PHARMACY BOARD OF SIERRA LEONE

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

CHECKLIST **PBSL Double check**

APPLICANT'S check list

☐	**COVERING LETTER**	☐	
☐	**SIGNED DECLARATION**		☐
☐	**FULLY COMPLETED APPLICATION FORM**	☐	
☐	**TRIAL PROTOCOL**	☐	
☐	**ETHICS COMMITTEE APPROVAL**	☐	
☐	**PATIENT INFORMATION/INFORMED CONSENT**	☐	
☐	**INVESTIGATORS BROCHURE**		☐
☐	**INVESTIGATOR'S CV**	☐	
☐	**CERTIFICATE OF ANALYSIS OF INVESTIGATIONAL PRODUCT**	☐	
☐	**INSURANCE CERTIFICATE**	☐	
☐	**FINANCIAL DECLARATION (SPONSOR & PI)**	☐	
☐	**COPY OF RECRUITMENT ADVERTISEMENT**		☐

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 22 229346
Email. info@pharmacyboard.gov.sl/wcnjohnson@pharmacyboard.gov.sl
Website: www.pharmacyboard.gov.sl

Study title
……..
……
……..

Proprietary Name of Product: …….

……..…….

Approved Name of Product: ……

…….

Dosage Form: ……..

……..

Route of Administration: ……..……...

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)…….

Type of Trial: ……..

……..

Clinical Trial Registration Number……. .

Name(s) of Trial Centre(s): …….

…….

Premises Address:……...…….

……..

……..

Phone ……..…… Fax ……..

e-mail ……...

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

Proposed date of completion of trial: ……..

Name of Sponsor: ……

Address: ……...

……..

Phone ……Fax ……

e-mail ……...

Name of Principal Investigator: …….Address:

……

…….

Phone …….. Fax ……..**.....**

e-mail ……..

Name of Independent Monitor: ……...

Address: ……..

……..

Phone …… Fax ……...

e-mail ……...

Name of Study pharmacist: ……..…..

Address: ……..

……..

Phone …… Fax ……...

e-mail ……...

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]		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: ……