



**MINISTRY OF HEALTH  
PHARMACY AND POISONS BOARD**

**Checklist for submission Clinical Trials Applications for Approval**

<b>No.</b>	<b>Item</b>	<b>Yes/No</b>
1.	Cover letter	
2.	Completed application form	
3.	The Study Protocol	
4.	Patient Information leaflet and Informed consent form	
5.	Investigators Brochure/Package inserts or Investigational Medicinal Product Dossier (IMPD)	
6.	Stability data of the investigational product	
7.	GMP certificate of the investigational product from the site of manufacture	
8.	Certificate of Analysis of the investigational product	
9.	Pictorial Sample of the investigational products. This sample should include the text of the labeling to be used	
10.	Signed investigator(s) CV(s) including that of study Pharmacist	
11.	Evidence of recent GCP training of the core study staff	
12.	DSMB Charter including the composition and meeting schedule	
13.	Detailed budget of the study	
14.	Financial declaration by Sponsor and/or PI	
15.	Indemnity cover for PI and investigators	
16.	Insurance Certificate for the participants	

17.	Copy of favorable opinion letter from the local Ethics Review Committee (ERC).	
18.	Copy of current Practice Licenses for the Investigators and study Pharmacist	
19.	Copy of approval letter(s) from collaborating institutions or other regulatory authorities, if applicable	
20.	Where the trial is part of an international study, sufficient information regarding the other participating countries and the scope of the study in these countries.	
21.	For multicentre/multi-site studies, an addendum for each of the proposed sites including among other things the sites' capacity to carry out the study i.e personnel, equipment, laboratory etc	
22.	Registration at the clinical trial registry at <a href="http://www.ctr.pharmacyboardkenya.org">www.ctr.pharmacyboardkenya.org</a>	
23.	A signed statement by the applicant indicating that all information contained in, or referenced by, the application is complete and accurate and is not false or misleading and that the study will be carried out according to protocol and applicable laws and regulations.	
24.	Payment of fees	
25.	Four bound hard copies of the above	

**Signed**

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