1.0 Central Trial Coordination Team

1.1 Contact List

1.2 Delegation and Signature Log

1.3 CVs

1.4 GCP Training Certificates

1.5 Other Training Certificates

2.0 Project Management

2.1 Trial Start-Up Checklist

2.2 Site Selection Documentation

2.3 Administration

2.4 Trial Meeting Agenda/Minutes, Notes, etc.

2.5 Significant Team Correspondence & Communication including Emails, etc.

3.0 Protocol/Protocol Amendments

3.1 Protocol Version Tracker

3.2 Current HREC Approved Study Protocol with Signed Protocol Signature Page / Investigator Agreement Page

3.3 Superseded Study Protocols with signed Protocol Signature Page / Investigator Agreement Page

3.4 Protocol – Evidence of review and approval by Sponsor

3.5 Peer Review – Evidence of Review

3.6 Non-Compliance Reports and Central Non-Compliance Log

3.7 Sponsor-level Serious Breaches and CAPAs

3.8 Copy of all Serious Breach reports to Sponsor-Investigator/HREC or Regulatory Authorities

3.9 Related Correspondence

4.0 Participant Information & Consent Forms

4.1 PGICF & PICF Version Tracker

4.2 Template Master PGICF & PICF – Current HREC Approved Version(s)

4.3 Other Approved Participant Information

4.4 Superseded Template PGICF & PICF

4.5 PGICF & PICF – Evidence of Review and Approval by Sponsor

4.6 Other Superseded Participant Information

5.0 Regulatory Documents

5.1 Site Green Light Approval form(s)

5.2 TGA Acknowledgement Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX)

5.3 CTN/CTX Submission(s)

5.4 Other TGA Correspondence

5.5 International Regulatory Submissions

5.6 International Regulatory Approvals

5.7 International Regulatory Related Correspondence

5.8 Supplementary FDA Documents

6.0 Sponsorship

6.1 Sponsor Authorisation Letter

6.2 Completed Risk Assessment/Management Tool

6.3 Related Correspondence and Meeting Minutes

7.0 Ethics Committee

7.1 Ethics Approval Letters (current and superseded)

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

7.3 Ethics Committee Composition, Constitution & Statement of Compliance

7.4 Annual Project Progress Reports and Final Project Report

7.5 Related Correspondence

8.0 Study-Specific Procedures/SOPs (applicable to either the Central Trial Coordination Team or all sites)

8.1 Current MoP / SoP

8.2 Superseded MoP / SoP

9.0 Site Training

9.1 SIV Presentation

9.2 Investigator Meeting

9.3 Other Presentations

9.4 Training Logs

9.5 Other training resources

10.0 Participant Recruitment

10.1 Pre-Screening Log Template

10.2 Consent, Screening & Enrolment Log Template

10.3 Participant ID Log Template

11.0 Participant Randomisation / Registration Procedures

11.1 Randomisation Manual or Participant Registration Procedure

11.2 Records of Unblinding (all participants)

11.3 Related Correspondence

12.0 Data Management – Forms & Procedures

12.1 Blank Sample CRF

12.2 Superseded CRF

12.3 CRF Completion Guidelines

12.4 Trial-Specific Data Management Plan

12.5 Database Management Documentation

12.6 Trial Database Design Approval Form

12.7 Electronic Data Capture (EDC) System Application Form - Template

12.8 Completed Electronic Data Capture (EDC) SystemApplication Forms

12.9 Related Correspondence

13.0 Safety Monitoring & Reporting (all sites)

13.1 Blank Expedited Safety Report Form Template (i.e. SAE Form) and Safety Reporting Guidelines

13.2 Copy of Completed Expedited Safety Report Forms and associated correspondence from all Sites

13.3 Copy of all Safety Reports sent to HREC, TGA, Regulatory Authorities and Participating Sites.

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

13.5 Other related correspondence

14.0 Study Quality Assurance, Monitoring, Audits & Inspections

14.1 Clinical Monitoring Plan

14.2 Clinical Monitoring Plan – Evidence of Review and Approval by Sponsor-Investigator

14.3 Monitoring Log

14.4 Monitoring Visit Reports, including Evidence of Review and Approval by Sponsor/Delegate

14.5 Related Monitoring Correspondence

14.6 Data Safety Monitoring Board (DSMB)

14.6.1 DSMB Charter

14.6.2 Charter – Evidence of Review and Approval by Sponsor-Investigator

14.6.3 DSMB Meeting Minutes

14.6.4 Related Correspondence

14.7 Trial Steering Committee (TSC)/Trial Management Committee (TMC)/Other Committees

14.7.1 Steering Committee Charter(s)

14.7.2 Documentation/Approval by Sponsor-Investigator

14.7.3 Committee Meeting Minutes

Local Research Governance Office

14.8 Documentation including audit reports – all sites

14.9 Regulatory Inspection reports and correspondence

15.0 Statistics

15.1 Statistical Analysis Plan (SAP)

15.2 Statistical Analysis Plan – Evidence of review and approval from Sponsor-Investigator

15.3 Statistical Reports, including reports to DSMB and other analyses

15.4 Related Correspondence

16.0 Centralised Laboratory

16.1 Research Sample Lab Manual

16.2 Centralised Lab Certification

16.3 Centralised 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 Legal Documentation

17.1 Master Clinical Trial Research Agreement (CTRA)

17.2 Other Agreements as applicable:

17.3 Correspondence with MCRI Legal

18.0 Finance Documentation

18.1 Budget Tracking – Forecasts and Actuals

18.2 Invoices/Receipts

18.3 Related Correspondence

19.0 Other Communication

19.1 Newsletters to Sites

19.2 Other General Correspondence

20.0 Publications/Abstracts

20.1 Publications

20.2 Abstracts

21.0 Clinical Study Report

21.1 Clinical Study Report

21.2 Statistical report

22.0 Study Register – Registration and Results Posting

22.1 Initial Registration with a Trial Registry

22.2 Updates to Trial Registry

22.3 Related Correspondence

23.0 Archiving

23.1 Archiving Details

23.2 Related Correspondence

24.0 Reference Safety Information for each Investigational Product (Drug/Device Trials Only)

24.1 Current Reference Safety Information (IB or PI)

24.2 IB Version Tracker and PI Signature Pages (if applicable)

24.3 Superseded Reference Safety Information

25.0 Investigational Product

25.1 Unregistered Product Manufacturing Records including COA, Quality Control release and correspondence

25.2 IP Ordering Information / Drug Order Form

25.3 IP Packaging and Labelling

25.4 Instructions for Handling IP and Trial Related Materials

25.5 Documentation of Central IP Shipment

25.6 Documentation of IP Dispensing, Accountability and Inventory

25.7 Documentation of IP Quarantines, Returns, & Destruction

25.8 Copies of Material Safety Data Sheets (MSDS)

25.9 Related Correspondence