**INDEX**

1. Index

2. Submissions Log

3. Review Checklist

4. Registration and Application form

5. All version of Study protocol and Informed Consent

6. Investigator Brochure

7. Other Related documents

8. Principal Investigator CV and co-Investigator

9. Reviewer’s assessment form

10. Approval Letters

11. Serious Adverse Event Report

 11.1 Onsite

 11.2 Offsite

12. Non-compliance Deviation or violation

13. Participants queries

14. Site Visit Report

15. Progress Report

16. Continuing review applications

17. Final Report

18. DSMC/ DSMB/ IDMC report/s

19. Miscellaneous communication

20. Borrower’s Log