GSER-IEC-AF/01/04-SOP03/04
Study Submission Application Form
(Original Copy)

Protocol Number:		**GSER –IEC Track No.**	**GSER_____**
		Date:	
Type of Submission:	Initial Review ☐ Protocol Amendments ☐ Resubmission of Protocols with Corrections ☐		Continuing Review ☐ Approved Protocols ☐ Protocol Termination ☐ Approval extension ☐
Protocol Title:			
Principal Investigator:			
Telephone number		**Fax:**	
E-mail:		**Preferred Contact:** ☐	Fax ☐ e-mail ☐
Site Address:			
Delivery route:	Post ☐	E-submission ☐	in Person ☐
Documents submitted	Complete ☐	Incomplete ☐	
	will submit on……..		

Documents submitted with package		**Check what documents will be submit later**	
Study protocol	☐	Informed consent form	☐
Informed consent form	☐	Case report forms (CRF)	☐
Case Report forms (CRF)	☐	Product monograph	☐
Others……	☐	**Other:**	☐

Received by:	**Date**

Note: Please bring this receipt with you when contacting the Good Society for Ethical Research -Independent Ethics Committee (GSER-IEC) office.

GSER-IEC-AF/01/04-SOP03/04
Document Receipt Form
(GSER Copy)

Protocol Number:		**GSER –IEC Track No.**	**GSER_____**
		Date:	
Type of Submission:	Initial Review ☐ Protocol Amendments ☐ Resubmission of Protocols with Corrections ☐		Continuing Review ☐ Approved Protocols ☐ Protocol Termination ☐ Approval extension ☐
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E-mail: _____		**Preferred Contact:**	Fax ☐ e-mail ☐
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Case Report forms (CRF)	☐	Product monograph	☐
Others……	☐	**Other:**	☐

Received by:	**Date**

Note: Please bring this receipt with you when contacting the Good Society for Ethical Research -Independent Ethics Committee (GSER-IEC) office.

GSER-IEC-AF/01/04-SOP03/04
Project Submission Application Form for Initial Review
(BA/BE Studies)

GSER-IEC Track no-	**GSER-**			
Status of Review	Initial Review	☐	Continuing Review	☐
	Protocol Amendments	☐	Approved Protocols	☐
	Resubmission of Protocols with Corrections	☐	Protocol Termination	☐
			Approval extension	☐

A. Summary of submission Package

1. Proposal Title:

2. Investigator details (*Please attach detailed Curriculum Vitae of all Investigators with protocol package. If additional collaborators attach details on separate page.*)

PI Name	**Designation & Qualifications**	**Contact Address**
		Tel No. _____ Fax No. _____ Email ID _____

3. Sponsor Information:	**Indian**	☐	**International**	☐

4. Contact Address of Sponsor:

5. Trial details

5.1 Type of Study:	Clinical	☐	Non-Clinical	☐	Interventional	☐	Non-Interventional	☐
	Phase-I	☐	Phase-II	☐	Phase-III	☐	Phase-IV	☐
	BE/BA	☐	Observationa	☐	PMS	☐	Other	☐
	Single centric	☐	Multi-centric	☐	If other specify			

5.2. Name and Address of the study centers/CRO:

5.3. Is drug approved for marketing :	Yes	No
If yes please specify country name……		

5.4. Whether DCGI's /Any other Regulatory authority's Permission is obtained?	Yes	No
If yes, Date of permission: _____		
5.5. Is it an Investigational New Drug?	Yes	No
If yes, IND No: _____		
5.6. Brief description of the proposal – (*Synopsis attached)*	Yes	No
5.7. Subject selection:		
i. Number of Subjects : _____(Male ____Female __ Transgender ____)		
ii. Duration of study : _____		
iii. Inclusion / exclusion criteria given	**Yes**	**No**
iv. Type of subjects	Healthy human volunteers ☐	Patients ☐
v. Vulnerable subjects/ Special group subjects	Yes	No
If yes, Specify _____		
6. Consent:	Written ☐	Oral ☐ Audio-visual ☐
7. Will any advertising to be done for Subjects recruitment? (Posters, flyers, brochure, websites – if so, kindly attach a copy)	Yes	No
Data Monitoring		
I. Is there a data & safety monitoring committee/Board (DSMB)?	Yes	No
II. **Is there a plan for reporting of adverse events?**		
If Yes, reporting is done to	*Sponsor* ☐ *Ethics Committee* ☐ *DSMB* ☐	
III. Are there plans for storage and maintenance of all trial database?	Yes	No
If Yes, for how long? _____		
IV. Is there compensation for participation		
If Yes, Monetary ☐ *In kind* ☐	*Specify amount and type:* _____	
8. Is there compensation for injury?	Yes	No
9. **Do you (or PI) have conflict of interest with study/sponsor? (financial/nonfinancial) *If Yes, specify:***	Yes	No
B. Check list (please tick yes or no for enclosed items)		
1. Protocol handling fee	Yes	No
2. Clinical study protocol	Yes	No
3. Informed consent document in English	Yes	No
4. Informed consent document in Hindi / local language with translation certificate	Yes	No
5. Back translated informed consent document with translation certificate	Yes	No

6. Case Report Form'	Yes	No
7. Randomization schedule	Yes	No
8. Product Monograph/ information Boucher / sheet	Yes	No
9. Proposed methods for patient accrual including advertisement (s) etc. proposed to be used for the purpose.	Yes	No
10. Principal Investigator's current CV	Yes	No
11. Insurance Policy / Compensation for participation and for serious adverse events occurring during the study participation.	Yes	No
12. Investigator's Agreement with the Sponsor.	Yes	No
13. Investigator's Undertaking	Yes	No
14. DCGI notification	Yes	No
15. NOC from head of Institution / Clinical trial site	Yes	No
16. NOC from head of Institution ethical community of clinical trial site (If applicable)	Yes	No
Others		
Place: **Date:** **Signature & Designation**		