of submission to be filed in chronological order, pre-approval amendments to be filed as part of final sponsorship approval.* *Note: Amendments cannot be submitted or implemented without sponsor authorisation to submit or implement, please file evidence of sponsor authorisation to submit and sponsor implementation of amendment.*  |
|  | Substantial amendments |  |
|  | **Research Team – Staff and Training**  |
|  | Delegation log for site and pharmacy team |  | *Delegation log template* |
|  | Signed and dated CVs & Good Clinical Practice certificates |  |  |
|  | Study specific/SOP training  |  | *Training template 10 of SOP 45 can be used* |
|  | **Medicinal products** |
|  | Pharmacy Approval |  | *Provisional and final approvals* |
|  | Investigator Brochure (IB) and/or Summary of product characteristics (SmPC) and updates, including acknowledgement of receipt |  |  |
|  | Pharmacy Manual |  |  |
|  | IMP Management Plan |  |  |
|  | Sample & Completed IMP Accountability/Dispensing logs |  |  |
|  | Sample & Completed Prescription(s) |  |  |
|  | Study Specific Dispensing procedures |  |  |
|  | Records of IMP destruction/return  |  |  |
|  | Decoding/Unblinding procedures (where applicable) |  |  |
|  | IMP documentation for ordering and receipt |  |  |
|  | Qualified Person (QP) release certificates for all IMP batches |  |  |
|  | Certificates of Analysis for all IMP batches |  |  |
|  | Sample IMP label including record of relabelling (if applicable) |  |  |
|  | QP Third Party Declaration - for IMPs manufactured outside of the EU (where applicable) |  |  |
|  | Transmissible Spongiform Encephalopathies (TSE) statement/certificate (if applicable) |  |  |
|  | Temperature Monitoring Records |  |  |
|  | Temperature storage records including records of all deviations |  |  |
|  | Calibration and service records |  |  |
|  | **Participant data** |
|  | Participant identification log |  |  |
|  | **Deviations and breaches** |
|  | Deviation log  |  |  |
|  | Potential Serious Breaches and Serious Breaches |  |  |
|  | Correspondence |  | *Assessment of potential serious breaches, serious breaches and any other pertinent/decision making emails to be included* |
|  | **Monitoring, Audits and Inspections.** |
|  | Internal pharmacy and sponsor risk assessments |  |  |
|  | Monitoring plan |  |  |
|  | Monitoring visit log  |  |  |
|  | Site Initiation Visit (SIV) documentation  |  |  |
|  | Pharmacy Monitoring documentation  |  |  |
|  | Close out visit documentation for Pharmacy  |  |  |
|  | Audit and Inspection certificates |  |  |
|  | **Correspondence** |
|  | Any pertinent correspondence not associated with the sections listed above |  |  |