APPLICATION FORM TO CONDUCT A CLINICAL TRIAL (ALLOPATHIC DRUG)

CHECKLIST

Applicant's check list		FDB double check
□	**COVERING LETTER**	□
□	**SIGNED DECLARATION**	□
□	**FULLY COMPLETED APPLICATION FORM**	□
□	**TRIAL PROTOCOL**	□
□	**ETHICS COMMITTEE APPROVAL**	□
□	**PATIENT INFORMATION/INFORMED CONSENT**	□
□	**INVESTIGATORS BROCHURE OR PACKAGE INSERT**	□
□	**INVESTIGATOR'S CV IN FDB FORMAT**	□
□	**CERTIFICATE OF ANALYSIS OF INVESTIGATIONAL PRODUCT**	□
□	**INSURANCE CERTIFICATE OR LETTER ENDORSING GENERIC APPROVAL CERTificate.**	□
□	**FINANCIAL DECLARATION (SPONSOR & PI)**	□
□	**COPY OF RECRUITMENT ADVERTISEMENT**	□

FOOD AND DRUGS BOARD

APPLICATION FORM TO CONDUCT A CLINICAL TRIAL FOR REGISTRATION OF A HUMAN DRUG

Addressed to:

THE CHIEF EXECUTIVE
FOOD AND DRUGS BOARD
P.O.BOX CT 2783
CANTONMENTS-ACCRA
GHANA.

Proprietary Name of Product: ……..

……..

Approved Name of Product: ……

……..

Dosage Form: …… .

…….

Route of Administration: ……..……..

Type of Trial: ……..

…….

Name(s) of Trial Centre(s): ……

……

Premises Address:……...……

……

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Phone ……..…… Fax ……

e-mail ……

Name of Sponsor: ……..

Address: ……

……

Phone ……Fax …….

e-mail ……

Name of Contact Person: …….

Address: ……

……

Phone ……..Fax ……

e-mail ……..…...

Name of Principal Investigator: ……Address:

……

…….

Phone …….. Fax ..……...

e-mail …….....

Name of Independent Monitor: ……..

Address: …….

……

Phone …… Fax ……..

e-mail ……..

Proposed date of commencement of trial: ……..

Proposed date of completion of trial: …….

Current work-load of Investigator(s): Number of studies currently undertaken by trialist(s) as principal and/or co-investigators, and the total number of patients/ represented by these studies. Time-commitments of the researcher(s) in relation to clinical work and non-trial work

Recommended format for response:

Investigator (Name and designation)			
Total number of current studies (all stages) on specified date	Number	Date	
Total number of patients/participants for which responsible on specified date	Number	Date	
ESTIMATED TIME PER WEEK [168 hours denominator]		**Hours**	**%**
Clinical trials	Clinical work (patient contact)		
	Administrative work		
Organisation (Practice/University/employer)	Clinical work		
	Administrative work		
Teaching	Preparation/evaluation		
	Lectures/tutorials		
Writing up work for publication/presentation			
Reading /sourcing information (e.g. Internet searches)			
Other (specify)			

Declaration

I/We the undersigned, hereby declare that all information contained herein is correct and true.

Sponsor's name/ Authorised Person: ……

Authorised signature: ………………………………………………………………

Date: ……………………………………..