MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD

Checklist for Submission Clinical Trials Applications for Authorization

Clinical Trial Tittle; .....

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No.	Item	Yes/No
1.	Cover letter ***(Should list all the submitted documents, their version numbers and dates)***	
2.	The Study Protocol.	
3.	Registration of the clinical trial in the registry at Pan African Clinical Trials Registry https://pactr.samrc.ac.za	
4.	Patient Information leaflet and Informed consent form.	
5.	Investigators Brochure/Package inserts.	
6.	Investigational Medicinal Product Dossier.	
7.	Adequate information and data from previous studies and phases to support the current study.	
8.	Stability data of the investigational product supporting the intended shelf life of the product.	
9.	GMP certificate of the investigational product from the site of manufacture.	
10.	Certificate of Analysis of the investigational product.	
11.	Pictorial Sample of the investigational products. This sample should include the text of the labeling to be used.	
12.	Signed investigator(s) CV(s) including that of study Pharmacist. **The CV should include the current workload of the Principal Investigator.**	
13.	Evidence of contractual agreement between sponsor and Principal Investigator.	
14.	Evidence of recent GCP training of the core study staff.	

No.	Item	Yes/No
15.	DSMB Charter including the composition and meeting schedule.	
16.	Detailed budget of the study.	
17.	Financial declaration by Sponsor and/or PI.	
18.	Signed Declaration by Sponsor or Principal investigator that the study will be carried out according to the protocol and applicable laws, regulations and GCP requirements.	
19.	Indemnity cover for PI, other investigators and study Pharmacist.	
20.	Clinical Trials Insurance Cover for the study participants.	
21.	Copy of favorable opinion letter from the local Ethics Review Committee (ERC).	
22.	Copy of current Practice Licenses for the Investigators and study Pharmacist.	
23.	Copy of approval letter(s) from collaborating institutions or other regulatory authorities, if applicable	
24.	For multicenter/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	
25.	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.	
26.	Payment of fees.	
27.	Statistical Analysis Plan.	
28.	Four bound hard copies of all the above.	

N/B

- **All submitted documents should be signed, dated and version referenced if applicable.**
- **The documents should be in English**

Signed

Applicant Name…… Sign…….. Date……

PPB Staff Name …… Sign…….. Date……