1.0 Site Trial Team

1.1 Contact List

1.2 Delegation and Signature Log

1.3 CVs including copies of Medical Licenses

1.4 GCP Training Certificates

1.5 EDC (Electronic Data Capture) Training Certifications

1.6 Other Training Certificates

2.0 Project Management

2.2 Internal Team Communication

3.0 Protocol/Protocol Amendments

3.1 Site Protocol Version Tracker

3.2 Current HREC Approved Study Protocol signed by PI

3.3 Superseded Study Protocols signed by PI

3.4 Local Site Non-Compliance Log

3.5 Non-Compliance Reports

3.6 Local Serious Breaches and CAPA Documents

3.7 Copy of all Serious Breach reports to Sponsor and local Research Governance Office or regulatory Authority

3.8 Related Correspondence

4.0 Participant Information & Consent Forms (Site-Specific)

4.1 Site-Specific PGICF & PICF Version Trackers

4.2 Current Site-Specific PGICF & PICFs

4.3 Other Authorised Site-Specific Participant Information

4.4 Superseded Site-Specific PGICF & PICFs

4.5 Other superseded Authorised Site-Specific Participant Information

4.6 Signed PGICF & PICFs

5.0 Regulatory

5.1 Current and superseded regulatory Authorisation or Acknowledgement

5.2 Supplementary FDA Documents

6.0 Ethics Committee

6.1 Ethics Approval Letters (current and superseded)

6.2 Ethics Submission Documentation (initial and amendments including queries + responses)

6.3 Ethics Committee Composition, Constitution & Statement of Compliance

6.4 Interim/Annual / Final Reports to Ethics Committee and Committee Acknowledgements of Receipt

6.5 Related Correspondence

7.0 Local Research Governance Office (RGO)

7.1 Governance Authorisation Letters (current and superseded)

7.2 RGO Submission Documentation (initial and amendments including queries + responses)

7.3 Annual Project Progress Reports & Final Project Report with Receipt acknowledgements

7.4 Related Correspondence (to and from local RGO)

8.0 Site-Specific Procedures/SOPs

8.1 Current Site-Level Manual of Procedures / trial-related Standard Operating Procedures, if applicable

8.2 Superseded Site-Level Manual of Procedures / trial-related Standard Operating Procedures, if applicable

9.0 Site Initiation

9.1 Site Initiation Meeting Documentation; including Agenda, attendance log, and Site Initiation presentation

9.2 Site Initiation Report and Follow Up Letter

9.3 Site Activation Documentation/Letter

10.0 Site Training

10.1 Investigator Meetings

10.2 Other Presentations

10.3 Trial Specific Training Log

10.4 Other Training Resources

11.0 Participant Recruitment

11.1 Pre-Screening Log

11.2 Consent, Screening & Enrolment Log Template

11.3 Participant ID Log

11.4 Related Correspondence

12.0 Participant Randomisation / Registration Procedures

12.1 Randomisation / Registration User Manual

12.2 Records of Unblinding (local participants)

12.3 Related Correspondence

13.0 Data Management – Forms & Procedures

13.1 Blank Paper CRF – current and superseded (if applicable)

13.2 CRF Completion Guidelines

13.3 Completed Electronic Data Capture (EDC) System Account Application Forms

13.4 Current and Superseded Site Source Document Plan

13.5 Related Correspondence

14.0 Safety Monitoring & Reporting

14.1 Current and Superseded Blank Expedited Safety Report Form

14.2 Current and Superseded Reference Safety Information

14.3 Copy of Completed Expedited Safety Report Forms (all SAEs, suspected SUSARs and USMs) sent to Sponsor-Investigator

14.4 Copy of all Safety Reports sent by PI to local Research Governance Office (RGO) or Regulatory Authority

14.5 On-Site procedure for unblinding in either the case of medical emergency or for safety reporting purposes

14.6 Related Correspondence

15.0 Study Quality Assurance, Monitoring, Audits & Inspections

15.2 Site Monitoring Log

15.4 Monitoring Correspondence including Feedback to Site

15.5 Trial Close-Out Report & correspondence

15.6 Local Research Governance audit reports and correspondence

15.7 Regulatory Inspections reports and correspondence

16.0 Local Laboratory Documentation

16.1 Research Sample Lab Manual

16.2 Local Lab Certificates of Accreditation

16.3 Normal Local Lab Reference Ranges

16.4 Biospecimen Log

16.5 Biospecimen Shipment Receipt Tracking

16.6 Biospecimen Storage Monitoring Documentation

16.7 Related Correspondence

17.0 Supplies/Shipping Records

17.1 Documentation relating to provision of Study Supplies (excluding Investigational Product/Medical Devices)

18.0 Legal Documentation

18.1 Fully Executed Clinical Trial Agreement

18.2 Other Agreements as applicable

18.3 Related Correspondence

19.0 Finance Documentation

19.1 Invoices/Receipts

19.2 Related Correspondence

20.0 Other Communication

20.1 Newsletters from Sponsor-Investigator

20.2 Other General Correspondence

21.0 Archiving

21.1 Archiving Details

21.2 Related Correspondence

22.0 Investigational Product

22.1 Instructions for handling IP and trial related materials

22.2 Documentation of IP Shipment / Receipt i.e. Drug Receipt

22.3 Documentation of IP Dispensing, Accountability and Inventory

22.4 Documentation of IP Storage Monitoring

22.5 Documentation of IP Quarantines, Returns, & Destruction

22.6 Related Correspondence