PhEAST *–* Investigator Site File Index

Cover Sheet

Trial Office contact sheet V1.0 20220214

Investigator Site File Index

**Section A – Pre-trial Opening**

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| A.1 Trial Development Documentation | File note from coordinating centre |  |
| A.2 Study protocol and associated documents – current versions | Current protocol | PhEAST Protocol Final V4.0 20220624\_clean |
| Superseded versions of protocol | PhEAST protocol final v3.0 – 20220225.docx |
| Signed PI protocol signature page |  |
| Superseded signed PI protocol signature pages |  |
| All current patient facing documentation | Aphasia Friendly PIS and ICF V1.0 20220629.docxConsultee Declaration Form V3.0 20220513 clean .docxConsultee PIS Final V3.0 20220513 clean.docxConsultee 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 V1.0 20220624.docxParticipant Re-consent Final V3.0 20220513 clean.docxParticipant consent Final V3.0 20220513 clean.docxLong PIS Final V3.0 20220513 clean.docx |
| Superseded patient facing documentation | PhEAST Consultee PIS Final v2.0\_ 20211202PhEAST long PIS Final v2.0\_20211202PhEAST Short Pictorial Final v2.0\_ 20211202PhEAST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 | GP letter Final V3.0 20220513 clean.docx |
| Superseded GP letters | PhEAST GP letter Final v2.0\_ 20211202 |
| **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  |  |
| **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 V3.0 20220811 |
| Superseded  | SIV V2.0 20220328SIV V2.1 20220412SIV V2.23 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 | V2.0 20220811 |
| Superseded Trial Manual | V1.0 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**

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| 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) |  |
| 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 |  |
| Newsletters |  |