



**MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD**

Checklist for Submitting a Request for Annual Approval

No.	Item	Yes/No
1.	Cover letter	
2.	Annual progress report	
3.	SAE Cumulative log	
4.	Latest Data Safety Monitoring Board (DSMB) report	
5.	Protocol Violations and Protocol Deviations log	
6.	Updated Investigators Brochure/Package inserts or Investigational Medicinal Product Dossier (IMPD)	
7.	Copy of current favorable opinion letter from the local Ethics Review Committee (ERC).	
8.	Copy of the Annual Practice for the investigators and Pharmacist	
9.	Copy of the current indemnity insurance cover for the investigators	
10.	Copy of the participants clinical trials insurance cover	
11.	Request for annual approval at the clinical trial registry www.ctr.pharmacyboardkenya.org	

Signed

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

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