Appendix E

Clinical Trials Details

E.1 Where will this trial be registered?
Please note that the Trial Registration Number should be submitted to the ERC prior to commencement of the trial.

E.2 Which phase clinical trial is being conducted?

Phase I ☐ Phase II ☐ Phase III ☐ Phase IV ☐ Other ☐

If OTHER specify,

E.3 Is it a multi-centre trial?

Yes ☐ No ☐

E.4 Describe the procedures for dealing with adverse events?

E.5 What is the procedure for reporting adverse events?

E.6 What is/are the criteria for termination of the trial?

E.7. How will the results of the study be disseminated?

E.8. List the collaborating institutes and its role

	Institution	Recruitment	Lab facility	Logistics	Intellectual	Any other
1.						
2.						
3.						

* Attach documentary evidence

E.9. Has this study been submitted to an ERC / similar body in the country/ countries of foreign collaborator/s? Yes / No

- **If yes,**

a) Name and address of the committee

Decision *

Date

b) Name and address of the committee

Decision *

Date

* Attach documentary evidence

- **If no, give reason/s**

E.10. What is the relevance of this study to Sri Lanka?

E.11. Are biological samples to be transferred abroad?

If yes,

a) Attach the material transfer agreement.

b) Describe the fate of the biological sample at the conclusion of the study.

E.12. What investigations and/or interventions will subjects have?

You should include details of all procedures and interventions which will contribute to the research data. Whether they would normally be part of these patients' routine care or extra because of the research programme. Please tick the relevant boxes.

Please attach copies of any non-standard questionnaires to be used

Investigation	Additional procedures		Routine procedures	
	Yes	No	Yes	No
Self-completion questionnaires				
Structured interviews/researcher Completed questionnaires				
Venepuncture				
Arterial puncture				
Biopsy				
Other tissue/body sample				
Ionising radioactive substances/X-rays				
Non-radioactive imaging investigations				
Non-invasive tests (e.g.,ECG)				
Anaesthesia, sedation				

Other medicinal products				
Medical devices/equipment				
Hospitalization				
Longer inpatient stays				
Additional outpatient attendances				
Other investigations not part of routine care				