PhEAST *–* Investigator Site File Index

Cover Sheet

Trial Office contact sheet V4.0 20221108

Investigator Site File Index

**Section A – Pre-trial Opening**

|  |  |  |
| --- | --- | --- |
| A.1 Trial Development Documentation | File note from coordinating centre |  |
| A.2 Study protocol and associated documents – current versions | Current protocol | PhEAST Protocol Final V5.0 20220908 |
| Superseded versions of protocol | PhEAST Protocol Final V4.0 20220624\_cleanPhEAST protocol final v3.0 – 20220225.docx |
| Signed PI protocol signature page |  |
| Superseded signed PI protocol signature pages |  |
| All current patient facing documentation (England, Wales & NI) | Aphasia Friendly PIS and ICF V2.0 20220809Consultee Declaration Form v3.0 20220513Consultee PIS Final V4.0 20220809Consultee Tel Declaration Form Final V3.0 20220513 clean.docxInformant Consent Form V1.0 20220624.docxInformant Information Sheet v1.0 20220624 clean.docxInformant Tel Consent Form England and Wales V2.0 20220727Participant Re-consent Final V3.0 20220513 clean.docxParticipant consent Final V3.0 20220513 clean.docxParticipant Informant Sheet V4.0 20220809 |
| Superseded patient facing documentation (England, Wales & NI) | Aphasia Friendly PIS and ICF V1.0 20220629.docxConsultee PIS Final V3.0 20220513 clean.docxInformant Tel Consent Form England and Wales V1.0 20220624.docxPhEAST Consultee PIS Final v2.0\_ 20211202PhEAST long PIS Final v2.0\_20211202PhEAST Short Pictorial Final v2.0\_ 20211202PhEAST Consultee Declaration Form Final v2.0\_ 20211202 PhEAST Consultee Tel Declaration Form Final v2.0\_20211202 PhEAST Participant consent Final v2.0\_ 20211202 PhEAST Participant Re-consent Final v2.0\_ 20211202 |
| Current GP letter (England, Wales & NI) | GP letter Final V3.0 20220513 clean.docx |
| Superseded GP letters (England, Wales & NI) | PhEAST GP letter Final v2.0\_ 20211202 |
|  | All current patient facing documentation (Scotland) | Participant Information Sheet V5.0 20221027Participant Consent Form V3.0 20220513Participant Recovered Capacity PIS V3.0 20221027Aphasia Friendly PIS & ICF V2.0 20221027Scotland Informant (WA.WG.NR) PIS V1.0 20220624Scotland Informant (WA.WG.NR) Tel Consent Form V1.0 20220624Scotland Informant (WA.WG.NR) Consent Form V1.0 20220624Legal Rep (WA.WG.NR) Consent Form V4.0 20220513Legal Rep (WA.WG.NR) Information Sheet V5.0 20221027Legal Rep (WA.WG.NR) Tel Consent Form V4.0 20220513Recovered Capacity Re-Consent V4.0 20220513 |
|  | Superseded patient facing documentation (Scotland) | Participant Information Sheet V4.0 20220513Participant Recovered Capacity PIS V2.0 20220513Aphasia Friendly PIS & ICF V1.0 20220629Legal Rep (WA.WG.NR) Information Sheet V4.0 20220513 |
|  | Current GP Letter (Scotland) | V3.0 20221027 |
|  | Superseded GP Letter(s) (Scotland) | V2.0 20220104 |
| **A.3 Approvals and Agreements** | Initial REC Approval Letter |  |
| England: dated 06/12/2021 |  |
| Scotland: dated 09/02/2021 |  |
| Initial HRA Approval Letter dated 07/01/2022 |  |
| Sponsor Regulatory Green Light |  |
| R&D Approval |  |
| Signed non-commercial research agreement |  |
| Organisation Information Document (OID) | PhEAST OID NonCommercial\_v1-6 authorised 20210930 |
| SoECAT (authorised 11/03/2020) |  |
| Sponsorship statement dated 04/10/2021 |  |
| Current Letter of Insurance  |  |
|  | Superseded Letters of Insurance |  |
| **A.4 Staff Participation** | PhEAST File Note A4 Site File - Delegation logs |  |
| Signed and dated CVs and GCP (in date) |  |
| SIV attendance log & Phagenesis Face to face training log (RF1 TA008) |  |
| SOP TA008 SIV  |  |
| Attendance at Investigator Training File Note |  |
| Current training slides (SIV) | SIV V5.0 20221412 |
| Superseded  | SIV V4.0 20221027SIV V3.0 20220811SIV V2.0 20220328SIV V2.1 20220412SIV V2.3 20220527SIV V2.2 20220504Signed Delegation Log (RF2 TA008) |
| **A.5 Medical Testing and Pharmacy** | Confirmation of MPE approval |  |
| Phagenesis training slides | EPSB Training slides practical  |
| Trial Manual | V3.0 20221027 |
| Superseded Trial Manual | V2.0 20220811V1.0 20220504 |
| Supplies log V1.0 20220308 |  |
| **A.6 Randomisation and Blinding** | File note from coordinating centre Superseded file note from coordinating centre | V2.0 20220426V1.0 20220218 |
| **A.7 Database Build** | File note from coordinating centre |  |

**Section B: Ongoing Trial**

|  |  |  |
| --- | --- | --- |
| B.1 Study Protocol Amendments and Approvals  | RF1 TA013 Amendment Log |  |
| All study amendments and approvals from TA013 amendment log |  |
| B.2 Staff Participation  | Updates where applicable |  |
| **B.3 Informed Consent** | Signed Informed Consent Forms (master copies) |  |
| Signed GP letters (master copies) |  |
| Participant screening and enrolment log (RF1 TA011) |  |
| Patient notes labels |  |
| **B.4 Medical Testing and Pharmacy** | Updates where applicable |  |
| **B.5 CRFs and Source Documents** | Paper CRFs (if site is using – found on trial website, superseded and current) |  |
| Any relevant participant results (radiology scans, blood test results etc) |  |
| **B.6 Serious Adverse Events** | SAE report forms signed and dated by PI (where applicable)Safety reporting notifications (where applicable)Protocol violation report forms (where applicable) |  |
| **B.7 Biological Materials** | File note from coordinating centre |  |
| **B.8 Audit and Reporting** | Site visit log |  |
| Monitoring reports  |  |
| Completed monitoring visit action lists |  |
| **B.9 Miscellaneous** | Correspondence |  |
| File note template |  |
| Completed file notes |  |
| WPDs:(i) 001 Screening and Enrolment Log(ii) 002 Consent(iii) 003 Emergency Randomisation(iv) 004 Decontamination of Equipment(v) 005 Trial Monitoring(vi) 008 Blinding(vii) 009 Document Preparation(viii) 010 Secure Vault Uploads |  |
| Newsletters |  |