



**MINISTRY OF HEALTH  
PHARMACY AND POISONS BOARD**

**Checklist for Submitting a Request for Annual Approval**

ECCT No.....

Title.....

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No.	Item	Version No.	Date
1.	Cover letter <i>(Should list all the submitted documents, their version numbers and dates)</i>		
2.	Annual progress report		
3.	SAE and SUSAR Cumulative logs		
4.	Latest Data Safety Monitoring Board (DSMB) report		
5.	Protocol Violations and Protocol Deviations logs		
6.	Updated Investigators Brochure/Package inserts or Investigational Medicinal Product Dossier (IMPD)		
7.	The Development Safety Update Report (DSUR)		
8.	Copy of current favorable opinion letter from the local Ethics Review Committee (ERC).		
9.	Copy of the Annual Practice license for the investigators		
10.	Copy of the Annual Practice license for the Pharmacist		
11.	Copy of the valid professional indemnity insurance cover for the investigators		
12.	Copy of the valid professional indemnity insurance cover for the study pharmacist		
13.	Copy of valid participants' clinical trials insurance cover		
14.	Evidence of registration of the study at Pan African Clinical Trials Registry <a href="https://pactr.samrc.ac.za">https://pactr.samrc.ac.za</a>		

**Signed**

Applicant Name.....Sign..... Date.....

PPB Staff Name. ....Sign..... Date.....