Pharmacy Board of Sierra Leone

APPLICATION FORM TO CONDUCT A CLINICAL TRIALS FOR MEDICINES, VACCINES, FOOD SUPPLEMENTS AND MEDICAL DEVICES

CHECKLIST

PBSL Double check

APPLICANT'S check list

☐	**COVERING LETTER AND APPLICATION FEE**	☐
☐	**SIGNED DECLARATION**	☐
☐	**FULLY COMPLETED APPLICATION FORM**	☐
☐	**TRIAL PROTOCOL**	☐
☐	**ETHICS COMMITTEE APPROVAL**	☐
☐	**PATIENT INFORMATION/INFORMED CONSENT**	☐
☐	**INVESTIGATORS BROCHURE**	☐
☐	**INVESTIGATORS AND PHARMACIST(S) CVs**	☐
☐	**CHEMISTRY, MANUFACTURING AND CONTROL (CMC)**	☐
☐	**INSURANCE CERTIFICATE**	☐
☐	**FINANCIAL DECLARATION (SPONSOR & PI)**	☐
☐	**DSMB/IDMC CHARTER AND CVs**	☐

Guideline No. : PBSL/PVGCT/APF/CCT/03-2018

Effective Date. :31st January, 2018

Version No. : 03

PHARMACY BOARD OF SIERRA LEONE
APPLICATION FORM TO CONDUCT A CLINICAL TRIAL FOR MEDICINES, VACCINES AND MEDICAL DEVICES

Addressed to:

The Registrar
Pharmacy Board of Sierra Leone
Central Medical Stores
New England Ville
Freetown
Sierra Leone
P.M.B.322
+232 25 282886
Email. registrar@pharmacyboard.gov.sl
Website: www.pharmacyboard.gov.sl

1. ADMINISTRATIVE DETAILS

Name of Sponsor: ……..

Address: …….....

……..

Phone ……Fax ……

e-mail …….....

Name of Principal Investigator: …….

Address:

…….

…….

Phone …….. Fax ……..

e-mail ……..

Date of last Good Clinical Practice (GCP) training (Attach CV and cGCP certificate)……

Name of Principal Investigator: ……..

Address:

……

……

Phone …….. Fax ..…….....

e-mail …….....

Date of last Good Clinical Practice (GCP) training (Attach CV and cGCP certificate)…….

Name of Study pharmacist(s): …….....

Address: …….

……

Phone …… Fax ……..

e-mail ……..

Date of last Good Clinical Practice (GCP) training (Attach CV and cGCP certificate)……....

Name of Local Monitor: ……..

Address: ……..

……..

Phone …… Fax ……..

e-mail ……..

(Attach CV and cGCP of local monitor)……

2. TRIAL DETAILS

Study title and Acronym

……

……

……..

Clinical Trial Registration Number……

Name(s) of Trial Centre(s): …….

……

Premises Address(es):……...…….....

……

……

Phone ……..…… Fax ……

e-mail …….....

Proposed date of commencement of trial: …….....

Proposed date of completion of trial: ……

Type of Trial: ……

……...

Number of participants expected to take part in the study……..

3. INVESTIGATIONAL PRODUCT DETAILS

Proprietary Name of Product: …….

……..…….

Approved Name of Product: ……

……..

Dosage Form: …….

Route of Administration: ……..……...

Dosing:……..

……..…….

Details of control (Name, dosage form, route of administration, dosing etc): …….

……..

……..

……

Indicate whether any other drug(s) will be given concomitantly. YES/NO*

If YES, state the name of the drug(s)……..

State the total quantities of all investigational products including products for control group(s) that would be required for the full conduct of the study……..

……

……

Attach the label and package insert of investigational product if product has already been registered for use in Sierra Leone.

State any adverse or possible reactions to the product

…… ……..

.....

.....

Has the drug been registered in the country of origin? YES/NO

If YES a valid certificate of registration in respect of such drug issued by the appropriate authority established for the registration of drugs in the country of origin shall accompany this application.

If NO state

details……..……...

……

……...

Have clinical trials been conducted in the country of origin? YES/NO
If YES state detail……...

If NO, give reasons

why……...……

……

……

Has the drug been registered in any other country? YES/NO

If YES state

details……

……

Has an application for registration of the drug been made in any other country? YES/NO

If YES, state details including the date on which the application was

made……

Has the registration of the drug been rejected, or refused, deferred or cancelled in any country? YES/NO

If YES, state details

……

……

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 [90 hours denominator]		**Hour**	**%**
Clinical trials	Clinical work (patient contact)		
Organization (Practice/University/employer)	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/ Authorized Person: ……..

Authorized signature: ……

Date: …….