**Participating Site File Index**

**1. Contact Information**

1.1 Sponsor

1.2 Chief Investigator

1.3 Principal Investigator

1.4 Key contact(s) detail(s)

1.5 24 hour contact number (for study participants and study site personnel), if applicable

**2. Study Correspondence**

2.1 General correspondence: letters, faxes, emails files, significant phone calls in date order with most recent at top

**3. Protocol and Amendments**

3.1 Current, signed version of protocol, numbered and dated

3.2 Superseded protocols

3.3 Amendments - numbered

3.4 R&D approval of amendment

3.5 Questionnaires (if applicable): all versions

3.6 GP letter: all versions

3.7 Posters/advertisements (if applicable): all versions

**4. Ethics**

4.1 Favourable opinion letter(s): REC

4.2 Amendments favourable opinion

4.3 Copy of final ethics report from Chief Investigator

**5. Funder**

5.1 Award letter

**6. NHS organisation approval**

6.1 Site Specific Information

6.2 R&D approval

6.3 Agreements/contracts (if applicable)

6.4 Honorary contract/letter of access

6.5 ARSAC certificate (if appropriate)

6.6 Study teams CVs: signed and dated

**7. Sponsor**

7.1 Related correspondence, filed in date order with most recent at top

**8. Safety information/reporting - (only applicable if study drug involved)**

8.1 Copy of procedure for recording and reporting Adverse Events if not written into protocol

8.2 Adverse Events/Serious Adverse Events at site

8.3 Adverse Events/Serious Adverse Events reported by Chief Investigator from other sites involved in the study

**9. Study documents**

9.1 Patient/Relative Information Sheet: all versions

9.2 Informed Consent Form: all versions

9.3 Responsibilities log: signed and dated by study team

9.4 Patient screening/recruitment/withdrawals record

9.5 Patient identification log

 **NB: The patient identification log should be stored securely and separately from the site file but be accessible for the relevant study team member(s) and for audit/inspection purposes.**

9.6 Original signed and dated versions of informed consent forms

9.7 Sample CRF/data collection form/questionnaire

 **NB: Completed CRFs/data collection forms must be stored securely and separately from the site file.**

9.8 Recruitment status

**10. Good Clinical Practice for research studies**

10.1 Audit report(s)

10.2 Training logs

10.3 Study specific Standard Operating Procedures/Work Instructions

**11. Body fluid/tissue sample retention**

11.1 Record of retained body fluids/tissue samples

11.2 Bio-repository paperwork

**12. Investigator meetings**

12.1 Minutes of Investigator meetings

**13. Laboratory / Equipment**

13.1 Calibration logs/other

13 2 Temperature logs

13.3 Reference ranges

13.4 Accreditation certificates

**14. Archiving**

14.1 Procedure for end of trial

**15. File notes**

15.1 Procedure for file notes

15.2 Completed, signed and dated file note(s)

**16. Other**