|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Sponsor Ref** |  | **EudraCT Ref** |  | **REC Ref** |  | **R&D** |  |
| **Protocol Title**  |  |
| **Chief Investigator** |  |
| **Trial Pharmacist** |  | **Address** |  |
| **Site Name** |  | **Site No.** |  |
| **IMP**  |  |
| **Document** | **Version** | **Date** | **Comments** |
| Protocol |  |  |  |
| IB/SmPc |  |  |  |
| MHRA Approval |  |  |  |
| REC favourable opinion |  |  |  |
| R&D Permission |  |  |  |
| Date of Co-sponsorship agreement |  |  |  |
| Confirmation of QP release (Active + Placebo) |  |  |  |
| Current Clinical Trials Insurance UoA/ CNORIS NHS-G |  |  |  |
| Confirm all conditions of approvals have been met |  |  |  |
| Technical agreements in place |  |  |  |
| Laboratory File/Folder in place |  |  |  |
| Authorised Prescribers’ Signature Log |  |  |  |
| Unblinding documentation in Pharmacy |  |  |  |

The CTIMP is approved to commence recruitment and for the dispensing of IMP/Placebo only when this document has been signed by both the NHS-Grampian CTP and the NHSG/University RGM

**Signed on behalf of CTP**: Signature: Date:

 Job Title: Print Name:

**Signed on behalf of the Co-Sponsor:** Signature: Date:

Job Title: Print Name: