DASH Site Monitoring Visit– Investigator Site File Checklist

**Centre No: Site Name:**

**Date of completion:**

Investigators present:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Yes | No | N/A | Comments |
| (please initial) | | |
| Is there an Investigator Site File? |  |  |  |  |
| Does it contain the following: |  |  |  |  |
| 1.  a. Contact details of trial office staff & emergency phone numbers  b. Delegation Log  c. Any further training logs  d. Signed and dated CVs and GCP (in date) and updated as per sites policies and procedures |  |  |  |  |
| 2.  a. Signed Protocol  Current: v2.0 26 August 2019  Superseded: v1.0 03 August 2018  b. Current approved Information Sheets and Consent Forms on local headed paper:  (i) Nominee consent form v2.0 26 August 2019  (ii) Participant consent form v2.0 26 August 2019  (iii) Participant information sheet v2.0 26 August 2019  (iv) Nominee information sheet v2.0 26 August 2019  (v) Short pictorial v2.0 11 January 2019  Superseded versions:  (i) Nominee consent form v1.5 09 October 2018  (ii) Participant consent form v1.5 09 October 2018  (iii) Participant Information sheet v1.0 23 July 2018  (iv) Nominee information sheet v1.0 23 July 2018  c. GP Letter  Current: v2.0 26 August 2019  Superseded: v1.0 31 May 2018 |  |  |  |  |
| 3.  a. Initial REC approval letter  b. Initial HRA Approval letter  c. Additional HRA documents  (i) Schedule of events v2  (ii) Statement of activities v2  (iii) CI Absence  c. Initial MHRA approval letter  d. Amendment approvals:  SA/01/19 and SA/02/19  SA/03/19  MA/04/19  MA/05/20  MA/06/20  MA/07/21  e. Initial R&D approval letter  f. Organisational Information Document |  |  |  |  |
| 4.  a. Current case report forms (CRFs)  (i) Randomisation v1.1  (ii) Day 1 follow-up v1.1  (iii) Day 2 follow-up v1.0  (iv) Discharge or death in hospital v1.1  b. Data correction request form. V1.0  c. Protocol violation form v1.1  d. Serious adverse event form v1.1  e. Site-to-site transfer form v1.0  f. Patient details v1.0  g. File note template  h. Recruitment fax cover sheet v1.0  i. Screening log fax cover sheet v1.0  j. Superseded versions of the above (where applicable):  (i) Randomisation v1.0  (ii) Day 1 follow-up v1.0  (iii) Discharge or death in hospital v1.0  (iv) Serious adverse event v1.0 |  |  |  |  |
| 5.  a. Letter of Insurance, dated:  (i) 1st Aug 2018 – 31st July 2019  (ii) 1st Aug 2019 – 31st July 2020  (iii)1st Aug 2020 – 31st July 2021  (iv) 1st Aug 2021 – 31st July 2022  b. Sponsor letter  c. UKCRN Adoption letter  (dated: 10th November 2016)  d. SOPs/WPDs  SOPs:  (i) TA008 Trial Initiation v3.5  (ii) TA009 CRF Design v1.0  (iii) TA010 TMF and TSF v2.0  (iv) TA011 ParticipantRecruitConsent v1.0  (v) TA012 Trial monitoring v1.0  (vi) TA013 Protocol amendments v4.5  (vii) TA014 SAE reporting v3.0  (viii) TA015 Trial closure v3.0  (ix) TA016 Serious GCP breach reporting v1.5  WPDs:  (i) 001 Data management v1.0  (ii) 002 Storage guidelines for desmopressin v1.0  (iii) 003 Entry of missing data v1.0  (iv) Database testing and change control v1.0  (v) Manual randomisation v1.0  (vi) 006 Emergency unblinding procedure v1.0  (vii) 007 Uploading images v1.0  e. Use of your personal data in research (pdf) |  |  |  |  |
| 6.  Signed Clinical Trial Agreement (Trust and sponsor signed)(Contract) |  |  |  |  |
| 7.  a. Drug Accountability Log  b. Summary of Product Characteristics (SmPC)  c. Screening and enrolment log  d. Freezer log |  |  |  |  |
| 8.  a. Sponsor site monitoring report  b. Internal monitoring/audit reports  c. Local Annual Reports |  |  |  |  |
| 9.  a. SAE report forms signed and dated by PI (where applicable)  b. SUSAR notifications (where applicable)  c. Protocol violation report forms signed and dated by PI (where applicable) |  |  |  |  |
| 10.  a. Signed informed consent forms (master copies)  b. Patient details form (if not filed separately) |  |  |  |  |
| 11.  Relevant, important correspondence |  |  |  |  |
| 12.  a. Are you able to check the blood samples collected? (Is the freezer available to check samples?)  b. Are blood samples appropriately labelled and stored? (Are they labelled with DASH, date taken, sample type (i.e. serum, plasma), and full trial ID? No patient identifiable information should be on samples).  c. Are the facilities adequate. Freezer temp: -…..c (preferably -80degree freezer required, but -40degree adequate).  d. Do the samples match the freezer log in ISF? (And the eCRF data entries). |  |  | X  X  X  X | Due to COVID, we weren’t able to visit site to perform these checks. |
| 13.  a. Laboratory accreditation certificate  b. Lab ranges |  |  |  |  |

**Any further comments:**

Principal Investigator signature: Date:

Research nurse/coordinator signature: Date: